Ethics *and* Law, and Ethics *as* Law: Legal Pluralism and the Normative Relationship Between the State and the Medical Profession

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Table of Contents

ABSTRACT **7**

ACKNOWLEDGEMENTS **9**

PREFACE **10**

CHAPTER 1: MEDICAL ETHICS, LAW AND LEGAL PLURALISM **11**

I. ETHICS, LAW AND LEGAL PLURALISM AS A TOPIC OF STUDY **12**

II. MEDICAL ETHICS, PHYSICIANS AND THE STATE **16**

III. WHAT FOLLOWS **18**

CHAPTER 2: SELF-REGULATION AND REGULATION OF THE US MEDICAL PROFESSION: A HISTORICAL PERSPECTIVE **21**

I. INTRODUCTION **22**

II. THE "PRE-PROFESSION" AND THE BEGINNINGS OF ORGANIZED MEDICINE **23**

A. Early Nationhood Until the Mid-19th Century *23*

B. The Organizing of the First National Medical Society *28*

C. "True" Medicine and Self-Regulation *32*

D. The Reformation of the AMA *37*

E. Conclusion *40*

III. THE FORMALIZATION OF STATE REGULATION OF THE MEDICAL PROFESSION AND THE REFORM OF MEDICAL EDUCATION **41**

A. The Return of State Licensure *41*

B. Medical Education Reform *45*

C. Conclusion *50*

IV. HEALTH INSURANCE, GOVERNMENT INTERVENTION IN THE MARKETPLACE, AND THE DECLINE OF PROFESSIONAL AUTONOMY **51**

A. Early Forms of Health "Insurance" *51*

B. Group Health Insurance *54*

C. Medicare, Medicaid, and Government Funded Health Care *57*

D. Managed Care and Professional Autonomy *60*

V. STATE REGULATION OF MEDICAL PRACTICE **64**

VI. CONCLUSIONS, AND THE CURRENT STATE OF THE PROFESSION **67**

CHAPTER 3: LEGAL PLURALISM – SOCIAL FIELDS AND LEGAL ORDERS 71

I. INTRODUCTION 72

II. WHAT IS LEGAL PLURALISM, AND WHY USE IT? 75

A. Legal Pluralism as a Descriptive Theory of What Law Is 75

B. Why Use Legal Pluralism to Describe Medical Ethics and the Medical Profession? 79

III. SEMI-AUTONOMOUS SOCIAL FIELDS AND THE CREATION OF LAW 83

A. The Semi-Autonomous Social Field 83

1. The Nature of the Semi-Autonomous Social Field 83
2. The Medical Profession as a Semi-Autonomous Social Field 87

B. What is Law? 91

1. Pluralists' Law and Their Detractors 91
2. Medical Ethics as a Legal Order 100

C. The Helpful Theory of Professionalism 104

IV. THE MEDICAL PROFESSION AND MEDICAL ETHICS "AS AN APPROPRIATE SUBJECT OF STUDY" 114

CHAPTER 4: THE "LAW" OF THE MEDICAL PROFESSION 116

I. INTRODUCTION 117

II. MEDICAL ETHICS 120

A. Oaths and Codes 120

B. Other Sources of Medical Ethics 129

C. Concluding Thoughts on Ethics and the Law of the Profession 134

III. CODES OF ETHICS AS PROFESSIONALLY-SOURCED LAW 137

A. Introduction 137

B. Methods 138

C. Results 139

1. General 139
2. Enforcement of Conduct 140

D. Discussion 141

1. Prominence of Ethics 141
2. Ethics and Normativity: The Importance of Words 145
3. Assessing Normativity: Enforcement and "Law" 151

E. Limitations *157*
IV. CONCLUSIONS **158**
TABLE 1. STATE AND SPECIALTY MEDICAL SOCIETIES **162**
CHAPTER 5: THE LAW OF THE STATE **165**
I. INTRODUCTION **166**
II. WHO CAN BE A DOCTOR? **168**
A. Introduction *168*
B. Physician Licensure and Discipline *169*
1. Medical Licensing Acts 169
2. Medical Board Disciplinary Action 173
a. What constitutes grounds for action? 173
b. How are physicians disciplined? 179
III. THE WIDE WORLD OF HEALTH LAW **183**
A. Introduction *183*
B. State and Federal Health Care Programs and Provision of Care *184*
C. Medical Emergencies and Active Labor *187*
D. Fraud and Conflicts of Interest *189*
E. Privacy and Confidentiality *191*
F. Contract Law and Insurance Regulation *192*
IV. AN EXTENSIVELY REGULATED PROFESSION **195**
TABLE 2. STATE MEDICAL LICENSING DISCIPLINARY PROVISIONS—UNETHICAL OR UNPROFESSIONAL CONDUCT SPECIFIED AS ACTIONABLE BY MEDICAL BOARD **198**
CHAPTER 6: POLITICS, MORALITY, MEDICAL ETHICS AND LAW **203**
I. INTRODUCTION **204**
II. THE IMPACT OF POLITICS ON MEDICAL ETHICS **206**
A. Ethics in the Shadow of Politics *206*
B. Abortion *208*
1. Introduction 208
2. Abortion as a Medical Procedure 209
3. *Planned Parenthood v Casey* and the New Informed Consent 213
4. *Gonzales v Carhart*, Medical Procedures and Medical Necessity 220
a. Partial-Birth Abortion 220

b. Mandatory Ultrasound 223
5. Abortion and a Growing Distrust Between the State and Profession 230
C. Gun Safety Speech Laws *231*
III. "PROTECTING THE INTEGRITY AND ETHICS OF THE MEDICAL PROFESSION," SOMETIMES 241
A. Introduction *241*
B. Physician-Assisted Suicide *241*
C. Physicians' Role in Capital Punishment *247*
IV. MEDICAL ETHICS, POLITICS, MORALITY AND LAW 260
CHAPTER 7: THE WEAKNESS OF PROFESSIONAL ETHICS 265
I. CONFLICTS OF INTEREST: WHAT, ME WORRY? 266
II. REGULATION OF CONFLICTS OF INTEREST: WHO'S THE LEADER AND WHO'S THE FOLLOWER? 268
A. Conflicts of Interest: Endemic in Medicine *268*
B. Fee Splitting, Fraud and Kickbacks *271*
1. The Problem 271
2. The Profession's Legal Order 276
3. The State's Legal Order 277
C. Physician Self-Referral *281*
1. The Problem 281
2. The Profession's Legal Order 290
3. The State's Legal Order 294
D. Physician-Industry Relationships *298*
1. The Problem 298
2. The Profession's Legal Order 305
3. The State's Legal Order 310
III. CONFLICTS OF INTEREST: THE LIMITS OF SELF-REGULATION AND ETHICS? 313
CHAPTER 8: LEGAL PLURALISM – A FRAMEWORK FOR THE PAST AND FUTURE OF NORMATIVE ETHICS AND THE PROFESSION-STATE RELATIONSHIP 320
I. LEGAL PLURALISM AND MEDICAL ETHICS 321
II. THE NATURE OF HEALTH CARE AND MEDICAL ETHICS: NECESSITATING COLLABORATION 325
A. Introduction *325*

B. External Impacts of Medical Ethics *326*
C. The Economic and Social Uniqueness of Health Care *328*
III. LEGAL PLURALISM: IMPERFECT, BUT A BETTER WAY **330**
A. Imperfect *330*
B. A Better Way *332*
IV. ETHICS AS CRUCIAL LAW FOR THE MEDICAL PROFESSION **338**
BIBLIOGRAPHY **344**

ABSTRACT

Medical ethics is a critical component of physician identity and professional self-regulation, and has been since the mid-19th century and the establishment of the American Medical Association (AMA) as the preeminent national medical society, and its *Code of Medical Ethics* as the preeminent set of ethics norms in the United States. Ethics, though, is not the only source of norms for physicians and the medical profession.

Since the late 19th century, the State has taken a greater role in regulating both physicians and health care, starting with public health measures and professional licensing and eventually extending into most corners of medical practice. Despite the growth of State regulation, though, the profession continues to revise and enact ethics norms for members of the profession, and today medical ethics remains a cornerstone of medical practice.

The concurrent—although not always congruent—regulation of physicians by the State and the medical profession raises serious questions of authority and what, exactly, physicians are bound to follow. Traditional theories that attempt to explain the relationship between the medical profession, State and medical ethics, such as professionalism, generally place the profession's authority as subsidiary to the State's. This assigns medical ethics a precarious position, making its relevance subject to changes in State law that could contradict ethics norms and therefore jeopardize its efficacy within the profession.

This Thesis seeks out other sources of authority for the medical profession and medical ethics, independent of the State and reflective of the traditional authority of the profession and ethics as the profession developed into its modern form. The theory of legal pluralism will be used here as the framework through which to explore the role of ethics and the relationship between the medical profession and the State, providing a different perspective on these questions. It will enlighten the relationships shaped by medical ethics *and* law, and medical ethics *as* law.

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L'éthique médicale est un élément crucial de l'identité des médecins et de l'autorégulation professionnelle. C'est le cas depuis le milieu du 19ème siècle, époque de la création de l'Association Médicale Américaine (AMA), et de l'établissement de son *Code d'Éthique Médicale* comme l'ensemble prééminent de normes éthiques aux États-Unis. L'éthique, en revanche, n'est pas la seule source de normes pour les médecins et la profession médicale.

Depuis la fin du 19ème siècle, l'État a progressivement joué un rôle grandissant dans la régulation des médecins ainsi que de la santé publique, en commençant par des mesures de protection de la santé des populations, l'établissement de licences professionnelles, jusqu'à son implication dans l'ensemble de la pratique médicale. Malgré l'accroissement de la

régulation par l'État, la profession médicale continue de mettre à jour et d'établir de nouvelles normes éthiques s'appliquant à ses membres, et l'éthique médicale est encore aujourd'hui une pierre angulaire de la pratique médicale.

La cohabitation parfois conflictuelle de normes de régulation provenant de l'État avec celles provenant de la profession médicale pose de sérieuses questions quant à l'autorité relative de chacune de ces sources, et quant ce qui régit l'activité des médecins. Les théories traditionnelles qui tentent d'expliquer les relations entre la profession médicale, l'État et l'éthique médicale, comme par exemple le professionnalisme, considèrent généralement l'autorité de la profession comme subsidiaire à celle de l'État. Cela assigne par conséquent une place précaire à l'éthique médicale, et soumet sa pertinence à l'évolution des lois étatiques, qui peuvent contredire les normes éthiques, et nuire à son efficacité au sein de la profession.

La présente Thèse cherche à trouver d'autres sources d'autorité pour la profession médicale et l'éthique médicale, qui soient indépendantes de l'État, et reflètent l'autorité traditionnelle de la profession et l'éthique en suivant les évolutions modernes de la profession. La théorie du pluralisme juridique sera utilisée ici comme cadre conceptuel à travers lequel nous explorerons le rôle de l'éthique, et la relation entre la profession et l'État, ce qui donnera une perspective renouvelée de ces questions. Nous éclairerons notamment les relations modelées par l'éthique médicale *et* la loi, et par l'éthique médicale *en tant que* loi.

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I would like to thank the individuals and organizations that assisted me in the gathering of information for the development of the concepts contained in this Thesis and its drafting. First and foremost, the American Medical Association (AMA) and the American College of Surgeons for allowing me to access their archives. I would like to especially acknowledge Amber Dushman at the AMA Archives, who provided invaluable assistance while I sifted through AMA historical documents, and Bette Crigger, Director of Ethics at the AMA, who lent a sympathetic ear and gave additional context to many of the issues I explore in this Thesis.

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PREFACE

Medical ethics is not a new or unique topic. There are also many, many examples in the medical, ethics, sociology, anthropological and legal literature that examine the history and normativity of medical ethics and the authority of the medical profession. Many of these discussion and debates appear as part of this Thesis, but the work contained within extends traditional concepts of ethics, professionalism and law in a new direction, using the theory of legal pluralism. Legal pluralism is not a new theory either, but neither has it been applied to the contexts of medical ethics and the medical profession. The application of legal pluralism to these contexts is what I consider original scholarship and a distinct contribution to knowledge.

CHAPTER 1: MEDICAL ETHICS, LAW AND LEGAL PLURALISM

I. ETHICS, LAW AND LEGAL PLURALISM AS A TOPIC OF STUDY 12
II. MEDICAL ETHICS, PHYSICIANS AND THE STATE 16
III. WHAT FOLLOWS 18

> Because the ends of medicine are fixed by its own internal discourse, and are informed by insights obtained at the bedside in the clinic…those external to it, whether in the health care bureaucracy or the legislature or wherever, cannot also define them without taking away medicine's unifying essential characteristic.[1]

I. Ethics, Law and Legal Pluralism as a Topic of Study

Ethics has been a cornerstone of medical practice for centuries.[2] It does not impart a technical understanding of medicine and health care, but provides a more abstract structure for how and why physicians should treat patients, address each other, and deal with relationships external to the medical profession that are necessary in the modern health care system. At times when government struggled to regulate either the medical profession or health care, ethics provided a basic set of rules to guide physician behavior.

Medical ethics and biomedical ethics[3] have expanded greatly in scope and focus in the past century. Advances in health care and medical technology have provided new areas for ethics policy, and changes in social convention, State[4] regulation and medical practice have caused the medical profession to revise on numerous occasions the target of medical ethics. Through centuries of change, though, medical ethics has remained an important aspect of the medical profession, and one of the few measures of professional self-regulation.

In this Thesis, I explore the continuing normative authority of medical ethics, its roots in ethics codes, and the resistance to this normativity from within and outside of the medical profession. My work is not the first to explore the self-regulatory role of ethics; in fact,

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[1] Joseph M Jacob, *Doctors and Rules: A Sociology of Professional Values* (London: Routledge, 1988) at 54.
[2] See e.g. June Goodfield, "Reflections on the Hippocratic Oaths" (1973) 1 Hastings Center Studies 79.
[3] I will explain the difference between these two and my reason for focusing on medical ethics in Chapter 4.
[4] When I use the term "State" (with the capital S) in this Thesis, I refer to any and all levels of US government. In appropriate context, I will use "federal" and "state" (with a lowercase s) to distinguish the level of government to which I am referring.

the discussion and debate over the role of medical ethics in the profession reaches back centuries. However, since early last century the focus has been on the normative role of ethics within the broader framework of State regulation. This outlook tends to place ethics in a subsidiary position to State law. Physicians and the medical profession develop ethics codes, but these are secondary to however the State regulates physicians and healthcare, something that changes with time, political parties and ideology. One of the more common theories for the authority of the profession and medical ethics is professionalism: what it means to be a profession and how professions are different from other occupations. Even this theory, which sources professional authority in part based on its expertise and commitment to self-regulation,[5] centers the authority of the profession and ethics on State approval. There is, then, a separation of "law" and medical ethics, with the line being the relative authority of each.

A reliance on professionalism or other conceptions of medical ethics that place the medical profession and ethics in an inferior position to the State leaves the medical profession perpetually subject to regulatory changes by the State that conflict with its own self-regulatory efforts. Further effectuating this are medical societies like the American Medical Association (AMA), which note that ethical obligations should supersede contradictory State law only "[i]n exceptional circumstances of unjust laws."[6] Disclaimers like this reinforce the authority of State law at the expense of professional self-regulation and the weight of ethics norms.

[5] See generally Eliot Freidson, *Profession of Medicine: A Study of the Sociology of Applied Knowledge* (Chicago: University of Chicago Press, 1970).
[6] Council on Ethical and Judicial Affairs, *Code of Medical Ethics of the American Medical Association, 2010-2011* (Chicago: American Medical Association, 2010) at 1.

To complement the theory of professionalism, there are also theories of State law: its origins and its authority compared to other sources of rules or norms. We are often confronted with a conception of law that places the sole or primary responsibility for its development and enforcement with the State.[7] The apparent acceptance of this conception—demonstrated by the actions of legislators, executives and judges—obscures other sources of laws, rules or norms, however they might be described, that also inform individuals' and groups' decision-making. Many groups, the medical profession included, have created their own rules that exist alongside or in absence of State law, or at times supplant State law. This is the way in which medical ethics operated for decades before the State claimed a stronger regulatory role, as the only or primary source of professional norms.

Resorting to the view of law as a creature created and controlled primarily if not entirely by the State does not bode well for the rules of these groups that claim their own authority, limited as it might be in scope, to adopt "law." To paraphrase the Bible (incidentally a source of normativity for many), a standard view of law would conclude that there is no other law than State law, denying authority to the rules of any other group if the State regulates to the contrary. This reflects our preconceptions of what "law" is, but does not necessarily reflect the reality of everyday life because State law is neither comprehensive nor ubiquitous for all who are under the State's authority. Everyday life—personal and

[7] See e.g. HLA Hart, *The Concept of Law*, 2d ed (Oxford: Oxford University Press, 1997). Hart wrote his treatise on law decades ago, but its concepts continue to inform legislators and judges who are tasked with creating and interpreting law.

commercial—presents a picture of individuals beholden to multiple sources of rules and expectations, some of these parallel to State law and some not.

This Thesis will depart from the constraints of professionalism and legal positivism by asserting medical ethics as a form of law within the medical profession, distinct and independent from State law, often intended to create clear rules for physician behavior and reinforcing these rules through institutional mechanisms used to discipline physicians who violate them. To aid in this, I will use legal pluralism as my theoretical framework, a theory that asks not what something looks like but how it is used within a community. Something might not be given the title of "law" and yet it performs essentially the same functions as State law, providing rules for behavior or transactions and some formula to ensure that these rules are followed. Much like the law of the State, the law of legal pluralism relies on the law's targeted population granting it legitimacy. The critical benefit of using legal pluralism lays in its ability to characterize behaviors and relationships by looking for their true nature, rather than only at labels applied by modern conventions. The root of the issue here, for medical ethics, is *how ethics is used*.

Beyond a basic connection of the concepts of legal pluralism to the practices of the medical profession and medical ethics—in the parlance of legal pluralism, a legal order for a semi-autonomous social field—I will show in this Thesis the reality of medical ethics in the modern profession and health care system: the often quiet but sometimes loud tensions that arise from attempts by two different social fields to create and enforce two different but parallel and at times conflicting legal orders. By using legal pluralism as the theoretical framework for these analyses, we can move beyond the strictures contained in our common

discourse of medical ethics, the medical profession, the State and the role of each in regulating physicians.

II. Medical Ethics, Physicians and the State

Medical ethics became a recognizable set of rules by the end of the 18th century with the publication of Percival's *Medical Ethics*.[8] This type of document contrasted with the Hippocratic Oath, an informal set of ethics that had been used off and on for centuries,[9] by its more detailed and comprehensive statements on a wide variety of medical and physician practices. In the US, the AMA's *Code of Medical Ethics* represented the first national ethics normative document, modeled in part on Percival's *Medical Ethics*.[10] Since its initial enactment in 1847, the *Code* has undergone numerous revisions, rewritings and amendments, and has also been joined by normative ethics documents of other medical societies. There is thus no shortage of concrete ethics rules in the US.

Due to the loose regulation of physicians during much of the 19th century, the AMA had nominal jurisdiction only over its members and the state medical societies that came to be under its umbrella. There were many "physicians" practicing who did not subscribe to the AMA or its ethics, and there was little that the AMA could do about them. It was not until the State began licensing physicians again starting in the late 19th century that medical ethics became a more effective normative system for all licensed physicians, not just those who were members of the AMA or their state or local medical society, primarily because

[8] Thomas Percival, *Medical Ethics; or, a Code of Institutes and Precepts, Adapted to the Professional Conduct of Physicians and Surgeons*, 3d ed (Oxford: John Henry Parker, 1849).
[9] Goodfield, *supra* note 2.
[10] American Medical Association, *Report of the Committee on a Code of Medical Ethics for the Government of the Medical Profession of the United States: Introduction to the Code of Medical Ethics* (Chicago: American Medical Association, 1847) [AMA, *Code of Medical Ethics (1847)*].

of the success of "regular" physicians (e.g. those affiliated with organized medicine) in supplanting other types of practitioners on state regulatory bodies. This resurgence of ethics was accompanied by a wave of State law and regulation of physicians and health care that has yet to subside. The combination of self-regulation through medical ethics and State regulation through licensure and other means created a complex interdependency between the medical profession and the State.

This interdependency has maintained some level of (semi-)autonomy for the medical profession. Medical ethics continues to be an important source of behavioral norms for physicians; practice standards are developed by professional organizations; medical education is regulated in part by an independent accrediting body, the Association of American Medical Colleges; and medical societies play a seminal role in designing and providing continuing medical education. Alongside these, the State broadly regulates physician licensure and many other aspects of the health care system, premised on its obligations to maintain the health of the populace and, more recently, its role as financier or direct provider of health care services.

I do not argue in this Thesis that the profession is completely separated from the State: this would be an obviously incorrect argument. The focus is rather on who regulates certain aspects of the profession and medical practice, and how it is done. It is about the historic and modern relationship between physicians and the State. The trajectory of modern medicine and the interests of all parties involved in the US health care system is leading towards a diminished independence for the medical profession, with fewer and fewer places to exercise its authority over the ethical comportment of its members. The traditional way of looking at the relationship between the profession and the State—that

the profession's authority is derived from the State's grace—does not provide a satisfactory solution to the future of medical ethics as a normative system. Nor would a return to a time of professional autonomy when ethics existed as the primary "law" for physicians.

The use of legal pluralism as a framework for this exploration of medical ethics as a legal order will be a unique application of the theory and provide perhaps better understanding for how relations between the profession and State should exist, and options for what these relations can become. This Thesis, therefore, aims to demonstrate the normative function of medical ethics for the medical profession, how it has been altered or diminished by the profession's relationship with the State and by internal challenges, and why ethics should remain a core function of the medical profession and a source of law for physicians.

III. What Follows

The remainder of this Thesis will be devoted first to reaffirming medical ethics as a form of law within the meaning of legal pluralism, and then exploring the reality of this law in the medical profession and its relationship with the State. To meet these ends, this Thesis has a number of components. The next Chapter explores the history of medical ethics and the medical profession in the US. While it is an interesting topic in general, it is useful to outline why the profession is the way it is today and how its relationship with the State developed, transitioning from fully autonomous to semi-autonomous. Following this, I will address the theory of legal pluralism and its utility for framing medical ethics as a form of law, as well as the separate but similar theory of professionalism, which can provide useful context for analyzing the medical profession and its relationship with the State that contrasts with legal pluralism.

Chapter 4 begins a discussion and analysis of medical ethics: what it is and how it is formulated. It examines medical society policies, bylaws and constitutions for evidence of ethics as a self-regulatory mechanism. This Chapter will show the origins of ethics as a form of law, its continued normative value, and its importance to physicians, patients and the State. Following this is a brief look at State regulation of physicians, primarily licensing structures with a lesser emphasis on peripheral regulation that impacts physician practice, to demonstrate the power of State law in professional life.

Chapters 6 and 7 explore specific topics in medical ethics and State law. In Chapter 6, topics that have traditionally been the wheelhouse of the independent medical profession are addressed, as well as more recent State actions that have heavily impacted the capacity of ethics to act as an authoritative source of control within the profession. Chapter 7 proposes areas of medical ethics and practice where the profession has shown limited ability to enact and enforce effective regulation. Both Chapters place the characteristics of legal pluralism in the reality of medical ethics and medical practice, moving beyond ethics on paper to the interactions between the profession and State that influence physician behavior, the normativity of medical ethics, and the autonomy of the medical profession.

Finally, Chapter 8 will bring these previous Chapters together to address, first, characteristics of medical ethics and the medical profession that allow for a consideration of ethics as a legal order and the profession as a semi-autonomous social field; second, the breadth of ethics and aspects of the health care system that call for some level of regulation by the State; and, finally, ways in which the relationship between the profession and State can be altered or improved to better reflect the need for and importance of medical ethics

as a legal order. The Thesis will conclude with an explanation of medical ethics as crucial for an effective and safe health care system.

CHAPTER 2: SELF-REGULATION AND REGULATION OF THE US MEDICAL PROFESSION: A HISTORICAL PERSPECTIVE

I. INTRODUCTION 22

II. THE "PRE-PROFESSION" AND THE BEGINNINGS OF ORGANIZED MEDICINE 23

A. Early Nationhood Until the Mid-19th Century 23

B. The Organizing of the First National Medical Society 28

C. "True" Medicine and Self-Regulation 32

D. The Reformation of the AMA 37

E. Conclusion 40

III. THE FORMALIZATION OF STATE REGULATION OF THE MEDICAL PROFESSION AND THE REFORM OF MEDICAL EDUCATION 41

A. The Return of State Licensure 41

B. Medical Education Reform 45

C. Conclusion 50

IV. HEALTH INSURANCE, GOVERNMENT INTERVENTION IN THE MARKETPLACE, AND THE DECLINE OF PROFESSIONAL AUTONOMY 51

A. Early Forms of Health "Insurance" 51

B. Group Health Insurance 54

C. Medicare, Medicaid, and Government Funded Health Care 57

D. Managed Care and Professional Autonomy 60

V. STATE REGULATION OF MEDICAL PRACTICE 64

VI. CONCLUSIONS, AND THE CURRENT STATE OF THE PROFESSION 67

I. Introduction

To address the topic of this Thesis, the US medical profession, medical ethics and legal pluralism, a few questions should be considered: what is the "medical profession" in the United States, and how has the historical progression of medicine influenced today's profession? First, when writing about something it is important to identify exactly what you are writing about. In using a term such as "medical profession" that can be defined from a variety of features, and which could include or exclude certain individuals depending upon the features chosen, clarifying what is intended is necessary.

Second, we can learn much from the past. The historical roots of physicians and medical societies grew into the medical profession that we have today, and decisions made two centuries ago left their imprint on modernity. Had certain events not occurred, such as the founding of the American Medical Association (AMA) in 1847, would we have a profession with the same characteristics that we now have? Would "irregular" practitioners that the "regular" physicians fought against for decades have retained their ability to practice? Would we have the advancements in medical science that now permit health care providers to more effectively treat many conditions? It is important to understand the events of the past that shape the medical profession—indeed, the health care system—of today.

This Chapter is intended to provide a brief historical account of the medical profession in the United States, especially as it developed after 1847 with the founding of the AMA. This history is incredibly rich and complex, and a number of authors have provided a more

in depth history of the profession than I do.[1] The focus here will be on those events and trends that place the profession within the construct of ethics and self-regulation, and the profession's developing relationship with the State and other non-professional entities.

First, the early period of the medical profession in the United States will be briefly examined, from the founding of the country until the mid-19th century. Next, the profession's place in society will be addressed, especially as it shifted following the formation of the American Medical Association and more organized attempts to control the practice of medicine in the absence of State regulation and support. These events led to a rebirth in state regulation and licensure in the latter third of the 19th century and educational reforms, the third section of this Chapter. The fourth section surveys the rise of health insurance, both private and public, from the early 20th century as drivers of patient, physician and State relationships. Finally, the fifth section identifies a number of State interventions in medical practice and the medical profession to address perceived or real deficiencies in the profession and the health care system.

II. The "Pre-Profession" and the Beginnings of Organized Medicine

A. Early Nationhood Until the Mid-19th Century

During the colonial period and early nationhood of the United States, there were few laws or regulations and little oversight over medical and healing practices, and thus little

[1] See generally James G Burrow, *AMA: Voice of American Medicine* (Baltimore: Johns Hopkins Press, 1963); Richard Harrison Shryock, *Medical Licensing in America, 1650-1965* (Baltimore: Johns Hopkins Press, 1967); Paul Starr, *The Social Transformation of American Medicine* (New York: Basic Books, 1982) [Starr, *Social Transformation*].

governmental refereeing to protect patients.[2] Various methods of healing were practiced and many practitioners had little or no formal training, even those calling themselves "physicians."[3] Physicians were often trained through apprenticeship,[4] and a few were educated in Europe's medical universities, which at the time were the world's preeminent medical educational institutions.[5] In reality, many of those who claimed to provide medical care had no proper education in either medicine or basic science.[6]

British authorities had established licensure regimes in the colonies, but these did not persist following the Revolutionary War.[7] Individual states began to take an interest in the regulation of physicians by the end of the 18th century,[8] but these attempts were both transitory[9] and insufficient to separate trained physicians from everyone else who sought

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[2] Henry E Sigerist, "The History of Medical Licensure" (1935) 104 J Am Med Assoc 1057 at 160. This was despite the fact that practice restrictions had already been in place in parts of Europe for some time, including England. *Ibid*. at 158-160. See also Starr, *Social Transformation*, *supra* note 1 at 44-47.
[3] Ted J Kaptchuk & David M Eisenberg, "Varieties of Healing 1: Medical Pluralism in the United States" (2001) 135 Ann Intern Med 189 at 189.
[4] Michael S Young & Rachel K Alexander, "Recognizing the Nature of American Medical Practice: An Argument for Adopting Federal Medical Licensure" (2010) 13 DePaul J Health Care L 146 at 151.
[5] *Ibid*. at 149. See also Starr, *Social Transformation*, *supra* note 1 ("[i]ncreasingly, Americans who had served an apprenticeship with a colonial practitioner sought a medical education in Europe…." at 39).
[6] Shryock, *supra* note 1 ("[h]ow uncontrolled practice was by the 1830s is best illustrated by the rise of medical sects without pretense to learning" at 32).
[7] Paul Starr, "Medicine and the Waning of Professional Sovereignty" (1978) 107 Daedalus 175 [Starr, "Professional Sovereignty"] ("[t]he first licensure act calling for the certification of physicians was passed in New York City in 1760, the first medical school was established in Philadelphia in 1765, and the first provincial medical authority was organized in New Jersey in 1766" at 179); Shryock, *supra* note 1; John Barry Bardo, "A History of the Legal Regulation of Medical Practice in New York State" (1967) 43 Bull NY Acad Med 924.
[8] See e.g. *ibid*. ("[l]egislation enacted in 1767 [in New York State] provided a measure of regulation of medicine; it permitted magistrates to license individuals by indorsing certificates of study issued by reputable physicians and surgeons" at 924); Georgia Medical Society, "History", online: Georgia Medical Society <http://www.georgiamedicalsociety.com/home.cfm?display=history> (the Society notes that the legislature adopted a medical licensing law in 1826 in conjunction with the Society). See also Shryock, *supra* note 1 at 24-25. New Jersey, New York and Alabama created state licensing boards in the latter quarter of the 18th century and into the 19th. Most other states left it to societies to license physicians.
[9] Most regulation of medical practice was repealed during the early- to mid-19th century due to resistance to licensure laws and monopolization of medical treatment. See "State Laws Respecting the Practice of Medicine" (1850) 42 Boston Med Surg J 109 ["State Laws"]; Starr, "Professional Sovereignty", *supra* note 7 ("[i]n the 1830s and 1840s, state legislatures repealed the medical licensing laws they had passed in the early years of the republic" at 179); Samuel L Baker, "Physician Licensure Laws in the United States, 1865-1915" (1984) 39 J Hist Med & Allied Sci 173 at 174 [Samuel Baker]; Shryock, *supra* note 1 at 27,

to provide "medical" treatment. In states where licensure acts were in force (though only temporarily), they were sometimes amended to the point of ineffectiveness, no longer providing the exclusivity initially promised.[10] Under some laws, the penalty for practicing without a license was merely the inability to sue in court for unpaid fees, meaning practitioners could still peddle their services without consequence unless a patient refused to pay.[11] More effective regulatory mechanisms were not established until much later in the 19th century.[12]

In the absence of operative state regulation, physicians attempted to create professional standards;[13] however, these lacked the scale that characterized attempts from the mid-19th century when the profession was better organized. One challenge was that the development of state and local medical societies—future drivers of professional unity—was sporadic and spread over decades in the late 18th and into the 19th centuries: they were not "well-established or influential bodies".[14] The development of organized and constant societies followed no discernable pattern: the Massachusetts Medical Society formed in 1781,[15] but

28-29, 30-31. Much of the decline of state regulation of physicians at that time has been associated with the anti-intellectualism of "Jacksonian democracy." *Ibid*. at 31; Starr, *Social Transformation*, *supra* note 1 at 57.

[10] For example, Georgia law was amended to prevent its operation "against the Thomsonian, or Botanic practice, or any other practitioner of medicine in this State". "State Laws", *supra* note 9 at 112.

[11] David A Johnson & Humayun J Chaudhry, *Medical Licensing and Discipline in America: A History of the Federation of State Medical Boards* (Lanham: Lexington Books, 2012) at 11.

[12] See e.g. Samuel Baker, *supra* note 9; Ronald Hamowy, "The Early Development of Medical Licensing Laws in the United States, 1875-1900" (1979) 3 J Libertarian Stud 73.

[13] See e.g. State Medical Society of New York, *A System of Medical Ethics* (New York: William Grattan, 1823); "Code of Medical Ethics" (1846) 35 Boston Med Surg J 39.

[14] Shryock, *supra* note 1 at 108.

[15] Massachusetts Medical Society, "About the Massachusetts Medical Society", online: Massachusetts Medical Society <http://www.massmed.org/AM/Template.cfm?Section=About_MMS&Template=/TaggedPage/TaggedPageDisplay.cfm&TPLID=92&ContentID=26284>. See also JN McCormack, "An Epitome of the History of Medical Organization in the United States" (1905) 44 J Am Med Assoc 1213. McCormack also notes that the first medical society in what would become the United States was formed in New Jersey in 1766.

the Pennsylvania medical society did not form until 1848.[16] In some states, societies formed, disbanded and then re-formed years later.[17]

It was within this minimally regulated medical environment that medical societies sought to limit medical practitioners to those like themselves and to differentiate the "regular" practice of medicine from the "irregular,"[18] which included the use of botanical and herbal remedies.[19] Although these efforts certainly benefitted the public in some respects, such as to hopefully identify and discredit the purveyors of harmful treatments, even those who claimed the mantle of "regular" physician often did more harm than good.[20]

In addition, while the early organizing of the profession meant to inhibit the spread of fraudulent care, there was still an overall lack of uniformity in what was considered appropriate medical treatment[21] and little by which the public could differentiate the safe

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[16] Pennsylvania Medical Society, "A Brief History of the Pennsylvania Medical Society", online: Pennsylvania Medical Society <http://www.pamedsoc.org/FunctionalCategories/About-/History.html>.
[17] See e.g. North Carolina Medical Society, "150 Years of Leadership: The History of the North Carolina Medical Society's Pioneering Physician Leaders", online: North Carolina Medical Society <http://www.ncmedsoc.org/media/pdf/NCMS_history_brochure1.pdf> ("[i]n 1804, members resolved to hold the next meeting in Chapel Hill on July 5, 1805; however, no such gathering is recorded thereafter until the formation of the Medical Society of the State of North Carolina in 1849" at 2).
[18] Kaptchuk & Eisenberg, *supra* note 3 at 190.
[19] Johnson & Chaudhry, *supra* note 11 at 17.
[20] Starr, "Professional Sovereignty", *supra* note 7 ("[a]t the same time, within medicine, prominent physicians raised severe doubts as to the validity of known therapies; a current of professional thought maintained that doctors had hardly any remedied of value" at 180); Johnson & Chaudhry, *supra* note 11 ("[p]atient treatments that involved scarification and cupping, blistering, bloodletting, induced vomiting via tartar emetic, intestinal purging through calomel, or profuse sweating with diaphoretics remained the bane of suffering patients well into the 1800s" at 14-15); Edward P Richards, "The Police Power and the Regulation of Medical Practice: A Historical Review and Guide for Medical Licensing Board Regulation of Physicians in ERISA-Qualified Managed Care Organizations" (1999) 8 Annals Health L 201 ("[m]edicine in 1790 did not work….Mainstream medical treatment consisted of purges, bleeding, and other regimes whose overall effect was to weaken the patient and increase the probability of death. More dangerously, since the germ theory and antisepsis had not been discovered, physicians did not practice good sanitation" at 206); Jeremy A Greene, David S Jones & Scott H Podolsky, "Therapeutic Evolution and the Challenge of Rational Medicine" (2012) 367 N Eng J Med 1077.
[21] See generally *ibid*.; Edmund Ramsden, "Science and Medicine in the United States of America" in Mark Jackson, ed, *The Oxford Handbook of the History of Medicine* (Oxford: Oxford University Press, 2011) 225.

from the unsafe. Why would anyone call on a regular physician when his treatment was as ineffective as an irregular's?

Furthermore, without the punitive authority of the states there was no one to enforce ethics[22] or practice standards promulgated by these groups. If a practitioner claimed to be a physician and yet violated all rules of the profession (as limited and unscientific as they were) to the detriment of patients, there was no entity that could prevent him from continuing to do so: medical societies had no authority over non-members.

Finally, the shift of medical education in the early 19th century into a profitable industry led to schisms even within the fraternity of regular physicians. The lack of uniform requirements and the unscrupulousness of many medical colleges rapidly increased the number of individuals with medical degrees without any improvement in the overall quality of physicians, since many degree grantors existed more as commercial enterprises than true training institutions.[23]

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[22] Percival's *Medical Ethics*, an early examination of medical ethics, was published in 1803 in Britain and was quite influential in the development of ethical codes by a number of US medical societies. Chauncey D Leake, "Percival's Code: A Chapter in the Development of Medical Ethics" (1923) 81 J Am Med Assoc 366. See also State Medical Society of New York, *supra* note 13.

[23] Young & Alexander, *supra* note 4 ("[a] professor in a proprietary medical school was paid directly by student fees, so the professor had no incentive to apply admission standards or fail admitted students" at 154); Starr, "Professional Sovereignty", *supra* note 7 ("[w]hile medical schools proliferated, especially in the western states, their standards declined, as nearly all of them became proprietary operations run by their professors for their own profit" at 179); Shryock, *supra* note 1 ("[p]rofessors in these schools, however genuine in their ideals, were paid directly by student fees, and they were often tempted to lower requirements so as to secure as many students as possible" at 28); Morris Fishbein, "History of the American Medical Association: Chapter 1 – The Organization is Conceived" (1946) 132 J Am Med Assoc 636 ("[b]ecause of the commercial character of these medical schools, the promotors sought by shortening of the curriculum and by the establishment of easy terms of graduation to induce great numbers of students to enter and to pay the fees" at 636).

Disarray of the regular physicians, increasing distress at competition that many physicians believed represented a danger to the public,[24] and the waning state efforts to address their concerns led to the establishment of a national organization to promote these physicians' profession. In 1846, representatives from many medical societies met to discuss the potential for a national association,[25] and they resolved to meet again the next year to "institute a national medical association for the protection of their interests, for the maintenance of their honor and respectability, for the advancement of their knowledge and the extension of their usefulness."[26] The AMA was, pursuant to this resolution, founded in 1847.

B. The Organizing of the First National Medical Society

The inauguration of the AMA as the first national physician organization in the US presaged the evolution of self-regulation in the continuing vacuum of State regulation. The AMA had a growing role in the trajectory of medicine, mainly due to its efforts to organize physicians and set practice (including ethical) and educational standards that reflected its view of what medicine should and could be.

The establishment of the AMA and state medical societies in those states where they did not already exist was intended to greatly enhance the economic and social standing of

[24] See e.g. CL Seeger, "On the Improvement of Medical Science" (1836) 14 Boston Med & Surg J 325 ("[o]thers, misled by indolence and credulity, and incapable of thinking for themselves, adhere mechanically to the dogmas of their teachers, and, as it often happens, are governed by mean avarice, considering their profession a mere trade to obtain wealth by any means, be they fair or foul" at 329).
[25] Shryock noted that the immediate purpose for the call to establish a national medical society "was a protest against permitting professors to license their own students—particularly when the latter might expect this reward in return for fees." Shryock, *supra* note 1 at 34.
[26] American Medical Association, *Digest of Official Actions, 1846-1958* (Chicago: American Medical Association, 1959) at 20 [AMA, *Digest of Official Actions*].

physicians in the United States, as well as promote uniformity in the practice of medicine.[27] The resolution envisioning the AMA was a romantic depiction of such a national professional organization: it was anticipated "that uniform and elevated standard of requirements for the degree of MD should be adopted by all the medical schools in the United States" and "that the medical profession in the United States should be governed by the same code of medical ethics."[28]

This *Code of Medical Ethics*, adopted at the same meeting that established the AMA, also set forth lofty goals for the profession. It grounded the *Code* in "religion and morality" and praised the "piety" of these physicians' predecessors.[29] It also decried fraudulent purveyors of dangerous treatments—"quacks who infest the land"[30]—and the lack of medical regulation by government as well as the support provided by the press to quackery in exchange for money (one must assume this refers to advertising income).[31] The *Code* was a foundation from which the profession could counter claims by quacks and irregulars that exceeded scientific reality, such as cures and prolonging of life where it was not medically possible.[32] The goal of the *Code* and of the profession as now officially organized under the AMA umbrella was to promote a form of medicine envisioned by *these* physicians in *this* time: "[b]y union alone can medical men hope to sustain the dignity and extend the usefulness of their profession."[33]

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[27] *Ibid*.
[28] *Ibid*.
[29] American Medical Association, *Report of the Committee on a Code of Medical Ethics for the Government of the Medical Profession of the United States: Introduction to the Code of Medical Ethics* (Chicago: American Medical Association, 1847) at 83 [AMA, *Code of Medical Ethics (1847)*].
[30] *Ibid*. at 86.
[31] *Ibid*.
[32] *Ibid*. at 87.
[33] *Ibid*. at 89.

Both pessimistic and optimistic interpretations of the goals of the AMA and organized medicine permeate historical analyses of this period of the profession.[34] It is likely a mixture of high-minded intentions[35] and self-interest that drove these physicians in the attempt to clearly separate themselves from other practitioners. Yet, even by the mid-19th century and beyond, there remained disagreement on what training was required for one to be called a "physician". Indeed,

> …distrust of elites and monopolies and an interest in the wealth that an open and competitive educational system could generate resulted in a more fluid medical marketplace in the United States. The result was a proliferation of proprietary medical colleges that continued to reduce fees, requirements, and, thus, the standard of education and training. As a consequence, a variety of specialisms and alternatives to therapeutic activism could remain, emerge, and develop—optometry, chiropractics, osteopathy, psychology, and midwifery.[36]

The physicians who formed many of the state medical societies and eventually the AMA saw the need to consolidate their own market position as legitimate practitioners. The benefits they anticipated for patients and the public thus coincided with economic drivers. In this manner, the tension between physicians as cogs in the wheel of a free-market economy and as trusted healers underlies the history of the profession and exists even

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[34] See e.g. Robert B Baker, "The American Medical Ethics Revolution" in Robert B Baker et al, eds, *The American Medical Ethics Revolution: How the AMA's Code of Ethics Has Transformed Physicians' Relationships to Patients, Professionals, and Society* (Baltimore: Johns Hopkins University Press, 1999) ("[t]he 1847 AMA Code of Ethics thus represents a twofold revolution: the revolutionary transformation of an ethics of character into an ethics of conduct, and the substantive moral transformation of Percival's status-sensitive morality into an egalitarian ethic acceptable to Jacksonian America" at 36); Burrow, *supra* note 1 ("[d]ivision, competition, and provincialism within the profession, however, prevented the establishment of a highly centralized and efficient organization" at 14); Shryock, *supra* note 1 ("…this society…viewed the deterioration of the medical schools with alarm and wished to bring them under professional control" at 34); Starr, *Social Transformation*, *supra* note 1 ("…monopoly was doubtless the intent of the AMA's program…" at 91).

[35] The Hippocratic tradition of medicine sets the avoidance of harm in providing care as the primary directive of the profession. "Hippocratic Oath", online: National Institutes of Health <http://www.nlm.nih.gov/hmd/greek/greek_oath.html>.

[36] Ramsden, *supra* note 21 at 227-228.

today.[37]

The American experience can be contrasted with British physicians of the time, and physicians in much of Western Europe, where the infrastructure for medical training was much better established than in the US.[38] Further, the culture of individuality and ingenuity that pervaded American politics and the mindset of the citizenry had no parallels in Europe. Although medical training for "regular" physicians in the US eventually developed along similar lines to that of European physicians, Americans faced a unique environment, the class and professional hierarchies of Europe having not made their way across the Atlantic.[39] Whereas physicians in Britain maintained social standing alongside the upper echelons of society, American physicians were relegated to a relatively low place in the social hierarchy, which persisted for decades after the AMA was established.[40]

The AMA provided a springboard to professional unity and uniformity previously unmatched in the US, but it also faced social and political resistance to monopolies and professions that dominated the American psyche of the time. As Starr pointed out, it was not until the population began to urbanize and rely more on medical professionals than family or irregular health practitioners that the role of the physician, as defined by the AMA and state and local societies, began to solidify into the profession that it eventually became.[41]

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[37] See e.g. Clark C Havighurst, "The Changing Locus of Decision Making in the Health Care Sector" (1986) 11 J Health Pol 697.
[38] See Shryock, *supra* note 1 at 5-12; Young & Alexander, *supra* note 4 at 146-148.
[39] Johnson and Chaudhry, *supra* note 11 ("[i]n England, the medical profession clearly reflected a hierarchical structure. Physicians were recognized as members of a learned profession, part of a cultural elite that was distinct from the 'lower orders of surgeons'…" at 6). See also Shryock, *supra* note 1 at 27-29.
[40] Starr, "Professional Sovereignty", *supra* note 7 at 180.
[41] Starr, *Social Transformation*, *supra* note 1 ("[t]he reduction of indirect prices from the local transportation revolution and the rise of cities put medical care within the income range of more

C. "True" Medicine and Self-Regulation

Despite the public's ambivalence towards all health practitioners in the mid- to late-19th century, the view of physicians regarding the irregulars was hardened. Following the AMA's creation, physicians and medical societies became more active in fighting practices deemed non-traditional, harmful and—using the term loosely here—unscientific.

The *Code of Medical Ethics* made clear that physicians, in their interactions with other physicians, should avoid those who engage in irregular practice; that is, those who follow an "exclusive dogma, to the rejection of the accumulated experience of the profession, and of the aids actually furnished by anatomy, physiology, pathology and organic chemistry."[42] Not only this, but physicians undertook a duty to "enlighten the public" on matters of quackery and expose its dangers.[43] This was the profession's attempt to freeze irregular practitioners out and to dominate the practice of medicine in a way that had thus far eluded it.

Even with these directives, the first decades of the AMA's existence saw continuing strife within the newly established societies as well as conflict with dogmatic competitors. From fellow regular physicians, the AMA's efforts to unify education were stymied due to the economic interests that many physicians retained in proprietary medical schools[44] and the difficulty of initiating uniform action by the AMA itself.[45] Increasingly rigorous

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people….Increasingly, one came to expect the doctor's intervention. Improved access ultimately brought greater dependency" at 71).

[42] AMA, *Code of Medical Ethics (1847)*, *supra* note 29 at 100.

[43] *Ibid*. at 106.

[44] Young & Alexander, *supra* note 4 at 155.

[45] See American Medical Association, "Address of NS Davis, President of the Association" in *Transactions of the American Medical Association*, vol 16 (Chicago: American Medical Association, 1866) ("[i]ndeed, most of the embarrassments attendant upon our past meetings, and the criticisms to which the Association has been subjected, have arisen from the difficulty of accommodating interests so important and varied, in

educational standards would mean the eventual end of most of these schools, which had little regard for a quality education, but during the period of State non-intervention they persisted. Non-physician health practitioners were successful at preventing state legislative action that could diminish their economic interests, often using the public's fear of monopolies to argue against more stringent medical licensure.[46] For the public, what mattered was their perceived or actual relief from illness and disease; it did not matter what the credentials of their healer were.[47] Many physicians believed that stricter discipline within the profession to support its standards and sway public opinion on irregulars was the answer to State and public apathy.

The loss of state recognition and licensing caused physicians to reconsider the role of the State in the delineation of medical practice. Some viewed this course of events as an opportunity for greater self-regulation rather than merely as a legislative and economic defeat. If the purpose of licensure laws was to defend "the public against their own rashness and folly",[48] than these laws were only appropriate so long as public sentiment supported them.[49] Once practice restrictions were removed it was up to the profession—the regular physicians—to ensure that the public was aware of the danger represented by quacks; the profession "would have to turn inward and rely on their own system of

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such a manner as to satisfy the advocates of each, in the very brief time hitherto allotted to our annual meetings" at 73).

[46] Thomas Hun, Joel A Wing & Mason F Cogswell, "State Legislation Respecting Medical Practice" (1844) 30 Boston Med & Surg J 469 at 474. See *contra* Reginald H Fitz, "The Legislative Control of Medical Practice" in Massachusetts Medical Society, *Medical Communications of the Massachusetts Medical Society*, vol XVI (Boston: Massachusetts Medical Society, 1895) ("[w]hat is open to all is no monopoly" at 287).

[47] Johnson & Chaudhry, *supra* note 11 at 20.

[48] Hun, Wing & Cogswell, *supra* note 46 at 473.

[49] *Ibid*. at 474.

regulation."[50] Thus, a more formal self-regulation was conceived, and for a short period in the mid-19th century the medical profession used self-regulation to improve its standing and sway the public in its favor.

Self-regulation by the medical profession was not unique to the US: in England, the crown had granted physicians this right by establishing the Royal College of Physicians in 1518.[51] However, outside of the right of the Royal College to examine and license physicians, English law did not otherwise forbid the practice of medicine by untrained individuals.[52] The self-regulation that American physicians turned to following the decline of state regulation did not even have the elements of State support that English physicians enjoyed. The profession was wholly reliant on itself to educate the public and ensure that only those properly trained were admitted to its ranks. Because the profession lacked any State assistance, it relied primarily on the *Code of Medical Ethics* to regulate members and its own efforts—alongside those of some of the more established medical schools—to create and enforce educational standards.

As mentioned previously, the AMA's *Code of Medical Ethics* prohibited physicians from interacting with irregulars.[53] This was probably one of the most important methods of controlling medical practice: by limiting the ability of physicians to consult with other health practitioners, the profession hoped to diminish the economic viability of these

[50] Starr, *Social Transformation*, *supra* note 1 at 91.
[51] Shryock, *supra* note 1 at 7.
[52] *Ibid*. Shryock noted that the law only forbade misrepresentation of status, which meant that anyone could do anything a physician could do so long as they did not claim to be a physician. See also Joseph M Jacob, *Doctors and Rules: A Sociology of Professional Values* (London: Routledge, 1988) ("[t]he [British Medical Acts] did not seek to outlaw unqualified or unorthodox practice: it made it an offence for the unqualified to pretend to be qualified" at 104).
[53] AMA, *Code of Medical Ethics (1847)*, *supra* note 29 at 100.

groups by denying them referrals. However, tensions arose within the profession in the decades after the AMA's founding about the benefits of relationships with these other practitioners, especially homeopaths.[54] At annual meetings of the AMA, physicians or societies who were accused of working alongside homeopaths or hiring them in health facilities had their AMA membership or delegation threatened.[55] This tension came to a head in 1882 when the New York State Medical Society (NYSMS) was denied the seating of its delegates at the AMA's annual meeting due to its disagreement with the AMA's *Code* on this point.[56]

This conflict was serious enough to cause the NYSMS to split in into two societies: a new society that retained the AMA's prohibition and the original society that permitted its members to collaborate or consult with irregular practitioners.[57] The NYSMS viewed the AMA's *Code* as anathema to modern medical practice, and promulgated its own ethics code that allowed members to associate with irregular practitioners if in patients' interests. These dissenters argued

> that the [AMA] code of ethics which obtained in the State of New York was an instrument which, however good at the time it was framed, no longer met the needs of the Medical Profession in the State; that its restrictions, if complied with,

[54] "Homeopaths had three central doctrines. They maintained first that diseases could be cured by drugs which produced the same symptoms when given to a healthy person….Second, the effects of drugs could be heightened by administering them in minute doses….And third, nearly all diseases were the result of a suppressed itch, or 'psora.' The rationale for homeopathic treatment was that a patient's natural disease was somehow displaced after taking a homeopathic medicine by a weaker, but similar, artificial disease that the body could more easily overcome." Starr, *Social Transformation*, *supra* note 1 at 96-98.

[55] For example, the Massachusetts delegation was asked to expel all homeopathic and eclectic members or face a non-seating of its annual meeting delegates—it gave in. Burrow, *supra* note 1 at 6.

[56] American Medical Association, *The Transactions of the American Medical Association*, vol 33 (Philadelphia: Times Printing House, 1882) at 60. See also Starr, *Social Transformation*, *supra* note 1 at 101.

[57] John Harley Warner, "The 1880s Rebellion Against the AMA Code of Ethics" in Baker et al, eds, *supra* note 34 at 58; Jeffrey Lionel Berlant, *Profession and Monopoly: A Study of Medicine in the United States and Great Britain* (Berkeley: University of California Press, 1975) at 121; Starr, *Social Transformation*, *supra* note 1 at 101-102. Ironically, it was the New York society that led the formation of a national medical society in 1846. Shryock, *supra* note 1 at 34.

> were embarrassing and absurd; that it did not command the respect of the Profession, and that it was no longer a living power, in guiding the sentiments of the medical men of the State. Moreover, the restrictions touching consultations with so-called irregulars, savored too much of the arbitrary rules of a trade-union, gave too strong a handle to quacks by raising the cry of persecution on partisan grounds, and were a serious obstacle in the way of legislative medical reform.[58]

This view of the AMA's *Code* reflected the idealism of the profession that accompanied the formation of the AMA in 1847—the morality and eminence of medicine that required the physician to place the patient at the forefront of his duties.[59] For the physicians of the NYSMS, many of the restrictions contained within the *Code* only denigrated the profession.

There was sufficient pressure on the AMA by the beginning of the 20th century that it revised its *Code* to, among other things, delete the prohibition against consultation with irregulars.[60] Subsequently, the NYSMS rejoined the AMA and once again represented a unified profession in New York.[61]

Attempts to enact education standards likewise caused tensions within the AMA, state societies, and the medical education establishment. From its founding, the AMA pushed for stricter standards:[62] it advocated pre-medical educational requirements, first a high school degree and then a university diploma, and then a lengthening of medical school education and strengthening of attendance requirements.[63] However, even those medical

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[58] Alfred C Post et al, *An Ethical Symposium: Being a Series of Papers Concerning Medical Ethics and Etiquette from the Liberal Standpoint* (New York: GP Putnam's Sons, 1883) at v-vi.
[59] See generally AMA, *Code of Ethics (1847)*, *supra* note 29.
[60] American Medical Association, "Proceedings of the Fifty-Fourth Annual Session, Held at New Orleans, May 5, 6, 7 and 8, 1903" (1903) 40 J Am Med Assoc 1364 at 1379 [AMA, "Proceedings, 1903"].
[61] "A United Profession in New York" (1902) 39 J Am Med Assoc 1054; "A United Profession in New York State" (1903) 41 J Am Med Assoc 968; Warner, *supra* note 57 at 65.
[62] American Medical Association, "Report of the Committee on Medical Education" in *Transactions of the American Medical Association*, vol 18 (Chicago: American Medical Association, 1867) at 363-368; Shryock, *supra* note 1 at 34.
[63] Burrow, *supra* note 1 at 10.

colleges that had long been supporters of regular physicians, such as Harvard and the University of Pennsylvania, initially resisted changes due to fears that if they unilaterally raised requirements they would quickly lose students to more forgiving schools.[64] The AMA's own membership also fought change, as "[m]any of its members held vested interests in weak colleges and the licenses provided by their degrees."[65] As will be discussed below, state licensure regulation eventually validated the AMA's position, but during the time when the AMA was reliant on self-regulation and cooperation[66] it was difficult to effect change in education unless the schools cooperated.[67]

D. The Reformation of the AMA

By the end of the 19th century, the AMA and other societies had yet to gain the prominence they sought through state and federal legislation and promotion of regular medicine.[68] In part, this was due to the inability of the AMA to act as a unified organization, both in its internal governance and in the development of policy positions.[69] Respected and active

[64] *Ibid*. at 8-9; Starr, *Social Transformation*, *supra* note 1 at 90-91.
[65] Shryock, *supra* note 1 at 35.
[66] S Oakley Vanderpoel, "The Futility of a Formal Code of Ethics" in Post et al., *supra* note 58 ("[e]ven were the American Medical Association, from the character of its organization or the nature of its attendance, entitled to speak authoritatively it would be a great strain of prerogative to act the part of a conscience mentor in conditions the peculiarities of which it could not anticipate. It has not, however, either in constitution or representation any such prerogative—for it is a purely voluntary organization without any chartered privileges and with no authority to enforce its own edicts…" at 37-38).
[67] Many schools eventually modified their curriculums, but some were faster to do so than others. Starr, *Social Transformation*, *supra* note 1 at 113-115. In addition, the opening of Johns Hopkins in 1893 created an educational blueprint that other universities couldn't ignore: a four-year curriculum as well as a requirement for a college degree prior to entrance. *Ibid*.
[68] See e.g. Charles AL Reed, "The President's Address: Delivered at the Fifty-Second Annual Meeting of the American Medical Association" (1901) 36 J Am Med Assoc 1599 ("[t]he American Medical Association, during the first fifty years of its existence, exerted relatively little influence upon legislation, either state or national" at 1601).
[69] *Ibid*. ("…the results that can be achieved only by the unification of our national profession cannot be attained under the present organization of our Profession" at 1605).

members of the association called for change in the structure of the AMA in order to meet the needs of the profession in a changing society.[70]

At its annual meeting in 1900, the AMA established the Committee on Organization to address the deficiencies in its structure that continued to inhibit its national effectiveness.[71] In 1901, the Committee proposed the House of Delegates (HOD) as the AMA's policy-making body, fixing its composition at a maximum of 150 members.[72] This was a solution to a major criticism of the AMA's democratic structure: it was unwieldy and permitted too many voting members.[73] The Committee also recommended that state societies reorganize their structures and make them more effective and hierarchical within the new AMA-state society structure,[74] including automatic membership in state societies for members of county and local societies.[75] This would permit the continued representation of these societies without the numerical hazard of allowing each to send delegates. Finally, the Committee recommended that HOD meetings be set in duration to allow for a full consideration of AMA business,[76] arguing that this change would help the AMA address such issues as medical education, licensing laws, reciprocity, medical-social considerations and scientific advancement—key to continuing self-regulation.[77] At the following annual

[70] *Ibid*. See also Burrow, *supra* note 1 at 27-28; "Association News: American Medical Association Fifty-Second Annual Meeting" (1900) 34 J Am Med Assoc 1544 at 1558 (adopting resolution calling for a committee to report on the organization of the AMA).
[71] *Ibid*.
[72] Committee on Organization, "Preliminary Report of the Committee on Organization" (1901) 36 J Am Med Assoc 1435.
[73] The apportionment of voting members at the AMA's meetings met the needs of the association in 1847 but had not been changed since, leading to over 1600 delegates at the last meeting before the change. *Ibid*. at 1438, 1446.
[74] *Ibid*. at 1436-1437.
[75] *Ibid*. at 1446.
[76] *Ibid*. at 1438.
[77] *Ibid*. at 1441-1442.

meeting, the AMA accepted the recommendations of the Committee and adopted a new constitution and bylaws.[78]

These changes have been credited with reinvigorating the AMA by dramatically increasing membership[79] and giving rise to the prominence it attained during the first half of the 20th century.[80] Certainly, they created a more streamlined organization, better suited to address the concerns of the modern profession.[81] These reforms also recognized the importance of the AMA in asserting the national interests of physicians on a wide range of issues, including medical education and licensure. Burrow titled his chapter on this matter "The Awakening of the AMA":[82] this title captures perfectly the magnitude of these events. Although we can never be certain that the profession as represented by the AMA would not have had the impact that it eventually had even without its restructuring, the acknowledgement of political impotence that drove the changes sparked a professional renaissance of sorts that led to education reforms, stricter licensing, and the demise of irregular practitioners[83] that the profession had sought since before the AMA's inception.

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[78] "Association News: American Medical Association Fifty-Third Annual Meeting" (1901) 36 J Am Med Assoc 1631 at 1648.
[79] Burrow, *supra* note 1 at 49-50. Burrow notes that "total membership had jumped from 8,401 in 1900 to 70,146 in 1910 and reached 83,338 in 1920." *Ibid*.
[80] *Ibid*. at 27; Starr, *Social Transformation*, *supra* note 1 ("[i]n a remarkably short period, physicians began to achieve the unity and coherence that had so long eluded them" at 110).
[81] The prominence given to the Committee on Legislation following the AMA's restructure also greatly aided the AMA's growing political influence. See generally Burrow, *supra* note 1.
[82] *Ibid*. at 27.
[83] This included the producers of "nostrums" that were believed dangerous to the public, either by adulteration of products or outright false claims combined with hazardous ingredients, and led to the profession's push for the Pure Food and Drugs Act during the first two decades of the 20th century. See e.g. *ibid*. ch 4; James Harvey Young, *The Medical Messiahs: A Social History of Health Quackery in Twentieth Century America* (Princeton: Princeton University Press, 1967); "Relations of Pharmacy to the Medical Profession" (1900) 34 J Am Med Assoc 986.

E. Conclusion

The shape of the medical profession changed rapidly in the mid-19th century, following centuries of disorganization first in the British colonies and then in the early years of the United States. Much of this tracked happenings in the profession as it existed in Europe, but the peculiarities of American governance and society influenced the speed and impact of these changes to a degree not experienced in Europe.

Even after the AMA was established in part to raise the public (and economic) status of the medical profession, physicians continued to conflict with irregular practitioners and even their own colleagues on a variety of matters, from education standards to the strict prohibitions contained within the *Code of Ethics*. The waning of state licensure laws put the AMA and state societies in the unenviable position of having to police their own members with few sticks or carrots to enforce standards and behavior, just a voluntary set of ideals that at times conflicted with economic self-interest. Public resistance to professional monopolies and the ability of irregulars to generate sympathy created additional barriers to a cohesive and strong profession.

In the end, professional self-regulation in the absence of any State sanction was not the means to professional supremacy that some physicians hoped for[84]—it was a "thirty years' hopeless experiment."[85] Public sentiment,[86] it turns out, is no replacement for State intervention.

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[84] Johnson & Chaudhry, *supra* note 11 ("…the AMA was no more successful than MSSNY had been in New York because neither organization had the legal right to impose penalties" at 19).
[85] Reed, *supra* note 68 at 1603.
[86] Hun, Wing & Cogswell, *supra* note 46 at 474.

III. The Formalization of State Regulation of the Medical Profession and the Reform of Medical Education

A. The Return of State Licensure

The formation of the AMA and its efforts to clearly separate trained physicians from everyone else claiming to practice medicine provided a new foundation from which to classify the profession. In addition, and perhaps more importantly, advances in medical science allowed states and the public to better distinguish between helpful and harmful practitioners because treatments began to actually work in many more instances than previously.[87] Finally, the anti-monopoly fervor that characterized populist politics and thus the de-regulation of medicine earlier in the century had ebbed, and was replaced with a wider movement to license trades and professions.[88]

Contrary to previous state practices of sporadic and non-uniform regulation of medicine in the 18th and early 19th centuries, efforts by the later 19th century were more widespread, exhibited some uniformity in legislative design and purpose,[89] and permitted states to "close what had been nearly uncontrolled entry into the practice of medicine".[90] Although still rudimentary by today's standards of (hyper)regulation, these new laws exhibited a concordance with the AMA's vision of the medical profession and greatly improved the

[87] See John C Burnham, "American Medicine's Golden Age: What Happened to It?" (1982) 215 Science 1474; Richards, *supra* note 20 at 209; Shryock, *supra* note 1 at 44; Johnson & Chaudhry, *supra* note 11 at 26.
[88] Starr, *Social Transformation*, *supra* note 1 at 103. See also Johnson & Chaudhry, *supra* note 11 at 22-23.
[89] Samuel Baker, *supra* note 9 at 173.
[90] *Ibid*. Baker noted that previous chronologies of state laws were incomplete. *Ibid*. at 173 n 2. He also indicated the difficulty in compiling historical state laws: "The chronology in this paper is based on a search of legislative session law volumes, generally unindexed. This awkward method was required because laws which have been repealed and replaced have no relevance for current cases and thus are not listed in compilations intended for lawyers." *Ibid*. at 173-174. Such difficulties remain today, and therefore I will rely on Baker's work here to provide details on early state legislation.

professional position of physicians.

The laws that were enacted by the late 19th century had a variety of avenues for licensure of regular physicians. Most allowed for a medical college diploma or formal examination to suffice, and some still linked licensure to medical society certification.[91] The use of a diploma as one route to licensure, though, ignored the continuing disparities in the quality of medical education: "[s]uch laws tended to encourage the proliferation of medical schools and thus depress the average quality of medical education."[92] However, when licensing boards sought to heighten requirements for practice, they sometimes faced challenges from graduates whose medical schools were considered suspect. The US Supreme Court upheld in general the capacity of state licensing authorities to deny applicants who attended substandard schools,[93] but not all of these early legal challenges to board determinations failed.[94]

As legislatures granted licensing boards more authority and requirements for licensure were heightened, it became easier to disqualify applicants who attended medical schools deemed second-rate.[95] However, the variation in license requirements between states[96]

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[91] *Ibid*. at 175 table 1.
[92] *Ibid.* at 178.
[93] *Dent v West Virginia*, 129 US 114 (1889) [*Dent*]. The Court determined that the state's medical certificate laws did not deprive individuals of a vested right, and upheld a state law that permitted the board of health to deny a certificate to an applicant who did not attend a "reputable" medical college (in this instance, it was an eclectic college).
[94] *State ex rel. Johnston v Lutz*, 38 SW 323 (Mo Sup Ct 1896) [*State ex rel. Johnston*]; Starr, *Social Transformation*, *supra* note 1 at 105. In *Lutz*, the applicant successfully challenged his license denial, as the board of health had only determined that his medical college did not meet their standards after he applied. See also *State v Pennoyer*, 18 A 878 (NH Sup Ct 1889) (state supreme court declared that the medical licensing statute could not discriminate in favor of physicians who practiced in a town for a specified amount of time by exempting them from licensing fees) [*Pennoyer*].
[95] See e.g. *Illinois State Board of Health v People*, 102 Ill App 614 (Ill Ct App 1902) [*Illinois State Board of Health*].
[96] "The Present Status of Medical Legislation in the United States" (1890) 14 J Am Med Assoc 167 ["Medical Legislation"].

confounded regular physicians, who continued to decry the admittance into practice of the unqualified. Many licensure laws continued to permit the licensing of irregular practitioners alongside the regulars by either including these individuals explicitly in the law or "grandfathering" them (i.e. they were practicing medicine prior to the passage of the law).[97] In addition, the effectiveness of boards was also quite varied, and none of them were "properly constituted, organized, and equipped."[98]

Over time, licensure qualifications were revised from the minimal and sometimes nearly meaningless requirement to hold a medical school diploma,[99] to review of medical schools by licensing boards,[100] to certification by medical societies, and finally to formal examination by licensing boards.[101] Eventually, license requirements became uniform and included a 4-year medical degree and passage of an examination, though it would be decades before the examination itself became uniform across states.[102] The Association of American Medical Colleges, originally established in 1890, became the preeminent guarantor of medical school quality and curriculum[103] and the Federation of State Medical

[97] Starr, *Social Transformation*, *supra* note 1 ("[r]ecognizing their inability to secure legislation on their own, many educated regular physicians accepted collaboration with sectarians to win licensing laws that would protect all of the against competition from untrained practitioners" at 103). See also Samuel Baker, *supra* note 9 at 179. Table 2 illustrates the inconsistency of state licensing laws—many of which permitted licensure of homeopaths and eclectics. See also "Medical Legislation", *supra* note 96 at 168.
[98] Abraham Flexner, *Medical Education in the United States and Canada: A Report to the Carnegie Foundation for the Advancement of Teaching* (New York: The Carnegie Foundation for the Advancement of Teaching, 1910) at 170.
[99] This requirement might be nearly meaningless in the context of proprietary schools that were essentially diploma mills, imparting little real training to their graduates. See Samuel Baker, *supra* note 9 at 178.
[100] The Illinois Board of Public Health reported on the number and type of medical colleges, including naming a few "fraudulent". Shryock, *supra* note 1 at 54.
[101] Subjects covered by exams and their difficulty varied between states. As well, the content of exams in some states permitted irregular practitioners to continue to become licensed, as topics where they and the regulars were most likely to disagree were either not included or "given by members of the applicant's sect." Samuel Baker, *supra* note 9 at 187.
[102] James N Thompson & Lisa Robin, "State Medical Boards: Future Challenges for Regulation and Quality Enhancement of Medical Care" (2012) 33 J Legal Med 93 at 95.
[103] The Association set minimum requirements for membership, including length of the degree program and subjects upon which applicants must be tested. Association of American Medical Colleges. "Constitution of

Boards provided a venue for state licensing policy development and cooperation.[104] Both of these entities still exist today, and continue to inform medical education and licensure standards.

The medical profession, especially state societies and the AMA,[105] played a vital role in the development of state licensing laws.[106] These enactments had the dual benefit of improving physicians' economic outlook and the overall quality of medical care. Although early laws continued to permit irregulars to practice through grandfather clauses, loose diploma requirements, and the establishment of separate boards to license eclectics or other irregular practitioners, by the second decade of the 20th century regular physicians dominated the ranks of licensees.[107] The gradual separation of the profession into practice specialties also tightened the profession's control, as specialists were certified by their own boards and developed their own educational and residency requirements.[108] The ascendancy of the medical profession's authority through membership on licensing boards[109] and in setting licensing standards[110] continued for much of the 20th century, although today physicians now share responsibility for professional regulation with non-

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the Association of American Medical Colleges" (1903), online: Association of American Medical Colleges <https://www.aamc.org/download/171070/data/aamc_constitution_bylaws_1905-1933.pdf> at 1-2.

[104] See generally Johnson and Chaudhry, *supra* note 11.

[105] AMA leadership advocated for uniform licensing requirements and state reciprocity from the early 20th century, although it would be years before there was much statutory uniformity and pure reciprocity still does not exist. John Allen Wyeth, "The President's Address, Delivered at the Fifty-Third Annual Session of the American Medical Association at Saratoga Springs, N.Y., June 10-13, 1902" (1902) 38 J Am Med Assoc 1551 at 1552. See also "Medical Legislation", *supra* note 96.

[106] Starr, *Social Transformation*, *supra* note 1 ("[r]ecognizing their inability to secure legislation on their own, many educated regular physicians accepted collaboration with sectarians to win licensing laws that would protect all of them against competition from untrained practitioners" at 102).

[107] *Ibid*. ("[w]hen homeopathic and Eclectic doctors were shunned and denounced by the regular profession, they thrived. But the more they gained in access to the privileges of regular physicians [e.g. licensure or certification], the more their numbers declined" at 107).

[108] Shryock, *supra* note 1 at 66-70.

[109] Johnson & Chaudhry, *supra* note 11 at 24.

[110] Many states required that applicants attend schools approved by the AMA or the Association of American Medical Colleges. Samuel Baker, *supra* note 9 at 190.

physician members of medical boards.

B. Medical Education Reform

Medical education reform went hand-in-hand with state licensing reform, as educational standards were one means of measuring the suitability of physicians for licensure, and states were already taking steps to address applicants with inadequate education.[111] Reforms were pushed by the AMA[112] and other societies and promoted heavily by major medical colleges, leading to more standardized medical education and further marginalizing many of the irregulars.[113] Increasing requirements for pre-medical education (high school, college), attempts to create curricular standards, and improvements in the science of medicine contributed as well to the decline of proprietary medical schools, whose focus was more on quantity of attendees than quality of graduates.[114] The AMA undertook a survey of medical schools in 1906, and the results were damning:

> …it inspected the 160 schools then in existence and fully approved of only 82, which it rated Class A. Class B consisted of 46 imperfect, but redeemable, institutions, while 32, beyond salvage, fell into Class C.[115]

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[111] See e.g. *Dent*, *supra* note 93; *Illinois State Board of Health*, *supra* note 95; *Pennoyer*, *supra* note 94; *State ex rel. Johnston*, *supra* note 94.

[112] However, for years following the AMA's establishment, it was ineffective at directing educational reform and the schools themselves generated many of the changes during this period. Shryock, *supra* note 1 at 45-46. See also Andrew H Beck, "The Flexner Report and the Standardization of American Medical Education" (2004) 291 J Am Med Assoc 2139.

[113] Homeopaths and osteopaths modified their practices and over time became more like regular physicians (now called allopaths). Shryock, *supra* note 1 at 44.

[114] *Ibid*. ("[i]n effect, the AMA council was saying by 1904 that if schools could not provide adequate education at a profit, they must give way to colleges supported by tuition, endowments and/or taxes. Such an outcome, combined with licensing controls, would put an end to schools which were proprietary in nature or inferior for other reasons" at 61); Flexner, *supra* note 98 at 11, 156; Starr, *Social Transformation*, *supra* note 1 at 118-119.

[115] *Ibid*. at 118. See also Morris Fishbein, "History of the American Medical Association: Chapter 18 – Development of the Councils" (1947) 133 J Am Med Assoc 687; Elton Rayack, *Professional Power and American Medicine: The Economics of the American Medical Association* (Cleveland: World Publishing Company, 1967).

Unfortunately, the continuing ethical convention against publicly denigrating fellow physicians persisted,[116] and these results were not widely publicized and no action was taken directly by the AMA.[117]

However, following pressure by physicians and medical associations, the Carnegie Foundation funded a study of medical education in the United States and Canada.[118] Abraham Flexner was assigned to perform this research, and his very public and harsh examination of the state of American medical education drove change far more effectively than anything the profession had previously been able to accomplish on its own. Flexner was unconstrained by professional niceties and perceived conflicts of interests that might inhibit professional (e.g. AMA) criticism or praise of medical education and educational institutions.[119]

Although he recognized the continued shortcomings of even the best medical schools, Flexner lauded the professional and scientific efforts motivating the betterment of medical education, as well as the actions of many medical schools in the face of the economic uncertainty that necessarily accompanied a shift to lengthier education requirements and more rigorous curriculums.[120] Yet he also argued that there were too many physicians, and

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[116] The recently adopted *Principles of Medical Ethics* (a revision of the *Code of Medical Ethics* of 1847) called on physicians to "honor the fraternity as a body." AMA, "Proceedings, 1903", *supra* note 60 at 1379. It is not clear whether this was the basis for not publicizing the results of the survey, as the *Principles* also recognized that the profession required purity of character and the highest moral excellence. *Ibid*. at 1380. It seems as though many of the faculty at the proprietary schools, especially those classified as "C," would not have met this standard.

[117] Starr, *Social Transformation*, *supra* note 1 at 118.

[118] Beck, *supra* note 112 at 2139; Rayack, *supra* note 115 ("[t]he A.M.A.'s Council on Medical Education had been in close contact with the foundation prior to the Flexner investigation and was instrumental in bringing it about" at 67); Shryock, *supra* note 1 ("…a council [on medical education] committee made up of one hundred physicians recommended a survey of all the nation's medical schools" at 62); Starr, *Social Transformation*, *supra* note 1 at 118.

[119] *Ibid*. at 119.

[120] Flexner, *supra* note 98 at 11.

too many of these were poorly educated and trained.[121] The primary direction of his report was that there should be fewer, higher quality medical schools graduating fewer, higher quality physicians.[122] This might seem counter-intuitive, as having a larger number of physicians would logically benefit the population, but the argument was framed in terms of what was actually necessary and sustainable moving forward from the current number of physicians: "[t]he region [rural, with small towns] is thus better served by one well trained man than it could possibly be even if over-production on a low basis ultimately succeeded in forcing an incompetent into every hamlet of five and twenty souls."[123]

Flexner differentiated the commercial nature of many schools from the true nature of medical practice—incidentally a distinction made by the AMA decades previous at its founding.[124] "The overwhelming importance of preventive medicine, sanitation, and public health indicates that in modern life the medical profession is an organ differentiated by society for its own highest purposes, not a business to be exploited by individuals according to their own fancy."[125] He found that many of the schools focused more on marketing and recruitment than on the sciences they were advertising as teaching their students.[126]

The report also differentiated the ideal pre-medical education from current reality. Flexner argued that a proper foundation in chemistry, biology and physics was necessary prior to a

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[121] *Ibid*. at 16.
[122] *Ibid* at 16-17.
[123] *Ibid*.
[124] The introduction to the 1847 *Code of Medical Ethics* was laden with lofty, and perhaps unrealistic, expectations of the education and character of physicians. AMA, *Code of Medical Ethics (1847), supra* note 29.
[125] Flexner, *supra* note 98 at 19.
[126] *Ibid*.

medical education.[127] Such an education, he asserted, was only available through college, as opposed to the high school degree or less that was required by many medical schools.[128] Only 16 medical schools—out of the 155 he investigated—required two or more years of college, though a number of others were nearly ready to introduce such a requirement.[129] The bulk of the schools required only a high school diploma or equivalent, an entrance examination in the absence of a diploma, certification by an official when an applicant presented written proof of education other than a diploma of an accredited high school, or, in the lowest level of school, grammar school education and possibly two years of high school.[130] Within this range of medical schools, Flexner noted that the extent to which the schools screened applicants varied greatly, with some schools taking seriously the high school degree equivalent and others accepting certificates from non-existent schools, ignoring rules or exerting pressure on external examiners to certify applicants.[131]

The *Flexner Report* provided a number of recommendations to address the deficiencies in medical education. In addition to strengthening and enforcing pre-medical school educational requirements[132] and laying out a more stringent medical curriculum,[133] Flexner recommended actions by state medical licensing boards, providing further evidence of the necessary intertwining of the State and the medical profession. He recognized that medical

[127] *Ibid*. at 25.
[128] *Ibid*. at 25-27.
[129] *Ibid*. at 28.
[130] *Ibid*. at 32, 36.
[131] *Ibid*. at 32-35. Flexner placed Canadian medical schools in the category of requiring only a high school degree, but also praised them for using more stringent measure to determine equivalency than what many US schools used. *Ibid*. at 35. Indeed, he characterized McGill University and the University of Toronto as "excellent." *Ibid*. at 325.
[132] *Ibid*. at 49-51. Flexner clearly disliked anything other than a requirement for college education prior to medical school, but accepted that in many regions, the south especially, a high school education would have to suffice for a time so long as admissions standards were more rigorously enforced.
[133] *Ibid*. at 52-70, 92-104.

boards "are the instruments through which the reconstruction of medical education will largely be effected."[134] This is what the AMA sought by pursuing professional licensure laws, and what the profession failed to achieve when completely self-regulating for much of the second half of the nineteenth century. Importantly, Flexner argued that the boards should exercise their right—where laws permitted—to deem deficient medical schools as such and reject the applications of graduates (in part as a stop-gap until educational pre-requisites were standardized and enforced).[135] In addition, boards should be made up of the best of the profession, including academic physicians who were at the time often excluded from these boards, and be properly funded so that they could exercise all of their proper functions of licensing and investigation.[136] No improvement in medical education would be possible without strong medical boards in each state.

In its investigation and classification of medical schools, the *Flexner Report* shed light on medical education that the organized medical profession had attempted for decades. Certainly, Flexner's caustic characterization[137] of many of the educational institutions in the US and Canada implicated AMA and state/county medical society members, who might have owned or taught at deficient schools, as well as the organizations themselves for failing to properly address the problems. Yet the report also garnered the attention of policy

[134] *Ibid*. at 167.
[135] *Ibid*. at 168. As noted in the previous Section some state boards were already doing this. See *Dent*, *supra* note 93; *Illinois State Board of Health*, *supra* note 95.
[136] Flexner, *supra* note 98 at 171.
[137] Starr wrote that Flexner "was much more severe in his judgment of particular institutions than the AMA had been in any of its annual guides to American medical schools." Starr, *Social Transformation*, *supra* note 1 at 119. Such a description is accurate. Flexner is extremely critical of those schools that justified their loose educational prerequisites and short, deficient curriculum as reflecting the needs of poorer, rural applicants who might need to spend part of the year helping out on the farm: "[b]esides, if poverty is to be a factor in determining entrance standards, just where does poverty cease to excuse ignorance? Apparently the inexcusable degree of ignorance begins just where the ability to pay fees leaves off." Flexner, *supra* note 98 at 43.

makers and the public, who might be more willing to believe an impartial investigator than a conflicted institution. And although both Flexner and others acknowledged the decline of proprietary medical schools before and during the period of his investigations, many since have recognized the impact that the report had on the trajectory of medical education and the role of physician and medical school associations in standardizing entrance and graduation requirements.[138]

C. Conclusion

The self-regulatory experiment of the mid-19th century demonstrated that the medical profession acting on its own had little capacity to shape medical care in the United States. Complete self-regulation was essentially a voluntary undertaking and did little to promote the betterment of the profession and health care. It was not until states again took an interest in professional licensing that the organized profession could assert control over the practice of medicine. The joining of professional and State efforts to regulate medical practice led to the shrinking influence of irregular practitioners, either through outright state abolition of their modes of practice (by non-inclusion in licensing statutes) or their inability to compete economically with physicians.

Medical education reform also contributed to the growing influence of the profession over the contours of medical care and the responsibilities of various professionals and occupations within the health care system. Again, though, it was only with the complicity of states that reform took place, as profession-only attempts were often met with resistance

[138] Beck, *supra* note 112; Rayack, *supra* note 115 at 67; Shryock, *supra* note 1 at 62-63. See *contra* Starr, *Social Transformation*, *supra* note 1 ("[t]he schools were condemned primarily by the changes in licensing rather than by *Bulletin Number Four* [another name for the *Flexner Report*]. At most, Flexner hastened the schools to their graves and deprived them of mourners" at 120).

by irregulars or even regular physicians with financial interests in the status quo, as well as by more established schools fearing the economic consequences of unilateral change. It was an independent study, the *Flexner Report*, that generated the attention necessary to initiate far-reaching and more permanent changes to the professional educational and licensing systems that had eluded both the profession and individual states for decades.

The reentry of the State into medical regulation after decades of absence left lasting marks on the medical profession. Although these early changes represented only a minor infringement on the authority of the profession,[139] they presaged a greater influence over the profession exercised by the State and others in the coming decades and to the present time.

IV. Health Insurance, Government Intervention in the Marketplace, and the Decline of Professional Autonomy

A. Early Forms of Health "Insurance"

From the early 20th century, physicians became concerned with the possibility of third parties intervening in payment for their services. Issues such as contract practice and fee splitting[140] and non-physicians "practicing" medicine (e.g. the corporate practice of medicine)[141] colored the debate over who paid for medical care and how it was provided. Physicians declared that their autonomy was at stake: if a third party controlled the purse

[139] Licensing and educational reforms were generally in line with what the organized profession wanted, as discussed above.
[140] Prior to formal medical insurance, there was "contract practice", where physicians would be paid a set fee to care for certain individuals. This fee might have been paid by a corporation, lodge or fraternal organization, or even a group of physicians. Starr, *Social Transformation*, *supra* note 1 at 207.
[141] *Ibid*. at 204.

strings, might they also want to control medical decision-making? These patient care concerns went hand-in-hand with economic considerations and the ability of physicians to set their own payment rates—there were worries of "unlimited services for limited pay" and reported incidents of competition for contracts that led to very low payments.[142] Physicians and medical associations fought against the establishment of various forms of health insurance, succeeding for a time but eventually succumbing to the market and technological realities of this new era.

Initial third-party involvement in health care payment began with corporations, as employers sought to cover the costs of injury to their employees especially when related to their employment and for health examinations of current and potential workers.[143] These arrangements—corporate practice contracts—though not necessarily viewed as beneficial to the medical profession, were accepted by the Judicial Council of the AMA because of their perceived necessity for the efficient operation of a business (limiting damage suits by employees and ensuring the health of employees) or due to geographic isolation of the employer otherwise limiting employee access to physicians.[144] Although these caused some consternation within the medical profession because of their negotiation of payments rather than the more typical fee-for-service, these plans diminished with the Great Depression of the late 1920s.[145]

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[142] *Ibid*. at 208; "Contract Practice" (1907) 49 J Am Med Assoc 2028.
[143] Starr, *Social Transformation*, *supra* note 1 at 200-202.
[144] American Medical Association, "Proceedings of the Minneapolis Session: Minutes of the Sixty-Fourth Annual Session of the American Medical Association" (1913) 60 J Am Med Assoc 1989 at 1997. See also Burrow, *supra* note 1 ("[a]lthough [the AMA] considered unobjectionable the practice, adopted by some industries and remote mining establishments, of contracting with physicians for the treatment of their patients, it strongly denounced most types of contract practice" at 139).
[145] Starr, *Social Transformation*, *supra* note 1 at 204.

Other forms of health care payment established in the early 20th century included sickness funds, often provided through employers as well but also by fraternities and lodges. These can be differentiated from corporate contract practice because the goal was to pay for health care regardless of cause. In the employment context, workers paid premiums and were screened similarly to modern health insurance (e.g. by discouraging the old and already sick from applying).[146] In other contexts, such as fraternities and lodges, the funds operated in a comparable way, by collecting payments from members and dispersing to physicians when necessary. There was greater negative reaction to these programs from the profession, as they represented the greatest potential for the negotiating down of fees,[147] which could impact the fees charged by physicians who were not part of these plans. However, sickness funds began to decline in the 1930s and 1940s as group health insurance supplanted them in cost and efficiency.[148]

During the time of corporate contract practice and sickness funds, the majority of health care was still provided via traditional fee-for-service. These other forms of payment, though threatening to the status quo, were transitory and set the stage for the evolution of group health insurance.

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[146] John E Murray, *Origins of American Health Insurance: A History of Industrial Sickness Funds* (New Haven: Yale University Press, 2007) at 7-8.
[147] Starr, *Social Transformation*, *supra* note 1 at 208. See also "Club Practice-How Shall We Meet It" (1900) 34 J Am Med Assoc 242; David T Beito, "The 'Lodge Practice Evil' Reconsidered: Medical Care Through Fraternal Societies, 1900-1930" (1997) 23 J Urb Hist 569; George Rosen, "Contract or Lodge Practice and Its Influence on Medical Attitudes to Health Insurance" (1977) 67 Am J Pub Health 374.
[148] Murray, *supra* note 146 at 229-235.

B. Group Health Insurance

With the cost of health care increasing due to surges in the use of physicians and health facilities,[149] potentially devastating the finances of poorly paid workers, new solutions for providing access to health care were necessary. The continual defeat throughout the early 20th century of any sort of national health insurance required private market action.[150] However, anything developed would have to address the health needs of large numbers of people in a way that limited their costs as well as ensured the economic viability of health care providers.

Several factors affected the development of insurance in the US, including moral hazard and adverse selection. Private insurance failed to develop in the early 20th century in part due to these barriers. Overuse of services by insureds who had little incentive to limit

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[149] The continual improvements in medicine since the latter part of the 19th century led to a focus on the medical profession and hospitals as sources of treatment and health. Much of the distrust of medicine that previously characterized public opinion dissolved with more successful care. See Starr, *Social Transformation*, *supra* note 1 at 260-266 ("…a new element in health insurance had developed quietly during the 1920s: the rising costs of hospital care and the new salience of such costs for middle-class families" at 295); Robert Cunningham III & Robert M Cunningham Jr, *The Blues: A History of the Blue Cross and Blue Shield System* (Dekalb: Northern Illinois University Press, 1997) at 3-4; Melissa A Thomasson, "From Sickness to Health: The Twentieth-Century Development of U.S. Health Insurance" (2002) 39 Explorations Econ Hist 233 at 236.

[150] See generally Starr, *Social Transformation*, *supra* note 1 at 235-289 for a detailed discussion of the many failed efforts in the first half of the 20th century to establish some form of public health insurance. Although organized medicine initially supported national, compulsory health insurance in the early 1900s, the association of such insurance with Germany led to a quick about-face during and after World War I, and the profession subsequently fought long and hard against any form of public health insurance. Cunningham & Cunningham, *supra* note 149 at 35-36. See also Burrow, *supra* note 1 at 139-151. Compare IM Rubinow, "Social Insurance and the Medical Profession" (1915) 64 J Am Med Assoc 381 ("[l]et us hope that in the development of social insurance we shall find in the American physician not the stubborn opponent that the British medical profession has been, but an enthusiastic ally, and thus once more prove that in social ethics we are able and willing to rise above European standards" at 386) with ML Harris, "Compulsory Health Insurance" (1920) 74 J Am Med Assoc 907 ("[i]t is by no means clear that [compulsory health insurance] would be an advantage even to the class that it is intended to benefit" at 907). At its 1920 Annual Meeting, the AMA House of Delegates adopted a resolution expressly opposing compulsory health insurance (and note that it had become "compulsory health insurance" from the previous "social insurance"—perhaps with the intention of creating a more negative view of such a program). American Medical Association, "Proceedings of the New Orleans Session: Minutes of the Seventy-First Annual Session of the American Medical Association" (1920) 74 J Am Med Assoc 1317 at 1319.

themselves (moral hazard) and the subscription by those more likely to need health care (adverse selection) made insurance economically risky,[151] as costs could easily exceed premiums. Group insurance addressed these risks in part by enrolling large numbers of individuals, often through an employer, who as a group would overall be healthier than individual purchasers of private insurance.[152]

The origins of modern group health insurance can be traced to Blue Cross, a well-known insurer that began during the Great Depression, in 1929, as a small program in Texas to insure schoolteachers for a limited number of days in hospital for a defined yearly premium of $6.[153] Unlike some of the earlier sickness funds the premiums were paid directly to the hospital by the insured groups and guaranteed the hospital care to be provided,[154] cutting out the middleman between the insured individuals and the care provider. These plans, though local in nature due to links with specific hospitals, spread to other states once their utility for safeguarding the payment of hospital bills was established.[155]

The Blue Cross plans demonstrated the financial viability of this form of insurance; however, they tended to cover only hospital costs and not physician fees.[156] Despite professional opposition to prepayment plans, physicians eventually recognized that they

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[151] Cunningham & Cunningham, *supra* note 149 at 8; Starr, *Social Transformation*, *supra* note 1 at 294.
[152] *Ibid*.; Murray, *supra* note 146 ("[t]he assurance of a wider pool enabled the insurers to accept poorer risks in the knowledge that the pool contained better risks as well to balance them out" at 229).
[153] Starr, *Social Transformation*, *supra* note 1 at 295; Cunningham & Cunningham, *supra* note 149 at 5-7. Cunningham and Cunningham characterize the Blue Cross concept as originally developed as a "prepayment plan" rather than group health insurance, but it is essentially the same thing: payment to the hospital (or hospitals) for a certain defined benefit to be used in the future, if necessary.
[154] *Ibid*.
[155] *Ibid*. at 12-17; Starr, *Social Transformation*, *supra* note 1 at 296-298. See also Thomasson, *supra* note 149 ("[t]he first organizations to offer modern health insurance were not commercial insurance companies, but rather hospitals, as health insurance originally developed as a means to ensure that patients paid their hospital bills" at 237).
[156] Starr, *Social Transformation*, *supra* note 1 ("[the plans] were only to cover hospital charges, thereby not infringing on the domain of private practitioners" at 296).

would need to develop new modes of payment for their patients (in part to defuse renewed calls for national health insurance) and deflate pressures to expand hospital plans to include physicians services (which would risk professional autonomy).[157] In 1934, the AMA developed ten principles for medical services insurance.[158] These principles asserted that control over medical services remain with physicians,[159] that patients have their free choice of physicians, and that the immediate costs of medical services be borne by patients if able to pay (implies that patients would be reimbursed for care).[160] If physicians were going to enter the insurance market, they intended to maintain control over their services, reflecting a long-standing fear of third-party interference with medical practice.

Isolated incidents of physician services plans occurred in the 1930s, but there was still a general reluctance to initiate the same types of plans that Blue Cross had successfully implemented.[161] However, by the end of the decade and into the 1940s, prepayment plans for physicians gained greater acceptance, and a number of state and local medical societies developed or approved insurance plans to complement the service provided by Blue Cross plans.[162] These plans eventually became the Blue Shield plans, and provided physicians with control over payment and medical services that the AMA's ten principles outlined in

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[157] *Ibid*. at 299; Thomasson, *supra* note 149 at 239.
[158] American Medical Association, "Proceedings of the Cleveland Session: Minutes of the Eighty-Fifth Annual Meeting of the American Medical Association" (1934) 102 J Am Med Assoc 2191 at 2200-2201 [AMA, "Proceedings 1934"].
[159] The profession feared that inclusion of medical services in the Blue Cross plans would lead to loss of professional autonomy. Starr, *Social Transformation*, *supra* note 1 at 299; Thomasson, *supra* note 149 at 239.
[160] AMA, "Proceedings 1934", *supra* note 158 at 2200.
[161] Cunningham & Cunningham, *supra* note 149 at 39-50. JAMA also pointed to the evils of profit-oriented insurance, using the case of a "racket" in California as a prime example. "New Forms of Medical Practice: Some California Health Insurance Rackets" (1934) 102 J Am Med Assoc 935 ("[i]t would be hard to find a better illustration of the evils that inevitably follow the introduction of lay control, the profit motive and solicitation into the field of medical service" at 936).
[162] Cunningham & Cunningham, *supra* note 149 at 50-55; Starr, *Social Transformation*, *supra* note 1 at 306-310.

1934 required, even though there was still much discomfort with these plans within the profession.[163]

The private arrangements to cover the costs of hospital and physician services represented by Blue Cross and Blue Shield were the foundation for group health insurance in the US for decades. Importantly for the profession, Blue Shield plans were designed specifically to permit physicians to retain control over medical services as well as a comfortable income. However, direct governmental involvement in the health care marketplace, successfully defeated by the profession in the first half of the 20th century, would again be raised in the second half and with far different results.

C. Medicare, Medicaid, and Government Funded Health Care

At the federal level, social welfare programs were put in place in the 1930s to address the economic needs of the population, such as Social Security, which was established to provide old-age benefits to reduce poverty levels amongst the elderly and unemployed (or unemployable).[164] However, the federal government generally refrained from providing health care services to the public, with the exception of public health initiatives that began as disease prevention efforts in the late 19th century[165] and the provision of medical treatment to the military. This is not for a lack of trying, as many attempts from the early 20th century were made to create a national health program.[166]

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[163] *Ibid*. at 306-307; Rayack, *supra* note 115 at 164-179.
[164] *Social Security Act*, Pub L No 74-271, 49 Stat 620 (1935).
[165] For example, the Marine Hospital Services, which later became the US Public Health Service, was given authority to control epidemic diseases in 1878 by the National Quarantine Act. Jerrold M Michael, "Public Health Chronicles – The National Board of Health: 1879-1883" (2011) 126 Pub Health Rep 123 at 126. See also John Duffy, "The American Medical Profession and Public Health: From Support to Ambivalence" (1979) 53 Bull Hist Med 1.
[166] See *supra* n 150 for additional detail.

By the 1950s and 1960s, as group health insurance began to dominate the market, large segments of the population remained unable to access or afford health care services. The Medicare[167] and Medicaid[168] programs were established in 1965 to address two of these groups: the elderly and the poor.

Medicare funds hospital and physician services, primarily for the elderly. It is paid for by a special tax (for Part A, the hospital services) and by premiums paid by beneficiaries (for Part B, the physician services).[169] All individuals covered by the Social Security System are eligible for participation in Medicare, and the federal government is solely responsible for administering the program.[170]

Medicaid is a more limited program to fund health care services for the needy, conditioning participation on economic status rather than age. Unlike Medicare, states are responsible for administering the benefits, with much of the funding coming from the federal government in return for federal oversight of individual states' programs.[171] This has led to a wide variation in benefits provided under the state plans as well as variation in payment levels to physicians. The Supreme Court recently upheld the discretion of states to structure their Medicaid programs as they see fit.[172]

The medical profession resisted these expansions of the government into the funding and provision of health care, using many of the same arguments that had been successfully

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[167] 42 USC ch 7 subch XVIII (§1395 et seq) (2013).
[168] 42 USC ch 7 subch XIX (§1396 et seq) (2013).
[169] Howard N Newman, "Medicare and Medicaid" (1972) 399 Ann Am Acad Polit & Soc Sci 114 at 116.
[170] *Ibid*.
[171] 42 USC § 1396a (2013).
[172] *National Federation of Independent Business v Sebelius*, 132 S Ct 2566 (2012). The decision prohibited the federal government from penalizing states for refusing to expand their programs to accept more beneficiaries, even though the costs of such expansions would be borne primarily by the federal government.

deployed to defeat previous efforts at national health insurance. Socialism and the lack of personal freedom to choose one's own physician were its battle cries,[173] as was the argument that these government-run programs were "unnecessary and would lower the quality of care rendered."[174] None of these arguments carried the day for the profession this time.

The fears expressed by the profession—especially concerning free choice of physician and payment reductions—proved unfounded in the original enactment of Medicare. The law built in free choice of health facility and practitioner,[175] and the payment structure of Medicare had the effect of *increasing* the costs of care at the time.[176]

Today, both programs still exist, though political debate over their contours is ongoing.[177] Additional mechanisms to control costs and ensure quality have been enacted, such as the *Patient Protection and Affordable Care Act*'s provisions for Accountable Care Organizations (ACO).[178] However, the medical profession continues to resist reductions in payments and has been successful in recent years in delaying proposed cuts,[179] and it

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[173] See e.g. "Medicare and the Physician's Responsibility" (1965) 273 N Eng J Med 447 ("[t]he American Medical Association predicted….[t]he complete socialization of medicine would then be but a matter of time" at 447); Jacobus H Verhave, "Personal Experience with Socialized Medicine" (1959) 171 J Am Med Assoc 178; "The Forand Bill" (1958) 167 J Am Med Assoc 743 (in reprint of AMA letter to members, the AMA asserted that "[the Forand Bill] would bring he aged under government controlled and supervised health care. The government would set and enforce standards of health care under bureaucratic control, limiting the choice of hospitals and physicians" at 744).

[174] "New Drive for Compulsory Health Insurance" (1960) 172 J Am Med Assoc 130.

[175] 42 USC § 1395a(a) (2013).

[176] Newman, *supra* note 169 at 120.

[177] The conflicting political ideology of the left and right continue to demand an expansion of the programs (left) or diminishment, especially of Medicaid (right). Interestingly, whenever *anyone* suggests changes to Medicare, right or left, they are attacked by the opposition for trying to harm the elderly, who make up a large voting block.

[178] See Elliott S Fisher & Stephen M Shortell, "Accountable Care Organizations: Accountable for What, to Whom, and How" (2010) 304 J Am Med Assoc 1715; *Patient Protection and Affordable Care Act*, Pub L No 111-148, 124 Stat 119 (2010), at title III.

[179] Jim Hahn & Janemarie Mulvey, *Medicare Physician Payment Updates and the Sustainable Growth Rate (SGR) System* (Washington DC: Congressional Research Service, 2012).

remains concerned with the impact of quality control measures on physician autonomy and the patient-physician relationship.

D. Managed Care and Professional Autonomy

Despite the success of group insurance and State health care programs with providing a large proportion of the population with health coverage, issues of cost and profit plagued the insurance industry. Under fee-for-service insurance typically provided by Blue Shield and imitated in large part by Medicare, there was little incentive for health care providers to control costs.[180] By the early 1970s, another health care model began to proliferate: managed care.[181] With the advent of managed care organizations (MCOs) and health maintenance organizations (HMOs), the profession began to experience the impacts on professional autonomy that it feared so much in previous decades. The idea of managed care was simple: if patients' care can be managed to avoid overuse, the insurer will spend less on that care.[182] Many different payment mechanisms to further this goal fall under the aegis of "managed care."

One early method was capitation. Pursuant to this, physicians were paid a specific amount per insured person to provide care.[183] The physician was incentivized to provide services

[180] See generally Newman, *supra* note 169; Havighurst, *supra* note 37.
[181] The federal government explicitly approved of the development of Health Maintenance Organizations via the *Health Maintenance Organization Act of 1973*. Pub L No 93-222, 87 Stat 914 (1973). Although these organizations had existed in a few locales for decades, this law provided federal support to the idea, and encouraged its widespread adoption. Marjorie Smith Mueller, "Health Maintenance Organization Act of 1973" (1974) 37 (vol 3) Social Security Bulletin 35.
[182] Thomas Rice, "Physician Payment Policies: Impacts and Implications" (1997) 18 Ann Rev Pub Health 549 at 551-552.
[183] See generally Uwe E Reinhardt, "Proposed Changes in the Organization of Health-Care Delivery: An Overview and Critique" (1973) 51 Milbank Mem Fund Q, Health & Soc'y 169. This is not dissimilar to the contract practices of the early 20th century that physicians believed would lead to unlimited services for limited pay.

within the constraints of these payments. This was the antithesis of fee-for-service—physicians were no longer in charge of their fees, though they retained their autonomy to make medical decisions. The caveat was that if they chose to provide "too much" care, their own income, or that of the facility in which they practiced, would decline.[184]

As managed care matured and found a place in the health care market nationwide, other structures were developed to control costs. Preferred provider organizations (PPOs) were established to provide a stream of patients to a select group of providers (physicians and hospitals).[185] These organizations supposedly provided more provider choice to patients, but also implemented centralized cost-savings measures such as utilization review and "gatekeepers".[186] Furthermore, insureds who obtained care from outside the network paid for a larger proportion of that care, as the costs to the PPO itself were higher since it had not negotiated the same beneficial rates with non-PPO providers.[187] Interestingly, this model of managed care turned away from the capitation format and back to fee-for-service, which was successful here in part due to the negotiated rates but also because of utilization review.[188] The model was dependent on both the growth of provider members of the network and insureds' choice to obtain their care within this network.[189] It also represented a limitation on physician autonomy by means other than financial—the utilization review.

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[184] Rice, *supra* note 182 at 551-552. Rice noted that although physicians have financial incentives to change practice patterns, the HMOs themselves face much of the pressure because they are dependent on physician decisions for profitability.
[185] James A Hester, Annemarie Wouters & Norman Wright, "Evaluation of a Preferred Provider Organization" (1987) 65 Milbank Quarterly 575.
[186] *Ibid*. at 577.
[187] *Ibid*. at 578; Catherine Butler, "Preferred Provider Organization Liability for Physician Malpractice" (1985) 11 Am JL & Med 345 at 346.
[188] *Ibid*. at 347.
[189] Hester, Wouters & Wright, *supra* note 185 at 578.

In the 1980s and 1990s, insurers began using contractual provisions to further isolate physicians from their patients and each other, and limit their own costs. Gag clauses, "all products" provisions, and utilization review mechanisms were developed to prevent physicians from discussing their contracts with patients and each other,[190] force physicians to accept patients from plans established by the same insurer even if not explicitly included in the physician-insurer contract, and analyze physicians' usage of health care resources.

These were very real limitations on physician autonomy, and shaped an antagonistic relationship between the profession and insurers. In some states physicians succeeded in limiting some of the insurers' practices,[191] but this has not led to cozy professional-insurer relations.[192] While the profession continued to oppose national health insurance as it had since early in the 20th century, for many physicians the insurance market that developed in its place could not have been much better—it was just a matter of a private company having control rather than the State.

It is debatable what effect managed care had on total health expenditures in the country. Although HMOs and MCOs multiplied exponentially from the 1970s to present day, the

[190] Julia A Martin & Lisa K Bjerknes, "The Legal and Ethical Implications of Gag Clauses in Physician Contracts" (1997) 22 Am JL & Med 433; Diane S Swanson, "Physician Gag Clauses – The Hypocrisy of the Hippocratic Oath" (1997) 21 S Ill ULJ 313; Michelle M Kwon, "Move Over Marcus Welby, M.D. and Make Way for Managed Care: The Implications of Capitation, Gag Clauses, and Economic Credentialing" (1997) 28 Tex Tech L Rev 829; American Medical Association, *Model Managed Care Contract, 4th ed* (Chicago: American Medical Association, 2005). See *contra* United States General Accounting Office, *Managed Care: Explicit Gag Clauses Not Found in HMO Contracts, But Physician Concerns Remain* (Washington DC: United States General Accounting Office, 1997).

[191] For example, "any willing provider" laws required insurers to accept any physician willing to agree to the negotiated payment as part of their provider panel and prompt pay requires insurers to pay claims within a certain time period. See Anne Carroll & Jan M Ambrose, "Any-Willing Provider Laws: Their Financial Effect on HMOs" (2002) 27 J Health Pol 927; 215 Ill Comp Stat 5/368a (2016) (Illinois' prompt pay law); 806 Ky Admin Reg 17:360 (2016) (Kentucky prompt pay regulation).

[192] The profession has challenged insurer mergers, arguing that the deals would be bad for patients and physicians. David Phelps, "AMA Opposes UnitedHealth Deal", *Minneapolis Star Tribune* (19 March 2007); David S Hilzenrath, "Aetna Gets Buyout Offer; Bid Would Continue Health-Care Trend", *Washington Post* (2 March 2000).

rate of health spending also increased at a quick pace.[193] The combination of MCOs and HMOs, traditional Blue Cross/Blue Shield and other fee-for-service programs, and government-funded programs likely all contributed heavily to increased health care usage and accessibility and therefore to these increasing costs. Where managed care stands out, though, is in its impact on physician autonomy. Whether or not intended, the limited forms of payment envisioned by managed care incentivized physicians to alter how they cared for patients. If a physician faced financial penalty for providing a level of care that exceeded the capitation payment for a patient, he or she might provide less care than otherwise. If a physician had his or her treatment decision questioned under a process of utilization review, the outcome for the patient might be different. Of course, as corporations were and continue to be forbidden to practice medicine,[194] MCOs and HMOs disclaimed responsibility for physician decision-making.[195] In the end, this was truly what physicians claimed to fear with the advent of health insurance in the early 20th century: he who controls the purse strings controls health care.

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[193] See e.g. Organisation for Economic Cooperation and Development, "Total Expenditure on Health as a Percentage of Gross Domestic Product", online: Organisation for Economic Cooperation and Development <http://www.oecd-ilibrary.org/social-issues-migration-health/total-expenditure-on-health-2013-1_hlthxp-total-table-2013-1-en>. In the US, expenditures increased by nearly two percentage points between 2005 and 2011. By contrast, expenditures in Canada increased by roughly 1.5% and in the UK by just over 1%. No country included by the OECD in this table spent as much a percentage of GDP as the US.

[194] See e.g. Nicole Huberfeld, "Be Not Afraid of Change: Time to Eliminate the Corporate Practice of Medicine Doctrine" (2004) 14 Health Matrix 243, for a description of the origins and state of the corporate practice of medicine doctrine.

[195] This was an especially successful tactic under medical malpractice lawsuits brought against insurers that implicated the Employee Retirement Income Security Act of 1974 (ERISA). Courts differentiated "eligibility" and "treatment" decisions made by insurers covered under the Act, and they were insulated from liability for decisions considered "coverage", although realistically these were not much different than "treatment" decisions if a physician determined not to provide a treatment because an insurer (wrongfully) determined it was not covered. See e.g. *Pegram v Herdrich*, 530 US 211 (2000) (declaring that mixed eligibility and treatment decisions were not fiduciary acts under ERISA).

V. State Regulation of Medical Practice

As discussed above, states took a greater interest in the practice of medicine starting in the late 19th century with licensure laws and then insurance regulation, and the federal government with the passage of Medicare and Medicaid as well as some controls based on hospital financing.[196] From the 1970s onward, though, more and more legislation and regulation has been adopted that outlines the contours of acceptable medical practice and physician behavior. In this Section, these will be briefly outlined, and Chapters 5, 6 and 7 will discuss them in more detail.

As the State became a larger and larger purchaser of health care services, through Medicare, Medicaid and various individual state programs,[197] legislation has been enacted to address real or perceived problems in how that money is spent. These in turn can impact physician decision-making and the physician-patient relationship.

An example of federal efforts to limit fraud is the Stark Law.[198] This statute prohibits "self-referral"; that is, a physician's referring of a patient to a facility that the physician (or an immediate family member of a physician) has an ownership interest in, allowing him or her to collect revenue from the direct patient care as well as the patient's use of the

[196] *Hospital Survey and Construction Act* (Hill-Burton Act), 60 Stat 1040 (1946). See also VM Hoge, "The Hospital Survey and Construction Act" (1947) 62 Pub Health Rep 49.
[197] Many states have adopted special programs to provide health benefits to children, and a few have enacted more comprehensive legislation to provide services to broad segments of the population. *Oregon Health Plan*, online: State of Oregon <http://www.oregon.gov/oha/healthplan/Pages/index.aspx>; *Green Mountain Care*, online: Green Mountain Care <http://www.greenmountaincare.org/>. Unfortunately, Vermont's plan, Green Mountain Care, was not successful as a comprehensive single-payer health system.
[198] 42 USC § 1395nn (2016).

facility.[199] The Stark Law applies only to care provided under the Medicare program,[200] but individual states have adopted their own anti-self-referral laws to address services paid for by Medicaid and even private insurers.[201] These self-referral prohibitions have changed physician practice with regards to where they can refer patients for certain types of care, although for reasons of fiscal integrity and patient protection. Self-referral restrictions have also changed how physicians structure their business organizations, as exceptions to the prohibition—such as for in-office ancillary services[202]—provide legal avenues for income still based on referrals.

Other federal statutes tied to the government's role as payor include the Emergency Medical Treatment and Active Labor Act (EMTALA),[203] which requires treatment and stabilization in instances of emergency and when a woman is in active labor (as the title of the law clearly suggests) and the Health Insurance Portability and Accountability Act's (HIPAA) privacy provisions,[204] which have dramatically changed privacy practices of physicians and health facilities by creating stringent rules and penalties.

Traditional self-regulatory mechanisms have also been modified by State intervention. For example, review of physician practice or behavior, once solely under the jurisdiction of a

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[199] 42 USC § 1395nn(a) (2016).
[200] *Ibid*. ("…designated health services for which payment otherwise may be made under this subchapter"). As health care regulation is generally a state concern, federal laws typically address only programs that are funded by the federal government.
[201] See e.g. *Health Care Worker Self-Referral Act* (Illinois), 225 Ill Comp Stat 47/1 et seq (2016); *Patient Self-Referral Act of 1992* (Florida), Fla Stat § 456.053 (2016); Cal Bus & Prof Code § 650.01-650.02 (2016). See generally American Medical Association Advocacy Resource Center, *Protecting Physicians' Business Interests: Physician Self-Referral* (Chicago: American Medical Association, 2009).
[202] 42 CFR § 411.355(b) (2016).
[203] 42 USC § 1395dd (2013).
[204] 42 CFR pt 164; *Health Insurance Portability and Accountability Act of 1996*, Pub L No 104-191, 110 Stat 1936.

physician's peers ("peer review"), is now required to meet certain standards as provided in state and federal law.[205]

Judicial decisions have further changed how physicians practice. For example, a state court in 1976 modified professional practices for confidentiality and danger to third parties.[206] The requirement to disclose information directly to third parties (rather than only to law enforcement) has now become the national norm.[207] Conversely, the US Supreme Court has upheld professional ethical standards on end-of-life issues, when it supported ethical prohibitions against physician-assisted suicide as part of its decision in *Washington v Glucksberg*.[208]

These are just a few examples of the many instances where the State has intervened to protect its own financial interests, the rights of patients, or the rights of professionals. The growth of State regulation of the medical profession will be examined in much greater detail in later Chapters, but the above makes clear that the State, although absent from the regulation of medicine for long periods during the first century of nationhood, has undertaken many initiatives in the past few decades that have impacted the profession.

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[205] See generally Katherine Van Tassel, "Hospital Peer Review Standards and Due Process: Moving from Tort Doctrine Toward Contract Principles Based on Clinical Practice Guidelines" (2006) 36 Seton Hall L Rev 1179. The imposition of basic requirements for the peer review process is intended to provide fairness to physicians under review. Historically, it was not uncommon for peer review to be used as a venue for settling personal or economic issues. See also *Health Care Quality Improvement Act of 1986*, 42 USC § 11101 et seq (2013).

[206] *Tarasoff v Regents of the University of California*, 551 P 2d 334 (Cal Sup Ct 1976).

[207] See e.g. Council on Ethical and Judicial Affairs, *Code of Medical Ethics: Current Opinions with Annotations, 2010-2011* (Chicago: American Medical Association, 2010) at 160.

[208] *Washington v Glucksberg*, 521 US 702 (1997).

VI. Conclusions, and the Current State of the Profession

Returning to the two questions asked at the beginning of this Chapter, a few conclusions can be reached. First, as to what the medical profession in the US is, the clearest answer is that it is made up of those individuals duly educated and licensed by the states. The historical roots of the modern profession began well before the US came into being, but it most clearly derives from the "regular" physicians who established state societies and eventually the AMA. Indeed, there is a direct line between the AMA and the modern profession, as the AMA played a role in most of the formative events of the late 19th and 20th centuries, from the re-regulation of medicine to educational reform to the circumstances leading to various forms of health insurance.

Second, I hope that this Chapter demonstrated the importance of even a brief and basic history of some of the more important events in the development of the profession in the US. The de-regulation and subsequent re-regulation of medicine illustrates the inability of the profession to effect change on its own, outside of its limited sphere of authority. The slow development of health insurance, leading to managed care in the latter third of the 20th century, shows that the profession's intransigence to the development of national health insurance led unintentionally to a system that had many of the characteristics the profession proclaimed to oppose (non-physician control of some decision-making being a primary outcome). Finally, the mixture of economic and benevolent goals that led to the organizing of physicians in the mid-19th century persists in the modern profession. For instance, the teaching of medical ethics and professionalism remains a foundation of

medical education, though this varies across specialties and institutions.[209] Conversely, individual decisions such as what specialty to practice and what type of organization to practice in can stem from purely economic considerations. The current deficit of primary care physicians can be traced to the economic incentives provided by other specialties.[210] As well, the enactment of the Stark Law and recent efforts to amend it[211] reflect continued prioritization by some segments of the profession of the financial over the patient, or at least the perception that this is still the case.

The current state of the profession is inextricably linked to this history, and the consequences of decisions made years or even decades ago. The profession's monopoly over medical care was not inevitable, though scientific advancement certainly aided in the eventual dominance of physicians. It took events such as states' recognition that the public needed protection against unscrupulous practitioners to establish that a certain type of practitioner deserved the protection of the State. If the practices of "regular" physicians remained mediocre and ineffective throughout the 19th century, I have little doubt that the physicians who eventually came to dominate the US health care system would have faced

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[209] See Lisa Soleymani Lehmann et al, "A Survey of Medical Ethics Education at U.S. and Canadian Medical Schools" (2004) 79 Acad Med 682; David J Doukas, Laurence B McCullough & Stephen Wear, "Reforming Medical Education in Ethics and Humanities by Finding Common Ground With Abraham Flexner" (2010) 85 Acad Med 318 at 322; David J Doukas, Laurence B McCullough & Stephen Wear, "Medical Education in Medical Ethics and Humanities as the Foundation for Developing Medical Professionalism" (2012) 87 Acad Med 334; Alberto Giubilini, Sharyn Milnes & Julian Savulescu, "The Medical Ethics Curriculum in Medical Schools: Present and Future" (2016) 27 J Clin Ethics 129.

[210] Michael E Whitcomb & Jordan J Cohen, "The Future of Primary Care Medicine" (2004) 351 N Eng J Med 710; Kent J DeZee et al, "Effect of Financial Remuneration on Specialty Choice of Fourth-Year U.S. Medical Students" (2011) 86 Acad Med 187; Suzy Frisch, "The Primary Care Physician Shortage" (2013) 347 Brit Med J f6559.

[211] US, Bill HR 2914, *Promoting Integrity in Medicare Act of 2013*, 113th Cong, 2013; US, Bill HR 2513, *Promoting Access, Competition and Equity Act of 2015*, 114th Cong, 2015; US, Bill S 2985, *World's Greatest Health Care Plan Act of 2016*, 114th Cong, 2016.

many more challenges—possibly remaining only one of many types of practitioners in a continually pluralistic medical system.

Yet, the profession's dominance is waning in many respects. Other health professionals, such as nurse practitioners and optometrists, are gaining ground in their efforts to expand scopes of practice, infringing on physicians' traditional responsibilities.[212] The medical profession has become more fragmented, as specialty societies proliferate[213] and AMA membership declines.[214] Initiatives to control health care costs have legitimized the development and use of quality control and utilization review mechanisms, which is not *per se* undesirable, but there is certainly the potential for misuse.[215] The development of the "medical-industrial complex" has slowly chipped away at professional sovereignty, as payers demand greater say in how moneys are spent and the profession, for various reasons, is limited in its ability to respond.[216] The explosive growth since the 1960s of health insurers, health care corporations, and pharmaceutical and device manufacturers has also

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[212] See e.g. Julie A Fairman et al, "Broadening the Scope of Nursing Practice" (2011) 364 N Eng J Med 193; Kristin E Schleiter, "Ophthalmologists, Optometrists, and Scope of Practice Concerns" (2010) 12 Virtual Mentor 941.

[213] American Medical Association, "National Medical Specialty Websites", online: American Medical Association <http://www.ama-assn.org/ama/pub/about-ama/our-people/the-federation-medicine/national-medical-specialty-society-websites.page>.

[214] Membership in the AMA has declined significantly over the years, and at the same time it competes with a large number of specialty societies for dues and influence. See Roger Collier, "American Medical Association Membership Woes Continue" (2011) 183 Can Med Assoc J E713.

[215] Certainly, insurers have been accused of using these measures as cover to limit their costs. See e.g. *Rosenberg v Bluecross Blueshield of Tennessee*, 219 SW 3d 892 (Tenn Ct App 2006); *McEvoy v Group Health Co-op*, 570 NW 2d 397 (Wisc Sup Ct 1997); Allen D Allred & Don L Daniel, "Upon Further Review: *Rush Prudential HMO, Inc. v. Moran* and a New Era of Managed Care Organization Liability (2003) 47 St Louis ULJ 309.

[216] For example, judicial interpretation of federal anti-trust law has prevented large groups of physicians from negotiating rates with insurers even when only one or two insurers dominate a market. See e.g. *Arizona v Maricopa County Medical Society*, 457 US 332 (1982) (holding that agreements set forth by medical societies, made up of competing physicians, to set maximum fees acceptable as full payment for services provided to insureds constitutes illegal price fixing under the Sherman Act); *Kartell v Blue Shield of Massachusetts*, 749 F2d 922 (1st Cir 1984) (holding that the use of market power is not unlawful restraint of trade or monopolization in violation of Sherman Act); Martin Gaynor, "Why Don't Courts Treat Hospitals Like Tanks for Liquefied Gases? Some Reflections on Health Care" (2006) 31 J Health Pol 497.

at times pitted these groups against professional associations in the quest for political influence, and although professional input remains crucial for much of the legislation that impacts health care, non-professional lobbying efforts have taken their toll on the profession.

Starr, writing in 1982, presented a prescient description of the direction of the medical profession: "[t]he prospect is not simply for the weakening of professional sovereignty, but for greater disunity, inequality, and conflict throughout the entire health care system."[217] This followed his detailed history of the profession up to this time, and reflected his beliefs based upon this history that the profession was not headed back to a golden age.[218] It is within this history that I will explore medical ethics and its normativity, for the medical profession does not exist in a vacuum but within the continual ebb and flow of its relationship with the State and a constant reexamining of its role in society and its capacities to govern itself.

[217] Starr, *Social Transformation*, *supra* note 1 at 421.
[218] According to Burnham, "[t]he golden days of the medical profession can be defined by the amount and the content of criticism that the profession received." Burnham, *supra* note 87 at 1478.

CHAPTER 3: LEGAL PLURALISM – SOCIAL FIELDS AND LEGAL ORDERS

I. INTRODUCTION 72

II. WHAT IS LEGAL PLURALISM, AND WHY USE IT? 75

A. Legal Pluralism as a Descriptive Theory of What Law Is 75

B. Why Use Legal Pluralism to Describe Medical Ethics and the Medical Profession? 79

III. SEMI-AUTONOMOUS SOCIAL FIELDS AND THE CREATION OF LAW 83

A. The Semi-Autonomous Social Field 83

1. The Nature of the Semi-Autonomous Social Field 83
2. The Medical Profession as a Semi-Autonomous Social Field 87

B. What is Law? 91

1. Pluralists' Law and Their Detractors 91
2. Medical Ethics as a Legal Order 100

C. The Helpful Theory of Professionalism 104

IV. THE MEDICAL PROFESSION AND MEDICAL ETHICS "AS AN APPROPRIATE SUBJECT OF STUDY" 114

> "Just as we find the ordered community wherever we follow its traces…so we also find law everywhere, ordering and upholding every human association."[1]

I. Introduction

My legal education was probably like that of many other American law students. I attended a university that neither required nor, so far as I was aware, even offered a course exploring legal theory. Consequently, for myself and probably for most of my classmates our understanding of the law is what we learned in school: law is what is developed, promoted and enforced by the State. Legislatures enact statutes (following approval from the executive or veto override, of course). State and federal agencies promulgate voluminous regulations, resulting in documents like the nearly incomprehensible *Federal Register*.[2] Courts determine what statutes and regulations mean, and whether they are constitutional.[3] This is consistent with Hart's positivism[4] and Griffith's exposition of legal centralism,[5] the former theory granting authority to State law primarily because of how it is developed and enforced and the latter finding primary authority in State law because of how most of us perceive it.

For a university that focuses on the practical application of law—making lawyers who lawyer—this makes some sense, although it ignores the value of a theoretical understanding of law that can improve critical thinking for any attorney. Attorneys do not generally file motions and briefs exploring the more esoteric aspects of law and legal theory, and legislatures and courts do not often create or interpret law except with reference

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[1] Eugene Ehrlich, *Fundamental Principles of the Sociology of Law*, translated by Walter Moll (Cambridge: Harvard University Press, 1936) at 25.
[2] *Federal Register*, online: US Government <www.federalregister.gov>.
[3] See e.g. *Marbury v Madison*, 5 US 137 (1803).
[4] HLA Hart, *The Concept of Law*, 2d ed (Oxford: Oxford University Press, 1997).
[5] John Griffiths, "What is Legal Pluralism?" (1986) 24 J Legal Pluralism 1.

to State (or international) law. We are not taught to ask why a statute is written or is granted the authority that we give it. We almost never wonder whether there is something just as important to guide our actions as State law. The construct of "law" as solely a vehicle of the State has been very successful in the minds of attorneys and the public, as well as the State itself since the breadth of its authority has only served to reinforce its role as arbiter of law.

This narrow view of what "law" is has proven incapable of encapsulating any other idea, rule or behavior that could have a similar impact to State's law. Yet there are many relationships—personal, commercial, religious or cultural—that raise expectations of voluntary or involuntary adherence to behavioral norms that exist outside of State law. The presence of these, even without an explicit recognition of the role they play in guiding individual and group behaviors, makes a monistic understanding of law inadequate.

The ethics of the medical profession presents an interesting case of law-finding. The previous Chapter traced the development of the profession and its ethics from a period of nearly complete autonomy and self-regulation to its present condition of being intertwined with the State, other health care providers, health facilities and insurers. Ethics, which was once the only source of normativity for physicians who were a part of mainstream medicine in the US—and was explicitly identified as "law" for physicians[6]—is now only one of a variety of "law." What effect does this have on the ability of the profession to control the behavior of its members? To influence State law? To influence the actions of other groups

[6] See e.g. American Medical Association, *Sixty-Third Annual Session, Held at Atlantic City, NJ, June 3-6, 1912, Minutes of the House of Delegates* (Chicago: American Medical Association, 1912) at 5. The AMA Judicial Council regarded the then *Principles of Medical Ethics* as a "code of laws."

that it must, by the exigencies of modern medicine, interact with? And how do these others influence the actions of the profession and physicians?

A singular notion of law—that of the State—cannot answer these questions satisfactorily. It implies that these other sources of influence, if not illegitimate, certainly do not have the same imprimatur as the State's law and are therefore of little consequence. It is necessary, then, to look elsewhere than these singular notions for an explanation of how individuals, groups and entities order their behavior when it is not explained by adherence to State law alone.

The theory of legal pluralism provides this opportunity, and represents the idea that law is everywhere. The work of legal anthropologists, sociologists and legal scholars[7] began the journey towards a formulation of pluralism by looking not just at what the State said on a matter, but also how individuals and groups *actually* functioned in light of other determinants of behavior. This led to the development of a theory of law and its origins that competes with more conventional theories. As a framework for exploring the role of different forms of normativity, legal pluralism does not *dictate* what law is, but presents us with possibilities without constraining the potential for something to be "law" even if it is not called "law."

Legal pluralism as the focus of this Chapter and the framework for the entire Thesis serves a few important functions. First, and as will be brought out in much more detail later in this Chapter and throughout the Thesis, utilizing a theory with an open view of what "law" can be permits the analysis of medical ethics on nearly equal footing as State law. This

[7] Sally Falk Moore, "Law and Social Change: The Semi-Autonomous Social Field as an Appropriate Subject of Study" (1973) 7 L & Soc'y Rev 719; Griffiths, *supra* note 5.

does not mean that medical ethics equates to State law—far from it, actually—but that the typically inevitable depiction of medical ethics as a subsidiary body of norms (if considered norms at all) can be circumvented. If legal pluralism leads to the conclusion that medical ethics can be considered a legal order and the medical profession a semi-autonomous social field,[8] we can use this framework to achieve a second function: to explore the foundations of the relationship between the medical profession and the State and the reality of medical ethics in professional life.

This chapter has three purposes: (i) to explore the literature of and provide a framework for the theory of legal pluralism; (ii) to begin to outline components of legal pluralism within and affecting the medical profession, including the concepts of semi-autonomous social field and legal order; and (iii) to briefly introduce the similar but unrelated theory of professionalism for clues of how the characteristics of legal pluralism can be applied to the medical profession.

II. What is Legal Pluralism, and Why Use It?

A. Legal Pluralism as a Descriptive Theory of What Law Is

The descriptive theory of legal pluralism is a relatively young theory,[9] at least as it is currently organized and formulated,[10] that considers the possibility "that a same situation…could be subject to or be confronted with more than one legal order or mechanism, and that people's actions could not be simply subsumed under 'their' law."[11] The legal orders that constitute "their" law can be broad, including indigenous norms, rule-

[8] Both "legal order" and "semi-autonomous social field" with be further defined later in this Chapter.
[9] Griffiths wrote his article in 1986, drawing on Moore's work from 1973. *Ibid*.; Moore, *supra* note 7.
[10] Sally Engle Merry, "Legal Pluralism" (1988) 22 L & Soc'y Rev 869.
[11] Franz von Benda-Beckmann, "Who's Afraid of Legal Pluralism?" (2002) 47 J Legal Pluralism 37 at 60.

making by institutions and organizations, and normative orders of social groups.[12] There is no concise definition of "legal order"[13] (the term used originally by Moore to describe the law of legal pluralism), and rules' or other normative systems' characterization as such is related more to their impact on the individuals or groups to which they apply than to their recognized status as "legal," "normative" or other, thus focusing more on effect than name.

Often, "their" law is that of the State,[14] which in the US consists of state and federal governments and their various institutions. Legal pluralism, however, moves beyond the State as the sole source of law to the "fact" of a multitude of legal orders,[15] and speaks to legal subjectivity,[16] legal normativity, and the scope of State laws and institutions.[17] It is an "approach to law and legal theory that offers the most hope for understanding the role of diverse normative regimes not connected to the State…."[18] In a way, it is a bottom-up approach to law, rather than top-down.

Legal pluralism "refers to the normative heterogeneity attendant upon the fact that social

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[12] Brian Z Tamanaha, "The Folly of the 'Social Scientific' Concept of Legal Pluralism" (1993) 20 JL & Soc'y 192 at 193 [Tamanaha, "Folly"].
[13] See also Griffiths, *supra* note 5 at 2. Griffiths does not supply a definition of legal order, but from the context in which he uses it throughout this article we can determine that it is used to denote the boundaries of the "law" to which individuals are subject, either by the State or a semi-autonomous social field. See also von Benda-Beckmann, *supra* note 11 ("Griffiths speaks of different legal orders that co-exist in one semi-autonomous social field, but he nowhere makes clear what a legal order is or where difference resides" at 62 n 37).
[14] See generally *Ibid*.; Griffiths, *supra* note 5; Moore *supra* note 7; Hart, *supra* note 4; Brian Tamanaha, "Understanding Legal Pluralism: Past to Present, Local to Global" (2008) 30 Sydney L Rev 375 [Tamanaha, "Understanding Legal Pluralism"].
[15] Griffiths, *supra* note 5 at 4.
[16] This is the idea that what law "is" can be a subjective matter determined by the individual or group. See generally James Boyle, "Is Subjectivity Possible? The Post-Modern Subject in Legal Theory" (1991) 62 U Colo L Rev 489.
[17] Roderick A Macdonald, "Metaphors of Multiplicity: Civil Society, Regimes and Legal Pluralism" (1998) 15 Az J Int'l & Comp L 69 at 70.
[18] *Ibid*. at 91.

action always takes place in a context of multiple, overlapping 'semi-autonomous social fields'…."[19] Or, put more simply, legal pluralism exists when "more than one kind of 'law' is recognized through the social practices of a group in a given social arena…."[20] An analysis within this framework evaluates the impact of legal orders (or rules, norms, dictates, etc.) on a given social field[21] and recognizes that social fields are interwoven with other social fields and legal orders.[22]

In Griffiths' conception of legal pluralism, he compared it to what he termed "legal centralism," an ideology[23] asserting that

> law is and should be the law of the state, uniform for all persons, exclusive of all other law, and administered by a single set of state institutions. To the extent that other, lesser normative orderings, such as the church, the family, the voluntary association and the economic organization exist, they ought to be and in fact are hierarchically subordinate to the law and institutions of the state….It is the factual power of the state which is the keystone of an otherwise normative system.[24]

Such a concept of law, he said, "…has made it all too easy to fall into the prevalent assumption that legal reality, at least in 'modern' legal systems, more or less approximates to the claim made on behalf of the state."[25] More recently, Sacco depicted a common perception of law: "[s]ocieties with courts, public officials and fiscal systems attest to the existence of a social power overwhelming individuals and minorities. All populations

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[19] Griffiths, s*upra* note 5 at 38. The term "semi-autonomous social field" was also coined by Moore to describe the groups that develop legal orders.
[20] Brian Z Tamanaha, "A Non-Essentialist Version of Legal Pluralism" (2000) 27 JL & Soc'y 296 at 315 [Tamanaha, "Non-Essentialist"].
[21] Macdonald, *supra* note 17 at 81.
[22] Martha-Marie Kleinhans & Roderick A Macdonald, "What is a *Critical* Legal Pluralism?" (1997) 12 CJLS 25 at 41.
[23] Griffiths called legal centralism an ideology to distinguish it from legal pluralism, which he regarded more as truth or fact. This distinction is not always viewed favorably, since what is called "ideology" may really just be a shared convention. See Tamanaha, "Folly", *supra* note 12 at 195.
[24] Griffiths *supra* note 5 at 3.
[25] *Ibid.* at 4.

sharing our culture experienced a centralized sovereign power."[26] Under a conception of law such as legal centralism, "we do ourselves a double disservice" of excluding diversity of potential law by construing the "law" narrowly and eliminating from the conversation important concepts of morality upon which law might be based[27]—what might be said to *underlie* the law. Yet it is this conception of law that dominates public discourse about the validity of non-traditional law within the legal order of the State. It is also the version of law closest to what many aspiring attorneys learn in law school.

Since Griffiths especially, legal pluralism has commonly been used to explore the norms of cultures and groups within a State that fall outside the law of the State, as well as international interactions.[28] However, legal pluralism can apply to more than just cultures within a society.[29] Indeed, one of Griffith's inspirations, Sally Falk Moore, examined the possibility of legal pluralism in both distinct cultures as well as business relationships.[30] Her work demonstrated that law[31] can exist separately from the State when behavior is modified and coerced by non-State actors, even in semi-autonomous social fields that are not distinct cultural groups or within post-colonial societies. In any given social field, legal pluralism is about competing legal orders, "each responsive to its own logic, and each mutually informing the other."[32] Legal pluralism is therefore a possibility even within the

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[26] Rodolfo Sacco, "Mute Law" (1995) 43 Am J Comp L 455 at 457.
[27] Macdonald, *supra* note 17 at 90.
[28] See generally Merry, *supra* note 10. "Global legal pluralism" has become a favored topic of study by legal pluralists and comparative theorists. See e.g. Paul Schiff Berman, "Global Legal Pluralism" (2007) 80 S Cal L Rev 1155; Alexis Galán & Dennis Patterson, "The Limits of Normative Legal Pluralism: Review of Paul Schiff Berman, *Global Legal Pluralism: A Jurisprudence of Law Beyond Borders*" (2013) 11 Int'l J Const L 783.
[29] *Ibid*.
[30] Moore, *supra* note 7.
[31] Moore shied away from using the term "law" to describe what was happening in the semi-autonomous social fields she studied, referencing Pospisil's use of "law" as dependent on "what one is trying to emphasize for analysis." *Ibid.* at 745.
[32] Macdonald, *supra* note 17 at 80.

medical profession, and expresses the function of medical ethics without regard to its title as "ethics" rather than "law."

B. Why Use Legal Pluralism to Describe Medical Ethics and the Medical Profession?

When developing a theoretical framework within which to analyze the presence, type and use of law or normativity in a given arena, there is a multitude of theories from which to choose. The choice must relate to the characteristics of the field of study,[33] and in the case of the US medical profession legal pluralism provides a framework to consider the *reality* of medical practice that might not be permitted under other legal theories such as positivism or realism, which continue to largely focus on the role of the State in developing law for all. Legal pluralism "provides a metaphor within traditional legal vocabulary for exploring the role of what have been…characterized as '…cultures, regimes, communities and groups.'"[34] As a "descriptive" theory as well,[35] it can be used to describe relationships as they actually occur, rather than to place them within a construct of law that might not permit so open an exploration. It also does not require a search for key terms (e.g. "law" and "legal") to identify what might be law, an important consideration since the profession does not itself commonly use these when referring to its norms.

Applying legal pluralism as a hypothesis[36] to social fields within the larger society means observing how members of that social field act and interact with their environment; it "frees

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[33] And as Macdonald described this choice, "definitions of social phenomena, being non-tautological, can never be logically true or not. They can, nonetheless, be more or less useful, more or less phenomenologically correspondent, and more or less coherent with values sought to be promoted." *Ibid*. at 72. See also von Benda-Beckmann, *supra* note 11 ("the study of legal pluralism can be done with different questions in mind. It will depend on what one is interested in…" at 71).
[34] Macdonald, *supra* note 17 at 70.
[35] See generally Griffiths, *supra* note 5.
[36] Macdonald, *supra* note 17 at 74.

the legal imagination from structuralist thinking."[37] We might title things as "law" because of how individuals or groups address specific situations that have a resemblance to responses of the recognized law of the State, or because they represent "patterns of behavior and norms that are recognized and respected among particular groups in a community."[38]

In the medical profession and its interaction with State and non-State entities, legal pluralism depicts quite well the *social* reality faced by physicians (as opposed to a State-law legal reality). For one, the use of the descriptor "semi-autonomous social field" aligns with the structure and history of the profession. As conceptualized by Moore, the semi-autonomous social field emphasizes autonomy and isolation and the "capacity to generate rules and induce or coerce conformity."[39] This description outlines the contours of the medical profession because autonomy, isolation and rule generation have been integral to medicine for centuries, first as a means to protect medical knowledge from becoming widely known (the Hippocratic Oath) and to handle departures from medical standards internally, and later to prevent or limit infringement on this autonomy by the State and others.

Legal pluralism also allows for the discard of the "law as sovereign" concept, and permits us to delve more deeply into the roots of professional behavior through the liberal description of "legal orders". This is not to say that the role of the State is irrelevant; we cannot "deny the symbolically significant, constantly-reinforced, and sometimes

[37] *Ibid*. at 71.
[38] David M Engel, "Legal Pluralism in an American Community: Perspectives on a Civil Trial Court" (1980) 1980 Am Bar Found Res J 425 at 432.
[39] Moore, *supra* note 7 at 722.

historically-rooted power of the nation-state in the collective imagination of its citizens."[40] Certainly, in medicine the very basic ability to perform as a physician is controlled by states through their monopoly on the licensing of medical professionals. However, there are a myriad of other legal orders that suggest, control, or prohibit various physician behaviors.[41] To fully understand the operation of law in the medical profession, "[i]t is necessary to understand the character and operation of multiple regimes of unofficial law in the same field."[42]

Finally, legal pluralism investigates how an unofficial legal system "stands on its own two feet" and is able to exist independent of and in some instances without regard to State law.[43] Though there are many occasions when the medical profession is reliant on the State, such as for licensing to actually practice medicine, there are also those in which physicians exercise judgment outside of any authority granted by the State—where they "control law as much as law controls" them.[44] The ability of a medical association to discipline members based upon the rules of the association is one example.

Thus, legal pluralism in the context of the US medical profession is about all of the ways in which the profession regulates itself and is regulated by non-State semi-autonomous social fields and "the formal legal system [which] has an impact on local systems—altering informal rules, strategies, and relationships to accommodate judicially obtained

[40] Berman, *supra* note 28 at 1181.
[41] See e.g. Tamanaha, "Non-Essentialist", *supra* note 20 ("[n]o one version of law is placed in a hierarchy above any other – the degree of actual influence in a given social arena can be determined only following investigation, based upon the results of the inquiry" at 318).
[42] Macdonald, *supra* note 17 at 77.
[43] Baudouin Dupret, "Legal Pluralism, Plurality of Laws, and Legal Practices: Theories, Critiques, and Praxiological Re-Specification" (2007) 1 Eur J Legal Stud 1, online: European Journal of Legal Studies <http://www.ejls.eu/1/14UK.pdf> at 23.
[44] Kleinhans & Macdonald, *supra* note 22 at 40.

outcomes."[45] It also allows for the framing of the medical profession and medical ethics within "a situation in which not all law is state law nor administered by a single set of state legal institutions, and in which law is therefore neither systematic nor uniform".[46]

These different sets of law are not necessarily equal, and even within legal orders and semi-autonomous social fields certain laws might have greater importance than others. For example, a statute setting forth requirements for licensure, while it must be complied with, may have less immediate meaning to a physician than a practice standard that furthers the safety of a patient (if we can also consider practice standards to be some form of legal order). In addition, the creator of a legal order is an important consideration for physicians and the profession. The profession might be more amenable to an ethics or practice standard designed by colleagues than one imposed by the State. Conversely, a decision revoking membership in a professional organization may have less impact on a physician than a State decision to the contrary (or even a lesser punishment). The incursion of one semi-autonomous social field into the traditional domain of another creates tensions that will become necessary to resolve. Legal pluralism provides a tool with which to resolve them.

The concise definition of legal pluralism used by Griffiths, "the presence in a social field of more than one legal order",[47] will serve well in the context of the medical profession and medical ethics. Each part of this definition—"social field" and "legal order"—will be further unpacked to demonstrate the utility and application of legal pluralism to the medical

[45] Engel, *supra* note 38 at 431.
[46] Griffiths, *supra* note 5 at 5.
[47] *Ibid*. at 1.

profession and medical ethics.

III. Semi-Autonomous Social Fields and the Creation of Law

A. The Semi-Autonomous Social Field

1. The Nature of the Semi-Autonomous Social Field

An important aspect of legal pluralism is defining the group to whom the proposed legal order applies. The semi-autonomous social field postulated by Moore[48] and similar groupings[49] has become a common denominator in discussions of legal pluralism. It "has rule-making capacities, and the means to induce or coerce compliance; but it is simultaneously set in a larger social matrix which can, and does, affect and invade it, sometimes at the invitation of the person inside it, sometimes at its own instance."[50] Such a portrayal does not imply necessary structural features. For instance, a lack of clear executive, legislative or judicial bodies does not disqualify a group from being considered a semi-autonomous social field if it otherwise falls within Moore's description. This broad depiction of the semi-autonomous social field also lends to its application to many types of relationships, from cultural groups to business, familial and professional interactions, and it has been described as "[t]he most enduring, generalizable, and widely-used conception of plural legal orders".[51] Yet the use of the semi-autonomous "social field" also implies a limitation of authority: only those who are a part of the field are clearly bound by its legal order.

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[48] Moore, *supra* note 7 at 721.
[49] See e.g. Tamanaha, "Non-Essentialist", *supra* note 20 at 315. He uses the term "group" in his definition of legal pluralism.
[50] Moore, *supra* note 7 at 720.
[51] Merry, *supra* note 10 at 878.

A semi-autonomous social field can consist of something as small as a family unit, but also as broad as an entire country or political subdivision, such as the United States or the individual states within, and even international semi-autonomous social fields (hence the modern academic focus on "global" legal pluralism). There are important distinctions, though, between State and non-State semi-autonomous social fields that should be addressed, at least as a limiting factor for the reach and power of non-State social fields. The State ostensibly asserts control over all within its jurisdiction—the entirety of the society including other semi-autonomous social fields—and it generally claims more autonomy than other social fields might, even if this autonomy is in fact more limited than the State assumes because of the multitude of legal orders that coexist with its own. Certainly, other semi-autonomous social fields and their legal orders can influence the State, and it may take up the "symbols" of these legal orders.[52] However, the question of whether pluralism is "strong" or "weak"[53]—and therefore the level of autonomy of the State and other semi-autonomous social fields—depends as much on the amount of control exerted by the State over social fields within its geographic jurisdiction as it does on the content of its law.

Much like the State, a non-State semi-autonomous social field asserts direct social control but generally only over those individuals and entities within its domain. Its legal order may impact a large swath of the surrounding population and those it must interact with, as

[52] *Ibid*. at 882.
[53] Griffiths, *supra* note 5 at 5. "Weak" legal pluralism occurs "when the sovereign (implicitly) commands... different bodies of law for different groups in the population" and the State recognizes the pre-existing "customary law". See also Dupret, *supra* note 43 ("[weak legal pluralism] refers to legal systems in which the sovereign commands or validates or recognises different bodies of law for different groups in the population; if it is a weak conception of legal pluralism, it is however mainly a (weak) conception of legal centralism, for it gives the central state the ultimate power to acknowledge or refuse the existence of such different bodies of law" at 5).

the medical profession's does,[54] but its control over these "outsiders" is limited. At times, a semi-autonomous social field (including the State) may also be subject to the legal order of another semi-autonomous social field within the "larger social matrix".[55] This represents the limitation termed semi-autonomy, whereby the semi-autonomous social field "can generate rules and customs and symbols internally, but…it is also vulnerable to rules and decisions and other forces emanating from the larger world by which it is surrounded."[56]

Legal pluralism does not necessarily attempt to place semi-autonomous social fields outside of the jurisdiction of the State, but recognizes the State's jurisdiction alongside the legal orders created by the social field. It does not assume the superiority of one legal order over another even though there might be a *de facto* superiority.

Griffiths' denigration of the ideology of legal centralism was not an attempt to deny the State the ultimate power of its laws as sovereign of the land. Rather, it was an argument that a centralistic concept of law fails to consider all those other sources of "law" that exist within society and are not officially recognized nor subject to enforcement (normally) by institutions of the State. However, the existence of these other legal orders alongside that of the State does not diminish the need "to see state law as fundamentally different in that it exercises the coercive power of the state and monopolizes the symbolic power associated with state authority."[57] Non-State semi-autonomous social fields do not have this capacity,

[54] A legal order based in medical ethics might be intended to control the behavior of physicians, but it also impacts patients and others who interact with physicians.
[55] Moore, *supra* note 7 at 720.
[56] *Ibid*.
[57] Merry, *supra* note 10 at 879. See also Macdonald, *supra* note 17 ("[t]here is no question that the State may claim a certain degree of commitment and may assert a certain degree of authority over its citizens resident within its geography" at 85).

and although its value can be debated this fundamental difference shapes the interactions and attitudes of States and other social fields.

The *political*[58] superiority of State law in a hypothetical hierarchy of law is facially accurate, as it is general in nature and intended to apply to all members of a society. However, political superiority over other legal orders does not necessarily translate into absolute control or jurisdiction, and this is the point made by Moore:

> [I]nnovative legislation or other attempts to direct change often fail to achieve their intended purposes….Legislation is often passed with the intention of altering the going social arrangements in specified ways. The social arrangements are often effectively stronger than the new laws.[59]

Thus, "[i]t is essential to recognise that the priority officially accorded to state law in these situations says nothing about the power of law in social life."[60] Indeed, there is no "transcendent virtue"[61] of either State or non-State law that determines which is more functional or appropriate in a given social field and for a given circumstance. The question might then be whether and how the social field applies its legal order when the State also regulates the social field.

The theory of legal pluralism revolves around these semi-autonomous social fields[62] and the role of those creating law within the fields.[63] They are the creators of legal orders and

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[58] von Benda-Beckmann, *supra* note 11 at 46, noted that the superiority of the State stemmed from its political position rather than a factual superiority of its law compared to that of other social fields. Griffiths, conversely, viewed the idea of a hierarchy with State law at the top as evidence of "weak" legal pluralism. See Tamanaha, "Folly", *supra* note 12 at 202. However, a simple view of the State versus all other legal orders within its jurisdiction permits the placement of the State in at least a theoretically superior position, though as noted the laws of the State do not always have their intended effect.
[59] Moore, *supra* note 7 at 723. See also Merry, *supra* note 10 at 880.
[60] Tamanaha, "Understanding Legal Pluralism", *supra* note 14 at 385.
[61] Macdonald, *supra* note 17 at 87.
[62] Griffiths, *supra* note 5, discussed a number of other theories contributing to his definition of legal pluralism and their characterizations of the groups to which 'law' applied. He found these to be inappropriate for a strong descriptive conception of legal pluralism.
[63] Kleinhans & Macdonald, *supra* note 22 at 38.

can be a source of inspiration for the law of the State. However, in grounding itself in legal orders and semi-autonomous social fields the theory of legal pluralism—like any other legal theory that attempts to explain law—is not perfect. Semi-autonomous social fields can be easy or difficult to discern, having strong or weak organization. There is no standard set of characteristics for how to identify a semi-autonomous social field, so what makes the medical profession one?

2. The Medical Profession as a Semi-Autonomous Social Field

In Chapter 2, the brief history of the medical profession demonstrated the importance of self-regulation in the absence of State law regulating physicians or the provision of health care. Despite the growth of State control over the practice of medicine, the profession still retains some authority over its members, hence its consideration here as a semi-autonomous social field.

Although when I refer to the medical profession in this Thesis I indicate physicians to the exclusion of other health professionals, practitioners and institutions, it is important to recognize that the medical profession is not a homogenous group of individuals with common goals, techniques and beliefs (though promotion of patient health is supposedly universal). Rather, physicians practice in different medical specialties and geographic locales, which can impact their day-to-day practice and decision-making. Thus, it *could* be appropriate to use semi-autonomous social *fields*—in the plural—when discussing legal pluralism in the medical profession.[64]

[64] See Macdonald, *supra* note 17 ("[e]ven the simplest legal regimes are constituted by a plurality of decision-making institutions, distributive criteria and cultural traditions" at 77). If we signify a social field in the medical profession by membership organizations, there are at least 150 independent medical societies making for at least 150 semi-autonomous social fields. The AMA provides a list of over 100 specialty

This phenomenon is possible within any semi-autonomous social field. There might be sub-groups in a social field that have their own ideals, adopting formal or informal rules to govern the behavior of members despite the rules or legal orders of the wider semi-autonomous social field to which they belong. In considering the State as a semi-autonomous social field, as all-encompassing as it is there is a multitude of semi-autonomous social fields that exist within it. When identifying the possibility of many social fields in medicine, I do not mean to discount the overarching semi-autonomous social field of the medical profession. The heterogeneity of physicians and the medical organizations that make up the medical profession only add complexities to its functioning, rather than deny its potential as a semi-autonomous social field.

This heterogeneity also leads to a few other points about the medical profession as a semi-autonomous social field. First, membership in a medical society is voluntary, and although most physicians are members of at least one society (specialty or state) the AMA—the largest medical society in the US—officially represents only a minority of physicians.[65] It has retained significant control over ethics and education policy compared to other societies, but the growth especially of specialty medical societies and the detachment that many physicians feel from the profession outside of their specialty has led to decreased interest in becoming a member of the AMA.

societies, in addition to the medical society of each state. American Medical Association, "National Medical Specialty Websites", online: American Medical Association <http://www.ama-assn.org/ama/pub/about-ama/our-people/the-federation-medicine/national-medical-specialty-society-websites.page>.

[65] Roughly 15%, according to a 2011 article. Roger Collier, "American Medical Association Membership Woes Continue" (2011) 183 Can Med Assoc J E713. However, its reach through ethics policies and education and practice standards is much broader.

Second, not all medical societies have the same purposes or goals. These associations often share policy and guidelines, influencing each other and creating some uniformity in the profession as a whole, but at times they will differ.[66] Many (if not most) also support education and ethics standards for the profession or their segment of it, sustaining the moral force of the profession, while others have failed to do so: "[t]oo many have already become corporatized entities in pursuit of profit to finance bulky administrative staffs or to lobby for the protection of privileges and the benefit of their members."[67] Economics have always been a factor in medicine, as alluded to in the last Chapter, and medical associations have on occasion put the financial welfare of physicians ahead of other responsibilities, including ethical ones, which will be discussed in later Chapters.

Although organized medicine is an imperfect representation of the semi-autonomous social field that is the medical profession, the ideals broadly represented and shared by medical societies outline the contours of a somewhat amorphous social field.[68] These societies provide the normative standards that all physicians are expected to use and adhere to regardless of membership, even if a society has no jurisdiction over a particular physician. These standards are generally derived from a few commonalities: a common ethic directed towards patients characterizes the profession regardless of specialty or geographic locale; and a common education that links members of the profession together despite individual

[66] See e.g. Utah Medical Association, "UMA and AMA are Separate Organizations", online: Utah Medical Association <http://www.utahmed.org/WCM/_About/UMA___AMA__Not_the_Same.aspx> ("UMA does not always agree with AMA and when UMA disagrees we express that disagreement and/or opposition").
[67] Edmund D Pellegrino & Arnold S Relman, "Professional Medical Associations" (1999) 282 J Am Med Assoc 984.
[68] Even within organizations like the AMA, there are different constituencies that have different needs and goals, so it is possible to have multiple semi-autonomous social fields within a single organization, though the ability of these social fields to fulfill the functions of social fields outlined by Moore and Griffiths may be to a large extent compromised by their allegiance to the umbrella association.

differences. While no single organization represents all physicians, a few are sufficiently large that their decisions on policy and practice have an effect beyond the constraints of their membership.

I will regularly refer to the American Medical Association and its *Code of Ethics* throughout this Thesis. This is not because the *Code*'s role in the AMA, since as alluded to above the AMA directly represents well under half of all physicians in the US.[69] Rather, the *Code*, and to a lesser extent the AMA, has an outsized impact on the development of the profession's own legal orders, and even State law to the extent that it coincides with the profession's. Partially, this is an effect of history: the AMA became the single organization that united state medical societies well before the development of medical specialties and their organizations and the subsequent decentralization of organized medicine. This history combines with that of medical ethics and the importance of the AMA *Code* to place the AMA at the top of the medical society hierarchy (if we are to have one) for ethics development, as most medical societies continue to look to the *Code* for ethics guidance. The structural relationships between the AMA and most other mainstream medical societies also grant a special status to the AMA since these societies all have representation in the AMA's legislative body, which is not generally reciprocated by AMA representation in their own.

Thus, while no single medical society or organization can claim to represent the entirety of the profession on its own, organized medicine as a whole expresses concurrent histories, traditions, goals and ethics that unite all physicians regardless of specialty or background.

[69] See Collier, *supra* note 65.

I refer to medical societies and their legal orders throughout this Thesis, but these are merely the vehicles through which the profession's legal order of medical ethics is devised. They create and enforce norms, and their effect is felt across the profession regardless of membership in a specific medical society. All physicians are bound by virtue of being part of a profession dedicated to providing beneficent care to follow a set of written and unwritten rules that guide their behavior towards patients, each other and the public. When I refer to the semi-autonomous social field in this Thesis, it is this broad, diverse group—and not just their medical organizations—to which I refer.

If the physicians trained and inducted into the medical profession, and their organizations, can be posited as a semi-autonomous social field, what of its legal order? The next subsection examines first what law consists of for a legal pluralist, and second establishes medical ethics as a legal order for the medical profession.

B. What is Law?

1. Pluralists' Law and Their Detractors

As I stated at beginning of this Chapter, determining what "law" is remains a contentious thing. There are a number of different theories of "law" and how it is created, and many of these exclude or include things that would not be excluded or included by other theories.[70] Hart recognized the difficulty of finding law by noting "[f]ew questions concerning human society have been asked with such persistence and answered by serious

[70] See e.g. Hart, *supra* note 4; Huntington Cairns, "What is Law?" (1970) 27 Wash & Lee L Rev 193; Lon L Fuller, *The Morality of Law, Revised Edition* (New Haven: Yale University Press, 1969); Lon L Fuller, "Human Interaction and the Law" (1969) 14 Am J Juris 1 [Fuller, "Human Interaction"]; Luis de Garay, "What is Law?" (1941) 16 Notre Dame Lawyer 261; Oliver Wendell Holmes, "The Path of the Law" (1996) 110 Harv L Rev 991.

thinkers in so many diverse, strange, and even paradoxical ways…."[71] Tamanaha wrote of the difficulty of defining law within any theoretical approach, and noted that a successful definition has never been formulated,[72] that "[w]hat law is and what law does cannot be captured in any single concept, or by any single definition."[73]

Fuller also pointed out the difficulties of hashing out different perspectives of law:

> A rule of law is—that is to say, it really and simply and always is—the command of a sovereign, a rule laid down by a judge, a prediction of the future incidence of state force, a pattern of official behavior, etc. When we ask what purpose these definitions serve, we receive the answer, "Why, no purpose, except to describe accurately the social reality that corresponds to the word 'law.'" When we reply, "But it doesn't look like that to me," the answer comes back, "Well, it does to me." There the matter has to rest.[74]

This does not mean that we cannot attempt to define law for our own purposes within the framework of legal pluralism, only that we must also recognize that our definition will not always coincide with others'.[75]

In many instances, and it will be the same here, the process of answering the question is permeated by the reason it is being asked, thus the multiple conflicting and non-universal definitions. For many, the law of the State is "The Law": statutes, regulations and judicial decisions,[76] all formulated under the aegis of the sovereign and generally applicable to the

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[71] Hart, *supra* note 4 at 1.
[72] Tamanaha, "Non-Essentialist", *supra* note 20 at 319.
[73] *Ibid*. at 313.
[74] Lon L Fuller, "Positivism and Fidelity to Law – A Response to Professor Hart" (1957) 71 Harv L Rev 630 at 631 [Fuller, "Positivism and Fidelity to Law"].
[75] Tamanaha, "Folly", *supra* note 12 at 202; von Benda-Beckman, *supra* note 11 ("[i]t is particularly under the name of 'theory' that many scholars claim universal value for their concept in an absolutist manner, struggling for conceptual hegemony" at 41).
[76] See e.g. Engel, *supra* note 38 ("[t]he relevance of legal pluralism to American society may not be immediately apparent, for we are not accustomed to viewing ourselves as subject to systems of legal obligation other than those founded upon federal, state, and local enactments and case law" at 427); Macdonald, *supra* note 17 ("[l]egal scholars…are so committed to the systematic singularity and coherence of law that the commonplace understandings of cognate disciplines are often dismissed out of hand" at 69).

population. Many theories of law have revolved around this form, rather than questioning its exclusive claim to the title.[77]

According to Tamanaha, attempts to define law fall into two categories: law as "concrete patterns of behavior within social groups" or as "institutionalized norm enforcement".[78] The first type leads to over-inclusion and the second might not be the primary source of legal order.[79] Hart fell into the second category when he characterized law as primary and secondary rules, with primary rules creating obligations and capabilities for those under the rule-maker's jurisdiction[80] and secondary rules to "provide that human beings may by doing or saying certain things introduce new rules of the primary type, extinguish or modify old ones, or in various ways determine their incidence or control their operations."[81] In this conception of law, patterns of behavior are largely irrelevant.

Unlike the many legal theories that focus primarily on the law of the State as *the* law, legal pluralism searches for legal orders in semi-autonomous social fields—for law within the State but at the same time separate from the State's law even if it exists *within* the State. Much of the law of semi-autonomous social fields will be similar to the primary rules identified by Hart, and without the accompanying secondary rules (rules determining behavior and setting forth obligations). In some instances, though, this law will be formed, applied and changed using something akin to secondary rules.[82] However, even these are

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[77] See e.g. Hart, *supra* note 4; Michael Steven Green, "Legal Realism as a Theory of Law" (2005) 46 Will & Mary L Rev 1915 at 1928.
[78] Tamanaha, "Non-Essentialist", *supra* note 20 at 300.
[79] *Ibid*. at 301.
[80] Hart, *supra* note 4 at 81.
[81] *Ibid*.
[82] For example, as will be discussed in later Chapters, medical associations often have written procedures for adopting new policies, as well as structures that serve legislative and judicial functions *within* the organization.

not generally considered law when examined from the perspective of the legal positivist.[83]

Griffiths, in his discussion of legal centralism, was most critical of a definition of law that limited it to the State, much as positivism does. He did not agree that law "is a single, unified and exclusive hierarchical normative ordering depending from the power of the state…."[84] By defining law in the manner he does—as the self-regulation of a semi-autonomous social field—Griffiths signals an openness to "law" that is fundamental to legal pluralism.[85] Such a conception of law has historical roots, as centralized sovereign authority is a relatively recent invention.[86] Even today, "[t]he world's legal systems may all be described as diversified blends of various ingredients: they may include chthonic laws, indigenous customs, exogenous customs, religious laws…, law merchant, natural law, Roman civil law, common law, and various statutes and codes."[87] The law that we commonly consider to be law—that of the State—is often a culmination of history and circumstances rather than a novel creation of new ideas.

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[83] See Brian Z Tamanaha, *A General Jurisprudence of Law and Society* (Oxford: Oxford University Press, 2001) at 137. In an analysis of Hart's theory of positive law, Tamanaha notes the implications of such an essentialist definition: "[a]lthough various mechanisms satisfy the function of law, it does not follow therefrom that we should append the label 'law' to all of them." Tamanaha also recognized that Hart would not call all systems that have primary and secondary rules "law" because they are not "conceptual or conventionalist equivalents" of what would normally be called "law". *Ibid*. at 138.

[84] Griffiths, *supra* note 5 at 4. See also Kleinhans & Macdonald, *supra* note 22 ("[t]he authoritative language of law in contemporary discourse is that promoted by faculties of law, the legal professions, judges, politicians and political commentators; this language either excludes non-State normativity from its realm, or incorporates this non-State normativity into State law by means of devices such as delegation, or referential incorporation" at 41); Gunther Teubner, "Global Bukowina: Legal Pluralism in the World Society" in Gunther Teubner, ed, *Global Law Without a State* (Brookfield: Dartmouth, 1997) ("…the tremendous resistance that Ehrlich's global Bukowina has to face in a legal world still conceptually dominated by the nation state" at 7).

[85] *C.f.* Tamanaha, "Non-Essentialist", *supra* note 20 at 320. Tamanaha argued that Griffiths and other pluralists use an essentialist definition of law that "dictate[s] for everyone else what law (properly understood) is", which his conventionalist definition challenges.

[86] See Berman *supra* note 28; Macdonald, *supra* note 17; Tamanaha, "Understanding Legal Pluralism", *supra* note 14; Sacco, *supra* note 26.

[87] Vernon Valentine Parker, "Mixed Legal Systems…and the Myth of Pure Law" (2006) 67 Louisiana L Rev 1205 at 1208.

Since Griffiths' seminal writing, others have attempted to provide a more workable notion of law, placing the forms of social control (often viewed as an identifying criteria of law) on a spectrum, "which runs from the clearest form of state law through to the vaguest forms of informal social control."[88] Recognizing the essential concept of pluralism that not all law has the same impact is important to the conclusion that pluralists have little interest in developing a restrictive definition of law. Aside from asserting that the law of the State is a legal order that often encompasses a semi-autonomous social field, pluralists are open to law being found "everywhere,"[89] whether it is written, contained in "the knowledge of the people," or evidenced by social interactions.[90]

An important description of the pluralist's conception of law is that "[t]here is no 'law *is*…'; there are these kinds of law and those kinds of law; there are these phenomena called law and those phenomena called law…."[91] If it is something that would control or coerce behavior, or give rise to obligations, it can be considered law.[92] It might be written or inferred, coerced or voluntary. Indeed, "[t]he existence of an elaborate body of rules is not decisive."[93] This dramatically increases the "grazing area"[94] of law, taking us beyond the fields of the State.

Concepts of law tend to be formulated to explain a "social reality"[95] of law that appears

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[88] Gordon R Woodman, "Ideological Combat and Social Observation: Recent Debate About Legal Pluralism" (1998) 42 J Legal Pluralism 21 at 45.
[89] Ehrlich, *supra* note 1.
[90] von Benda-Beckmann, *supra* note 11 at 65-66.
[91] Tamanaha, "Non-Essentialist", *supra* note 20 at 313. See also von Benda-Beckmann, *supra* note 11 ("[i]t is clear that no reader could conclude that all phenomena called law would be 'the same'" at 50).
[92] Or, as von Benda-Beckmann put it, "these conceptions recognize and restrict society's members' autonomy to behave and construct their own conceptions." *Ibid*. at 48.
[93] Teubner, *supra* note 84 at 9.
[94] LL Fuller, "American Legal Realism" (1934) 82 U Penn L Rev 429 at 437 [Fuller, "Legal Realism"].
[95] Fuller, "Positivism and Fidelity to Law", *supra* note 74 at 631.

before us. In conceiving of "law" for application in this Thesis, it is the social reality of the medical profession that dictates its boundaries. Thus, "law" is broad, encompassing not only the law of the State but also the legal orders of semi-autonomous social fields, appearing as rules, norms, policies, administrative decisions or other forms that have the impact of State-created law: coercing, requiring, encouraging, limiting, prohibiting or advocating for certain behaviors and actions. Fundamentally, law can be defined as "whatever people identify and treat through their social practices as 'law'."[96] The questions become *who* identifies *what* as law, and *why*,[97] because "neither belief nor behaviour exists apart from believers and behavers."[98] This admittedly broad definition of law allows for the examination of phenomena that *might* be considered "law" from an expansive perspective, rather than beginning from a very narrow one and similarly narrowing our field of exploration.

The expansiveness of legal pluralists' law has caused discomfort for some, and legal pluralism has been criticized for using the term "legal" primarily because this expansive use is seen as diluting what is typically viewed as "legal." "Law" is often identified with the "trappings of the state"[99] and in most instances when it is discussed in a practical sense

[96] Tamanaha, "Non-Essentialist", *supra* note 20 at 313. See also Dupret, *supra* note 43 ("…law is what people refer to as law" at 16); Fuller, "Human Interaction", *supra* note 70.
[97] Tamanaha, "Non-Essentialist", *supra* note 20 at 318. See also von Benda-Beckmann, *supra* note 11 at 68. Dupret describes the true purpose of an examination into the pluralistic nature of something as answering the "what" and "how" questions. Dupret, *supra* note 43 at 18.
[98] Kleinhans & Macdonald, *supra* note 22 at 27.
[99] Tamanaha, "Folly", *supra* note 12 at 201.

("lawyer's law"[100]) the "law" refers *only* to the law of the State.[101] It has been argued that the expansion of "legal" and "law" to all those things that legal pluralism intends can have the effect of confusing things and diminishing the impact of "law" as it is commonly used outside of the parlance of legal pluralism.[102]

One aspect of this criticism that is of particular importance is the failure of legal pluralists to provide a common, useable definition of "law."[103] Tamanaha found this to be the death knell of the theory as it is currently entitled.[104] In his view, the description of all normative ordering as "legal" created a roadblock to the effectiveness of the theory—the importance of "what's in a name".[105] He pointed to Merry's assertion that the "legal system" includes "non-legal" norms as indicative of the incoherence of legal pluralism.[106] However, her classification more likely relates to how we commonly view law as something created by the State (Griffith's legal centralism), and trying to find the correct terminology to identify something as potentially law. By using the term "non-legal," she does not necessarily create a contradiction but rather includes within the legal system things that are not

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[100] Macdonald, *supra* note 17 ("…law is about only those forms, processes and institutions of normative ordering that find their legitimacy in the political State or its emanations" at 72); Kleinhans & Macdonald, *supra* note 22 ("[s]cholarship penned by jurists usually presumes that the traditional image of lawyer's law…offers a satisfactory intellectual framework for inquiry" at 27). See also von Benda-Beckmann, *supra* note 11 at 58.

[101] *C.f.* Fuller, "Legal Realism", *supra* note 94 ("[i]n truth, the judge's decision represents a reaction to the whole situation, including many facts which from the standpoint of legal theory are irrelevant" at 456).

[102] Tamanaha, "Folly", *supra* note 12 at 193. See also von Benda-Beckman, *supra* note 11 at 55; Dupret, *supra* note 43 at 11.

[103] See e.g. Tamanaha, "Non-Essentialist", *supra* note 20 at 297; Kleinhans & Macdonald, *supra* note 22 ("…the objection is apparently methodological: legal pluralism lacks a criterion for distinguishing non-State law from anything else that has a normative dimension…" at 32).

[104] Tamanaha has come to embrace legal pluralism since this article was written. See Tamanaha, "Non-Essentialist", *supra* note 20; Tamanaha, "Understanding Legal Pluralism", *supra* note 14. See also Tamanaha, "Folly", *supra* note 12 at 193, citing Merry, *supra* note 10 at 870; SF Moore, "Legal Systems of the World" in L Lipson & S Wheeler, eds, *Law and the Social Sciences* (New York: Russell Sage Foundation, 1986) at 15.

[105] Tamanaha, "Folly", *supra* note 12 at 212.

[106] *Ibid*. at 193.

generally considered law (hence the "non-legal"), but *should* be considered law, using terminology that all might understand.

Tamanaha also argued that

> [a]s should be immediately apparent, so generous a view of what law is slippery slides to the conclusion that all forms of social control are law. Not only does the term "law" thereby lose any distinctive meaning—law in effect becomes synonymous with normative order—other forms of normative order, like moral or political norms, customs, habits, rules of etiquette, and even table manners are swallowed up to become law.[107]

Woodman seconds this discomfort, wondering at the inability of legal pluralists to distinguish between the legal and non-legal of these "non-state phenomena".[108] Again, though, this is a slanted view of what legal pluralism is and what it seeks to do. Not all forms of social control will be "law": it is dependent on the characteristics of the group and how *they*, rather than those who are not members of a semi-autonomous social field, perceive the authority of the social field and its legal order.

However, the difficulty of providing a clear and exacting definition of law is a significant and valid criticism of legal pluralism (and probably most legal theories). Griffiths' answer to the question "what is law?" does not diminish this assessment: "…law is the self-regulation of a 'semi-autonomous social field'".[109] This is a very broad definition, open to interpretation. Yet this breadth is probably what is intended by legal pluralists.

Why can there not be a different term used, reserving "law" for what we commonly view it as, at least in the United States? Suggested terminology to avoid these problems has

[107] *Ibid*.
[108] Woodman, *supra* note 88 at 44.
[109] Griffiths, *supra* note 5 at 38.

included "normative pluralism"[110] and "informal laws."[111] However, such attempts misconstrue the objective of legal pluralism to compare non-State legal orders to each other and the State—you cannot compare apples by calling four of them apples and the fifth an orange. If new terminology is invented to differentiate non-State legal orders from the State, this could have the unintended effect of diminishing the import of these orders at the first instance of consideration. It also might be an intended consequence of legal pluralists to reduce the standing of State law in relation to the law of other social fields. Making State law one of many sources of law, rather than *the* source of law, is within the general outlook of legal pluralism.

Despite these deficiencies in the use of "legal," pluralists would likely not argue that they intend all forms of social control identified by Tamanaha to be considered law, at least not in the Western context. His use of a slippery-slope-type argument, though, begs the question of why cannot theorists, when applying legal pluralism to specific examples such as a cultural group or business associations, identify what they mean by "legal" without being bound by a general definition? Indeed, von Benda-Beckmann pointed out that this criticism "confuses the discussion about the *theoretical possibility* of legal pluralism with the question of what criteria make (any) normative ordering 'legal'".[112] One purpose of an analysis using legal pluralism is to determine why "legal" should be used for a given order.[113] Anything can be titled "law," but then this assertion must be supported.

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[110] Tamanaha, "Understanding Legal Pluralism", *supra* note 14 at 395, citing John Griffiths, "The Idea of Sociology of Law and its Relation to Law and to Sociology" (2005) 8 Curr Legal Issues 49 at 63-64.
[111] Gad Barzilai, "Beyond Relativism: Where is Political Power in Legal Pluralism?" (2008) 9 Theor Inq L 395 at 401.
[112] von Benda-Beckmann, *supra* note 11 at 56 [emphasis added].
[113] Tamanaha, "Non-Essentialist", *supra* note 20 at 319.

In the end, legal pluralism seeks to break through restrictive notions of what law is and how it is used within groups. By devising a broad definition with only spectral boundaries, it is left to the theorist to determine whether something is law, whether it has the same import amongst members of a semi-autonomous social field as do the commands of the State—where we speak of law instead of describing social life.[114] The next subsection will apply a legal pluralist's conception of law to the medical profession and its legal order of medical ethics.

2. Medical Ethics as a Legal Order

"Legal order" has never been clearly defined within the theory of legal pluralism.[115] It is a broad term that can apply to many normative systems, formal or informal, as well as the law of the State, and does not require executive, legislative, or judicial activity. The legal order of medical ethics, if it is to be deemed a legal order, is on the more formal end of this spectrum. There are other sources of rules arising from within the profession such as practice standards and best practices, which provide technical guidance to physicians and are also devised through somewhat formal mechanisms. Medical ethics, though, remain the primary *normative* system for the profession. As indicated in Chapter 2, and as will be discussed further in the next Chapter, the codification of ethics first by Percival and eventually by the AMA provided tangible systems for physician behavior not previously embraced by physicians or any other profession at the time. Some believed these were

[114] Merry, *supra* note 10 at 878.
[115] *Supra* note 13.

merely rules for "etiquette,"[116] but as the AMA *Code* and other medical society ethics pronouncements evolved their utility as "law" also evolved and improved.

The development of mechanisms to enact and enforce ethics standards—similarly evolving over time to become more effective—is also indicative of a legal order. Medical ethics became something more than just statements of behavioral preferences by professional bodies; the embrace of a judicial body to oversee disciplinary actions against physician violators of medical ethics, particularly by the AMA, was a substantial step towards even a positivist's view of law.

The association-based roots of medical ethics point to a potentially important limitation of ethics as a legal order: membership in medical associations. That is, medical societies have direct jurisdiction only over their members, as these are the only physicians they can actually discipline. Although the vast majority of physicians probably belong to at least one medical society, no society can claim membership of a majority of physicians.[117] With this limitation on *direct* disciplinary jurisdiction, is medical ethics as a legal order applicable to the semi-autonomous social field of the medical profession—that is, all physicians—regardless of medical society membership?

The role of medical ethics in the practice of medicine and in the training of physicians has become super-organizational; that is, it is not limited to physicians who are members of professional societies. These societies play the crucial roles of enforcing ethics standards for members and designing ethics norms for the entire profession, but medical ethics do

[116] Chauncey D Leake, "Percival's Medical Ethics" (1927) 197 N Eng J Med 357; Ivan Waddington, "Development of Medical Ethics – A Sociological Analysis" (1975) 19 Med Hist 36.
[117] See e.g. Collier, *supra* note 65.

not reside solely within and are not practiced solely by medical societies. Medical students are taught the importance of medical ethics as a way to guide patient care. Licensed physicians can have their ethics knowledge expanded through continuing education. Ethics has an influence—sometimes large and sometimes small—in the development of State law that in turn reinforces the importance of professional control over the ethical aspects of medical practice. The broad and general acceptance by all physicians of the authority of medical ethics regardless of medical society affiliation, rooted in the codified ethics developed by medical societies, is indicative of a legal order that extends beyond these societies.

Although the *Code* does not explicitly state that it is binding on *all* physicians, it does note that the Principles of Medical Ethics, which are the foundation for more detailed ethics Opinions, are "the core ethical principles of the *medical profession*."[118] The AMA does not view the *Code* as applicable only to its members and members of constituent societies, but to all physicians. Its further recognition in the preamble to the Principles that they are "standards of conduct"[119] solidifies the notion that these Principles and Opinions in the *Code*, although not called law, are intended to be normative rules.

Ethics also serves the same function of social control that State law is presumed to promote, except on a much smaller scale. Enforcement mechanisms of medical societies represent one effort to exert control, but the general expectation within the profession that members adhere to basic ethics can also be a powerful form of social control existing alongside

[118] Council on Ethical and Judicial Affairs, *Code of Medical Ethics: Current Opinions with Annotations, 2010-2011* (Chicago: American Medical Association, 2010) at xi [CEJA, *Code of Medical Ethics*] [emphasis added].
[119] *Ibid*. at xvii.

whatever medical societies do. Really, the purpose of adopting the *Code of Medical Ethics* in 1847 was to assert control over physicians by those who believed the actions of "irregular" physicians represented a danger to both patients and "regular" physicians. Its success in at least *appearing* to be a normative system is advanced by the belief that all physicians are expected to "be ethical."

Enforceability of a legal order is an important characteristic in legal pluralism, but explicit enforcement is not necessarily a determinative factor.[120] If this were the case medical ethics as a legal order would be seriously threatened. The AMA and other societies tend to base their own disciplinary actions on those taken by the State, limiting the threat of sanction for violation of ethics norms that do not have parallels in State law. This does not mean that ethics has no backbone—the threat of sanction is sufficient to create the perception that ethics codes are indeed rules. This is also comparable to the State regularly enacting laws that are not enforced or are not enforceable in any meaningful way, supporting the claim that *actual* enforcement is not necessary to the existence of a legal order if that legal order retains authority *within* the social field.

In legal pluralism, what is truly important is that the members of the semi-autonomous social field view and use something as a determinant of behavior.[121] In this case, it is clear that medical societies intend medical ethics to act as a form of law (without using the title "law") and that physicians in general, regardless of medical society membership, view ethics as a set of norms to guide their professional lives. Even though individuals and

[120] Moore, *supra* note 7 ("[d]espite the symbolic ambience of choice, there are strong pressures to conform to this system of exchange…." at 728). For the medical profession, physicians can follow ethics codes because of social pressure to do so, in addition to threats against medical society membership.
[121] *Ibid*.

groups regularly challenge current ethics norms as inappropriate, outdated or unnecessary, they do not challenge the underlying conception of ethics as rules binding on physicians—the vibrancy of ethics debates within the profession and medical societies is evidence of this.

Despite the congruence of the structure of the medical profession and the normative utility of medical ethics to the indicators of legal pluralism, resistance to the characterizations of semi-autonomous social fields and legal orders is possible (if not likely), especially from outside the profession. It is useful, then, to point to theoretical approaches to the medical profession that predate the growth of legal pluralism as a vehicle for explaining normative relationships. The next subsection briefly brings to the fore the theory of professionalism. My purpose here is not to question the propriety of legal pluralism as my analytical framework, but rather to demonstrate that a consideration of the normative aspects of medical ethics and the self-regulatory authority of the profession is not outside the realm of historical possibility, if not probability.

C. The Helpful Theory of Professionalism

The previous subsections place the medical profession in the context of a semi-autonomous social field and its medical ethics a legal order. As the profession has never been explored in detail in the context of legal pluralism there is little to guide us in the legal pluralism literature: few proposed semi-autonomous social fields have such a complex relationship with the State and other social fields as the medical profession.

Although the medical profession has not before been claimed as a semi-autonomous social field, its prominence both in society and as a subject of sociologic and economic study

provides indicators of behaviors and activities that we might be able to associate with legal pluralism. To this end, I will briefly survey the well-established theory of professionalism, which developed over the past century to describe and define the relationship between the medical profession and the State, and the profession and society. Like legal pluralism it has been applied to a variety of groups and relies on concepts like autonomy and self-regulation, but unlike pluralism it has a lengthy record of gauging medicine as a self-regulatory profession.[122]

I do not bring up professionalism here to propose an alternative theory to legal pluralism in this Thesis, but to highlight it use of parallel concepts and therefore its utility for exploring the medical profession within the framework of legal pluralism. There are many similarities between the two theories, but also important distinctions. We might be able to say, though, that the characteristics of a *profession* exhibited by physicians as a group can be traced to their work as a *social field* to develop a *legal order*—that long before legal pluralism became a working theory its essence was at work in the US medical profession. This essence set the stage for professionalism.

The theory of professionalism characterizes some groups as "professions." It advances the idea that these groups have special rights and attendant obligations that other groups (or occupations) do not.[123] Applying the term "profession" to an occupation has become common today,[124] and many occupations that claim the title do not share many similarities

[122] See e.g. Irving King, "Professionalism and Truth Seeking" (1908) 16 The School Rev 241; Hubert Langerock, "Professionalism: A Study in Professional Deformation" (1915) 21 Am J Sociol 30; CF Taeusch, "Fees and Charges as an Index of Professionalism" (1925) 35 Int'l J Ethics 368.
[123] See e.g. Edmund D Pellegrino, "Professionalism, Profession and the Virtues of the Good Physician" (2002) 69 Mt Sinai J Med 378.
[124] See e.g. Harold J Wilensky, "The Professionalization of Everyone?" (1964) 70 Am J Sociol 137.

with medicine. However, the voluminous literature of professionalism and what constitutes a profession tends to agree "that if anything 'is' a profession, it is contemporary medicine."[125]

A number of characteristics of professions have been posited:[126] (1) "the occupation has gained command of the exclusive competence to determine the proper content and effective method of performing some task";[127] (2) "[t]he occupational group…must be the prime source of the criteria that qualify a man to work in an acceptable fashion";[128] and (3) there is "a general public belief in the consulting occupation's competence, in the value of its professed knowledge and skill."[129] In simpler terms, these can be construed as expertise, control and public acceptance.

These characteristics are not necessarily something we would look for in a legal pluralism analysis, except perhaps a profession's control over qualifying criteria. Once we get past these basic characteristics of a profession, though, we reach a few commonalities between the theories of professionalism and legal pluralism. Professionals are permitted a greater

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[125] Eliot Freidson, *Profession of Medicine: A Study of the Sociology of Applied Knowledge* (Chicago: University of Chicago Press, 1970) at 4 [Freidson, *Profession of Medicine*].

[126] Note that many of the occupations that have used the title "profession" do not necessarily meet these criteria of a "classic" profession.

[127] Freidson, *Profession of Medicine*, *supra* note 125 at 10; James L Reinertsen, "Zen and the Art of Physician Autonomy Maintenance" (2003) 138 Ann Intern Med 992 (professionals "have specialized knowledge that is not easily understood by the average citizen" which "is to be used in the service of individual patients and society in an altruistic fashion" at 1190). I will not challenge the specialized knowledge aspect of the definition, as I do not think it can be done with any sincerity. While some have questioned the legal profession's claim to a specialized knowledge and its educational requirements I think the barriers to entry for medicine are, generally speaking, a legitimate reflection of the knowledge and skill required to practice in the field. See e.g. Richard L Abel, *American Lawyers* (New York: Oxford University Press, 1991) ("…it would be hard to argue that the credentials required of lawyers are necessary to practice law, given the considerable national variation in legal pedagogy" at 22). See also Wilensky, *supra* note 124 at 144-145.

[128] Freidson, *Profession of Medicine*, *supra* note 125 at 10. See also Wilensky, *supra* note 124 at 141.

[129] Freidson, *Profession of Medicine*, *supra* note 125 at 11.

autonomy in their work than are other types of workers,[130] leading to some kind of autonomy or semi-autonomy. In return for this, the profession has the responsibility to ensure that its members meet the expectations of the public and State—to regulate itself in the absence of or limitation on State regulation.[131] For the medical profession, medical ethics has come to signify both an autonomy to develop a set of behavioral rules and expectations for use within the profession, and a self-regulatory system that allows the profession, the State and society to hold physicians accountable.

Within professionalism, autonomy can be separated into autonomy for individual physicians and autonomy for the profession. For physicians, autonomy is the ability to make decisions free from the interference of others.[132] In recent years, these "others" often consist of State policymakers or insurers[133]—generally those who fund health care—and non-physician health occupations, but it can also mean fellow physicians.[134] Indeed, many of the early ethics rules in the AMA's *Code of Medical Ethics* were directed towards

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[130] See e.g. TH Marshall, "The Recent History of Professionalism in Relation to Social Structure and Social Policy" (1939) 5 Can J Econ & Pol Sci 325; Friedson, *Profession of Medicine*, *supra* note 125 at 76, 82.
[131] *Ibid*. ("[j]ust as autonomy is the test of professional status, so is self-regulation the test of professional autonomy" at 84). The 1847 AMA *Code of Medical Ethics* implies a need for self-regulation, but given the novelty of the organization at the time and the limitations on its authority the *Code* was viewed as a means to unify physicians of the same training and to identify and decry other forms of medical practice deemed quackery. Presumably, a member of the AMA who was found to be practicing in such a manner would be expelled under the terms of the *Code*. American Medical Association, *Report of the Committee on a Code of Medical Ethics for the Government of the Medical Profession of the United States* (Chicago: American Medical Association, 1847) [AMA, *Code of Medical Ethics (1847)*].
[132] Marie R Haug, "A Re-Examination of the Hypothesis of Physician Deprofessionalization" (1988) 66 Milbank Quart 48 at 53; Criton A Constantinides, "Professional Ethics Codes in Court: Redefining the Social Contract Between the Public and the Professions" (1991) 25 Ga L Rev 1327. Freidson extends this to the ability to regulate others, which for physicians means other health occupations. Freidson, *Profession of Medicine*, *supra* note 125 at 369.
[133] Reinertsen, *supra* note 127; Mark J Schlesinger, Bradford H Gray & Krista M Perreira, "Medical Professionalism Under Managed Care: The Pros and Cons of Utilization Review" (1997) 16 Health Aff 106; Stefan Timmermans, "From Autonomy to Accountability: The Role of Clinical Practice Guidelines in Professional Power" (2005) 48 Perspec Biol & Med 490.
[134] Reinertsen, *supra* note 127. Reinertsen focuses on the resistance to loss of individual autonomy by physicians as a source of practice variation and quality/safety problems. See also Timmermans, *supra* note 133.

relationships *between* physicians rather than the patient-physician relationship.[135] Although the modern *Code* focuses much less on individual physician autonomy, there remains substantial concern within the profession about the decline of individual autonomy rather than autonomy for the profession, including medical associations.[136]

The autonomy of the individual physician must be viewed within the confines of, and as dependent on, the autonomy of the medical profession as a whole. The profession's autonomy includes the ability to adopt ethics/practice standards and educational curricula (including continuing education), and regulate member behavior free of State constraints. It is also concerned with the plight of the individual physicians, which is often reflected in policies meant to counter any loss of individual autonomy, such as those that direct physician-insurer relationships.[137] The profession, represented by medical societies, also tries to influence the trajectory of medicine *as a profession*, with lesser emphasis on individual physician autonomy. For example, its efforts to establish "evidence based standards" that seek more uniformity in medical practice might justify some of the autonomy the profession seeks, but as Armstrong pointed out these standards might also conflict with many physicians' desire for autonomy within their individual practice.[138]

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[135] AMA, *Code of Medical Ethics (1847)*, *supra* note 131 at 97-104. Many of the provisions in the first *Code* were intended to protect physicians from having patients stolen by other physicians. Cooperation was encouraged, but the initial physician's interest prevailed. *Ibid*.

[136] This is apparent in the profession's resistance to greater control over health care decision making by insurers, especially mechanisms such as utilization review. See e.g. Schlesinger, Gray & Perreira, *supra* note 133 ("…the lifeblood of the medical profession draining away from the accumulated wounds of millions of tiny paper cuts" at 108).

[137] CEJA, *Code of Medical Ethics*, *supra* note 118 at 210, 229, 232, 235, 240, 284, 295.

[138] David Armstrong, "Clinical Autonomy, Individual and Collective: The Problem of Changing Doctors' Behaviour" (2002) 55 Social Sci & Med 1771 at 1776. See also Stefan Timmermans & Hyeyoung Oh, "The Continued Social Transformation of the Medical Profession" (2010) 51 J Health & Soc Behav S94 at S98-S99. Recent events in Florida, however, demonstrate the fragility of professional standards in the face of State action. See Elizabeth Cohen & Katherine Grise, "Heart Doctors Outraged Florida Dumps Hospital Standards After Big Gift to GOP", *CNN* (18 January 2016), online: CNN <http://www.cnn.com/2016/01/13/health/florida-hospital-standards-republican-gifts/> (a CNN

Many society policies also take issue with the transference of responsibilities that were traditionally physicians' to other health professions/occupations or entities, which can reduce the near-monopoly on authority that the profession has grown accustomed to.[139]

Justifications for the medical profession's autonomy (or claims to autonomy) include its specialized, technical knowledge that laypeople might have difficulty accessing or understanding without education and training,[140] or "the cultural beliefs and deference that people exhibit toward doctors as healers."[141] Whether autonomy is based on a needed distinction between those who are qualified to practice medicine and those who are not, or on a societal construct that is unnecessary in the reality of modern health care, it is an important identifier for a profession that sets it apart from other occupations. It also provides a useful foundation for identifying autonomy (or semi-autonomy) for the medical profession in the context of legal pluralism.

Similarly, notions of self-regulation in professionalism can be used to identify means and mechanisms that are analogous to legal pluralism. In professionalism, the medical

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investigation found that a hospital had continually violated a set of quality standards, and Florida recently repealed the standards following a donation to the GOP by that hospital corporation).

[139] For example, the Florida Medical Association has a section on scope of practice in its 2012 Public Policy Compendium. Florida Medical Association, *2012 Public Policy Compendium* (Tallahassee: Florida Medical Association, 2013) at 102. The Florida Medical Association opposes legislation allowing optometrists to use drugs or have hospital staff privileges; legislation authorizing dentists to administer non-dental anesthesia; and the "encroachment of nonphysicians on the practice of medicine", among other things. The AMA has a section in its Health Policy on allied health professions, which includes a specific policy on "protecting physician led health care". American Medical Association, "H-35.966, Protecting Physician Led Health Care", online: American Medical Association <https://searchpf.ama-assn.org/SearchML/searchDetails.action?uri=%2FAMADoc%2FHOD.xml-0-2973.xml>.

[140] See generally Freidson, *Profession of Medicine*, *supra* note 125; Kathryn A Koch, Bruce W Meyers & Stephen Sandroni, "Analysis of Power in Medical Decision-Making: An Argument for Physician Autonomy" (1992) 20 L Med & Health Care 320.

[141] Donald Light & Sol Levine, "The Changing Character of the Medical Profession: A Theoretical Overview" (1988) 66 Milbank Quart 10 at 12. See also Freidson, *Profession of Medicine*, *supra* note 125 ("[f]urthermore, as its great prestige reflects, [the medical profession] is highly esteemed in the public mind" at 5); Pellegrino, *supra* note 123 at 378.

profession is expected to monitor the activities of members and ensure that they comply with established rules in return for its autonomy. As will be discussed in detail in Chapter 7 on conflicts of interest, this self-regulation is something that the profession has struggled with at times. Yet by rhetoric and practice it is fundamental to the profession's identity, and the delegation of much regulatory authority to state medical licensing boards has done little to diminish the profession's attachment to this aspect of being a profession.

As a characteristic of professionalism, self-regulation can take a number of forms. We might typically view self-regulation as a formal set of rules and procedures that a profession enforces against its members. The medical profession has this, as will be discussed at length in the next Chapter, but self-regulation in the profession is more expansive than just rules, procedures and disciplinary bodies.

We might also consider informal mechanisms not associated with disciplinary actions that serve to control physician behavior. Professional organizations

> …establish the standards for admission to medical school; select among a plethora of qualified applicants who will actually become future physicians; determine the content of medical school curriculum; establish the criteria for awarding the MD or DO degree; distribute medical school graduates to accredited residency programs; devise and implement standards for accrediting graduate medical education and continuing education programs; determine what knowledge and skills are required to pass licensing examinations; choose what criteria to use for board certification in each medical specialty; make peer-based decisions about research awards by both government and private funders; set the requirements for awarding hospital privileges to individual physicians; devise and implement the standards for accrediting hospitals and other health care organizations; and general voluntary guidelines for acceptable clinical practice.[142]

[142] Jordan J Cohen, "Tasking the 'Self' in the Self-Governance of Medicine" (2015) 313 J Am Med Assoc 1839.

The medical profession controls or influences a wide range of activities that regulate physicians from their earliest days in medical school throughout their careers. The existence of informal self-regulatory mechanisms demonstrates that it is not necessarily the establishment of disciplinary bodies and disciplinary rules—although these certainly help—but how the profession's norms are enforced and distributed, if at all. It can be the "intrinsic values that uniquely define the profession" that further the ethical responsibilities of medical professionals,[143] as well as the formal review bodies that act as the profession's judiciary.

Modern medical regulation has greatly diminished the efficacy of formal self-regulation outside of official State bodies. Importantly, "[v]irtually none of the other myriad professional medical organizations in the United States [e.g. medical societies] have legal standing or authority."[144] Yet despite this ceding of authority to State-based physician regulation, medical societies "have historically been highly influential in shaping the policies and conventions that define medical practice."[145]

It is this influence that the profession relies upon to demonstrate its self-regulatory authority, but society's "trust is dependent on the profession meeting its responsibilities."[146] When society grants a profession a certain amount of autonomy and the profession fails to ensure that autonomy is exercised in line with expectations,

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[143] James L Madara & Jon Burkhart, "Professionalism, Self-Regulation, and Motivation: How Did Health Care Get This So Wrong?" (2015) 313 J Am Med Assoc 1793.
[144] Howard Bauchner, Phil B Fontanarosa & Amy E Thompson, "Professionalism, Governance, and Self-Regulation of Medicine" (2015) 313 J Am Med Assoc 1831. See also Madara & Burkhart, supra note 141. That the Madara and Burkhart article reaches this conclusion is interesting because these authors are respectively the CEO and Chief of Staff/VP, Executive Offices of the AMA.
[145] *Ibid*. at 1793.
[146] Richard L Cruess, Sylvia R Cruess & Sharon E Johnston, "Professionalism and Medicine's Social Contract" (2000) 82 J Bone & Joint Surg 1189 at 1190.

autonomy may be limited and the status of medicine as an independent profession might be jeopardized—"the codicils in the social contract with society are always at risk of unilateral modification by the public."[147] This is the promise (and premise) of professionalism.

The conceptualizations of autonomy and self-regulation used by professionalism are not necessarily essential to legal pluralism, and in fact their formality makes professionalism much less inclusive than legal pluralism. However, their history in a well-established theory like professionalism can help to identify the semi-autonomy of physicians and the boundaries of its legal order of medical ethics. The similarities between the two theories, though, do not mean that they are equal or interchangeable.

The primary difference between the theories—and one that I believe makes legal pluralism the source of greater normative potential for the medical profession's legal order of medical ethics—is the basis of the profession's authority. Under professionalism this authority is derived from the State, rather than developing independently of it. That is, the autonomy enjoyed by professionals is subject to reversal or limitation if the profession does not comply with its corresponding obligations; we can reasonably identify instances of State regulation of physicians that stem from the profession's failure to properly regulate itself and its member physicians (e.g. conflicts of interest). While the State's parallel regulation of a social field is not unexpected in legal pluralism, the social field is not dependent on

[147] Cohen, *supra* note 142 at 1840.

the State for its authority: the social field's capacity to regulate and discipline stems from members' acceptance of its authority regardless of the extent of State regulation.[148]

In part, we can look to the history of the US medical profession and its interpretation under either of these theories to guide us as well. Although both theories can be founded on the profession's early history of independence and near-complete self-regulation, a divergence occurs at the point when states began to again license physicians. Professionalism might perceive the subsequent events as a natural progression of independence in exchange for some degree of self-regulation. Legal pluralism, alternatively, continues to seek out semi-autonomy and law-making based not on the profession-State relationship and the limits on autonomy imposed therefrom, but rather on the continuity of the legal order of medical ethics and the authority vested in the profession (primarily in its medical societies) by its members with a lesser regard to the restrictions imposed by the State.

As the goal of this Thesis is to address the status of the medical profession as a semi-autonomous social field, the comparison between legal pluralism and professionalism must be satisfied with their analogous uses of autonomy and self-regulation; this is where professionalism provides the best context. Professionalism does not necessarily answer the question of *why* the profession is able to do these things and *how* it does so today. That is something may be best left to legal pluralism, with its semi-autonomous social fields and legal orders—complex jargon to be sure, but potentially a better foundation for explaining

[148] It is true that the legitimacy of professional organizations is dependent on membership under a theory of professionalism as well, but the primary source of authority for the profession as a whole derives from the State and society rather than from professional bodies.

what medical ethics really is, how it is used, and how the State and medical profession do and should interact.

IV. The Medical Profession and Medical Ethics "as an Appropriate Subject of Study"

Freidson wrote "that if anything 'is' a profession, it is contemporary medicine."[149] Similarly, if any group can realize the characteristics of legal pluralism, it is the medical profession. It has the trappings of a semi-autonomous social field—the "capacity to generate rules and induce or coerce conformity"[150]—and the fundamentals of a legal order in its medical ethics. If the concept of legal pluralism is that law is "everywhere,"[151] then certainly we can find law in this set of rules that has been used by the medical profession—essentially as law—for over a century and a half.

Finding the characteristics of legal pluralism, though, is only one part of a complex equation. Certainly, merely calling something a legal order and a semi-autonomous social field does not make it so. Within the framework of legal pluralism, and using concepts taught to us by the unrelated theory of professionalism, we can more deeply explore the relationship between medical ethics and the medical profession, and the profession and the State. We can examine the social reality of ethics and how it orders physician behaviors. We can also contrast the profession's use of medical ethics with the breadth and authority of the State's legal order. Doing these things allows for an interpretation of the role of medical ethics in medicine that might not be acceptable within other theories of law or medicine.

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[149] Freidson, *Profession of Medicine*, *supra* note 125 at 4.
[150] Moore, *supra* note 7 at 722.
[151] Ehrlich, *supra* note 1.

What makes the medical profession and medical ethics an especially interesting subject of legal pluralism is its relationship with the State. This complicates the existence and function of the legal order, and the cohesiveness of the semi-autonomous social field as well, in a way that is uncommon to legal pluralism, and which has made theories like professionalism more palatable because some of the more difficult questions raised by legal pluralism are avoided.

Moving beyond defining the medical profession as a semi-autonomous social field and medical ethics a legal order, the next Chapter will contextualize these within the practices of the medical profession; that is, *who* identifies *what* as law, and *why*.[152] Addressing these questions will allow for a more robust exploration in Chapters 6 and 7 of how ethics equates to normativity in medicine, and how State regulation of physicians and the medical profession impacts the profession's legal order and its semi-autonomy. The final Chapter will address the tensions that arise between the profession's expectations for medical ethics and the State's preferences for its own legal order. Can legal pluralism be the reality for a semi-autonomous social field like the medical profession, with all its interconnections to the State and other social fields, when the State intends for its legal order to subsume all others?[153]

[152] Tamanaha, "Non-Essentialist", *supra* note 20 at 318. See also von Benda-Beckmann, *supra* note 11 at 68.
[153] See e.g. *ibid*. at 60.

CHAPTER 4: THE "LAW" OF THE MEDICAL PROFESSION

I. INTRODUCTION **117**
II. MEDICAL ETHICS **120**
A. Oaths and Codes *120*
B. Other Sources of Medical Ethics *129*
C. Concluding Thoughts on Ethics and the Law of the Profession *134*
III. CODES OF ETHICS AS PROFESSIONALLY-SOURCED LAW **137**
A. Introduction *137*
B. Methods *138*
C. Results *139*
1. General 139
2. Enforcement of Conduct 140
D. Discussion *141*
1. Prominence of Ethics 141
2. Ethics and Normativity: The Importance of Words 145
3. Assessing Normativity: Enforcement and "Law" 151
E. Limitations *157*
IV. CONCLUSIONS **158**
TABLE 1. STATE AND SPECIALTY MEDICAL SOCIETIES **162**

> Ethics are principles. They represent generations of experience by trial and error. As such, they are blueprints for the practices and behavior of the individuals who make up the group. They instill the best of the past, sustain the needs of the present, and point to the possibilities for improvement of the future.[1]

I. Introduction

In Chapter 3, legal pluralism was introduced as a construct through which to examine whether and how medical ethics might exist as law, and how this can be used to revise the way that we view ethics and its normative powers. The concept of semi-autonomous social field is a crucial component of legal pluralism, and is both the origin and subject of the law of the field. As demonstrated, the medical profession exists as a semi-autonomous social field and, like other social fields, creates and applies its own legal order. The purpose of this Chapter is to examine what this legal order consists of as it is used in this Thesis, how it is created, and how it is applied to members of the medical profession.

Law is a very broad term, and anything, really, that is identified or treated as law by those who are subject to it can exist as law within a particular semi-autonomous social field.[2] The experiment of complete professional self-regulation for the few decades following the establishment of the American Medical Association (AMA) in 1847—when the law of the profession was the *only* law—very clearly failed, necessitating the complex relationship between the profession and the State, wherein there was established a power-sharing of sorts. Physicians now look to State law for many aspects of practice, not the least being licensure laws that grant the right to practice medicine within a specific state in the first place. The profession was and remains reliant on the exercise of authority by the State to ensure that the bounds of professional education and training,

[1] American Medical Association Judicial Council, *Minute of Meeting, November 27-28, 1955, Supplementary Report* (Chicago: American Medical Association, 1955) at 1.

[2] See Brian Z Tamanaha, "A Non-Essentialist Version of Legal Pluralism" (2000) 27 JL & Soc 296 at 313.

dictated primarily by the profession itself since the latter half of the 19th century, are respected. This capacity of the State to coerce and punish is an important and inescapable aspect of medical practice today.

Yet, the medical profession continues to assert authority over physicians, which exists parallel to and sometimes in conflict with the dictates of the State. This is the exercise of the profession's semi-autonomy and the reason why it exists as one semi-autonomous social field amongst many. Thus, this Chapter will focus on that authority and the normative avenues for demarcating the conduct of physicians used by the profession exclusive of State law.

It is important to note that physicians have a very, very long history of creating their own rules for behavior. For instance, the Hippocratic Oath originated in the pre-Christian era as a guide for physician conduct,[3] and remains an ethical foundation for the modern profession. During periods when physicians and medicine were either not or only lightly regulated by the State, the principles contained in the Oath remained core to professional identity, as was the case during the early years of the American medical profession.[4] Although much of the "original" Oath is no longer relevant to modern medical practice, such as its limitations on the transmission of medical knowledge[5] and

[3] University of Virginia, *Antiqua Medicina, From Homer to Vesalius: Hippocrates*, online: University of Virginia <http://exhibits.hsl.virginia.edu/antiqua/hippocrates/>. This source notes that the date of origination, as well as the Oath's attribution to Hippocrates, is questionable.
[4] See e.g. State Medical Society of New York, *A System of Medical Ethics* (William Grattan: New York, 1823); CL Seeger, "On the Improvement of Medical Science" (1836) 14 Boston Med & Surg J 325; American Medical Association, *Report of the Committee on a Code of Medical Ethics for the Government of the Medical Profession of the United States: Introduction to the Code of Medical Ethics* (Chicago: American Medical Association, 1847) [AMA, *Code of Medical Ethics (1847)*].
[5] June Goodfield, "Reflections on the Hippocratic Oaths" (1973) 1 Hastings Center Studies 79 at 81. The modern Oaths examined by Goodfield removed this limitation on disseminating medical knowledge to outsiders. *Ibid*. at 84.

its prohibitions against abortion,[6] some provisions are still very important, including constraints on disclosure of patient information and prohibitions against certain relationships with patients.

The informal rules guiding the behavior of physicians eventually led to the devising of formal codes of conduct to provide a more comprehensive set of norms. Percival's *Medical Ethics*, a product of late 18th and early 19th century England,[7] served as a blueprint for ethics codes in the US, including the AMA's.[8] Ethics codes set behavioral expectations for physicians at a time when there was little or no State regulation of medicine. In 1847, when the AMA adopted its first *Code of Medical Ethics*, self-regulation was the only option to address real and perceived deficiencies in the profession, and ethics became one of the foundations of self-regulation and the basis for the formation of a relatively cohesive social field.

The *Code* remains a benchmark ethics document—hence my focus on it throughout this Thesis—and has been revised a number of times since 1847 to reflect changes in the profession and society,[9] as well as evolving conceptions of the duties of physicians towards patients and each other. Despite the increase in State regulation of medicine over the past century, ethics codes and standards continue to thrive: specialty medical societies have developed their own ethics standards

[6] The 14th century Oath states: "[s]imilarly I will not give a pessary to a woman to cause abortion." *Ibid*. at 81. The AMA's *Code of Medical Ethics* permits physicians to perform abortions "in accordance with good medical practice and under circumstances that do not violate the law." Council on Ethical and Judicial Affairs, *Code of Medical Ethics: Current Opinions with Annotations, 2010-2011* (Chicago: American Medical Association, 2010) at 5 [CEJA, *Code of Medical Ethics*].

[7] Thomas Percival, *Medical Ethics; or, a Code of Institutes and Precepts, Adapted to the Professional Conduct of Physicians and Surgeons*, 3d ed (Oxford: John Henry Parker, 1849). See also Joseph M Jacob, *Doctors and Rules: A Sociology of Professional Values* (London: Routledge, 1988) at 100-101. Jacob noted that Percival was "a provincial practitioner, that is, outside the centres of English medical power; those who knew how to behave to others or even what changes should be implemented did not need it explained." *Ibid*.

[8] Chauncey D Leake, "Percival's Code: A Chapter in the Development of Medical Ethics" (1923) 81 J Am Med Assoc 366.

[9] In 1903, the *Code* was renamed *Principles of Medical Ethics*, although it was in substantially the same structure as the previous *Code*. American Medical Association, "Proceedings of the Fifty-Fourth Annual Session, Held at New Orleans, May 5, 6, 7 and 8, 1903" (1903) 40 J Am Med Assoc 1364 at 1379 [AMA, "Proceedings, 1903"].

to address concerns specific to their members,[10] and a new generation of academics continue to push the boundaries of ethics as it developed through the latter part of the 20th century.

This Chapter will examine the status of ethics as a legal order, as applied by the semi-autonomous social field of the medical profession rather than by the State. The next Section will address ethics, beginning with the development and use of codes of ethics. The third Section will detail the content and function of codes and medical society bylaws as a form of "law" within the medical profession, and their application and enforcement by professional organizations.

II. Medical Ethics

A. Oaths and Codes

If there is any constant in the practice of medicine in the past few millennia, it is the place of ethics at the center of what it means to be a physician.[11] Modern medical ethics traces its roots to Hippocrates and his ethos for physicians, which continues to be used in medical school graduation ceremonies and nominally informs the content of modern codes of ethics.[12]

Hippocratic ethics, as represented by the Oath, placed physicians in a peculiar relationship with patients. Due to their knowledge, physicians were prohibited from doing certain acts and required

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[10] See e.g. American Academy of Neurology, *Code of Professional Conduct* (Minneapolis: American Academy of Neurology, 2009), online: American Academy of Neurology <https://www.aan.com/uploadedFiles/Website_Library_Assets/Documents/8.Membership/5.Ethics/1.Code_of_Conduct/Membership-Ethics-American%20Academy%20of%20Neurology%20Code%20of%20Professional%20Conduct%20(2).pdf> [American Academy of Neurology, *Code of Professional Conduct*]; Mary E Fallat, Jacqueline Glover & the Committee on Bioethics, "Professionalism in Pediatrics" (2007) 120 Pediatrics e1123; American College of Physicians Ethics, Professionalism and Human Rights Committee, "American College of Physicians Ethics Manual" (2012) 156 Ann Intern Med 73.

[11] Tom L Beauchamp & James F Childress, *Principles of Biomedical Ethics*, 6th ed (New York: Oxford University Press, 2009) ("[m]edical ethics enjoyed remarkable continuity from the time of Hippocrates until the middle of the twentieth century…" at 1).

[12] The AMA continues to promote this connection in the historical introduction to the *Code*. CEJA, *Code of Medical Ethics*, *supra* note 6 at xiii.

to do others. An early form of the Oath required physicians to keep themselves "free from all intentional wrongdoing and harm" (hence the common ethical construct "first, do no harm"), and prohibited them from providing poison or pessary and performing surgery.[13] The Oath was not explicitly placed within any specific theory of ethics, but rather was a "tool"[14] that described the duties of a profession.

By the 19th century, and despite the relative ineffectiveness of medicine,[15] physicians relied on their ethics to invoke a moral superiority against competitors and to set themselves apart. This is apparent in the AMA's initial 1847 *Code*, which explicitly contrasted "quacks who infest the land"[16] with the physicians who formed the AMA, who were instead devoted "to the relief of their fellow-creatures from pain and disease, regardless of the privation and danger…encountered in return…."[17]

Despite the proclaimed goals of those who created early ethics codes some have argued that medical ethics is not ethics at all, but etiquette[18] or a guild-like protectionism. Percival's *Medical Ethics*, the first ethics code of its kind and a foundation for many codes in the US, has often been described in this manner. In the early 20th century, Leake portrayed both Percival's *Medical Ethics*

[13] Goodfield, *supra* note 5 at 81.
[14] *Ibid*.
[15] See e.g. Jeremy A Greene, David S Jones & Scott H Podolsky, "Therapeutic Evolution and the Challenge of Rational Medicine" (2012) 367 New Eng J Med 1077.
[16] AMA, *Code of Medical Ethics (1847)*, *supra* note 4 at 86.
[17] *Ibid*. at 83.
[18] Etiquette is defined by Merriam-Webster as "the conduct or procedure required by good breeding or prescribed by authority to be observed in social or official life." Merriam-Webster, "Etiquette", online: Merriam-Webster <http://www.merriam-webster.com/dictionary/etiquette>. The use of "etiquette" in describing Percival and later ethics codes often seems to focus on the "good breeding" characteristic of etiquette, viewing these ethical statements as furthering a specific social hierarchy or position for physicians rather than promoting the interests of patients.

and the AMA's *Code* as etiquette,[19] and was echoed later by Waddington.[20] Berlant focused on the monopolization impact of *Medical Ethics*, as its trust-building, consultation, payment and other provisions were, in his analysis, characteristic of a monopoly.[21]

In describing features of codes of professional ethics Davis also discounted Percival, arguing that his *Medical Ethics* was not really a code because it "had *no* authoritative formulation"[22]—it could not legitimately influence the conduct of the wider profession across England.[23] Although Davis would deny Percival's work the status of a "code", he considered the content ethics because it consisted of "morally permissible standards of conduct governing members of a group simply because they are members of that group."[24]

The early ethics codes adopted by local and state medical societies in the US were somewhat more authoritative, but remained limited in geographic scope. The enforcement of the *Boston Medical Police*, for example, led to expulsions, but only of Boston Medical Society members.[25] It was not until the AMA was formed that there was a broader authority upon which to build a more ethically and scientifically homogenous and better-regulated medical profession across the country.

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[19] Chauncey D Leake, "Percival's Medical Ethics" (1927) 197 N Eng J Med 357.
[20] Ivan Waddington, "Development of Medical Ethics – A Sociological Analysis" (1975) 19 Med Hist 36 at 39. Waddington incorporates Leake's definition of etiquette to argue that Percival's *Code* was etiquette because it was written "specifically to resolve a purely intra-professional dispute." *Ibid*.
[21] Jeffrey Lionel Berlant, *Profession and Monopoly: A Study of Medicine in the United States and Great Britain* (Berkeley: University of California Press, 1975) at 69-77.
[22] Michael Davis, "What Can We Learn by Looking for the First Code of Professional Ethics?" (2003) 24 Theoret Med 433 at 437.
[23] *Ibid*. at 435-437.
[24] *Ibid*. at 438. This is not a far stretch from a legal pluralist's conception of law and legal orders.
[25] Robert Baker, "An Introduction to the Boston Medical Police of 1808" in Robert Baker, ed, *The Codification of Medical Morality: Historical and Philosophical Studies of the Formalization of Western Medical Morality in the Eighteenth and Nineteenth Centuries* (Dordrecht: Kluwer Academic Publishers, 1995) 25 at 32, 38.

The primary purpose of the physicians founding the AMA was to improve medical education standards,[26] and ethics was included in the originating resolutions that led to the 1847 convention to address some of the concerns of the delegates about appropriate physician activities—thus its origins as a source of normative behavior control.[27] Despite this less than illustrious beginning, the AMA's *Code* soon became a primary source of professional self-regulation due to its clear specifications for physician behavior and the State's continuing regulatory absence.

The AMA quickly discovered that the *Code*'s value as a governing document—essentially as a professional "law"—was quite limited due to a lack of organizational structures to address member discipline. Unlike the well-established committees and procedures that characterize the modern AMA and many state and specialty medical societies, the first few decades of the AMA passed without clear jurisdiction over ethics violations of members. The AMA initially relied on state societies to undertake policing, but this proved unworkable as many societies continued to overlook violations or were themselves in violation of the *Code*.[28]

By 1853, a mere 6 years after its creation, the AMA saw the need to clarify the status of the *Code* and adopted a resolution requiring that "every graduate in Medicine be required to subscribe to a pledge to submit to the revocation of his diploma upon conviction of having knowingly violated the Code of Ethics of this Association."[29] Leaving aside the facts that (i) the AMA had very little control over medical education at this point and (ii) there was no State law upon which to convict

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[26] American Medical Association, *Proceedings of the National Medical Conventions Held in New York, May, 1846, and in Philadelphia, May, 1847* (Philadelphia: TK & PG Collins, 1847) at 17.
[27] Robert Baker, "The Historical Context of the American Medical Association's 1847 *Code of Ethics*" in Baker, ed, *Codification of Medical Morality*, *supra* note 25 at 50.
[28] See Bernard D Hirsch, *The History of the Judicial Council of the American Medical Association* (Chicago: American Medical Association, 1984). Hirsch detailed the regular debates, reports, and rejections at AMA membership meetings of state societies who continued to associate with dogmatic practitioners.
[29] American Medical Association, *The Transactions: American Medical Association*, vol VI (Philadelphia: TK and PG Collins, 1853) at 48.

a person of violating ethics, this was a substantial step towards the normalizing of medical ethics. Two years later, the AMA took the additional step of conditioning the good standing of entities (mostly medical societies) represented in the AMA on their adoption of the *Code*.[30] However, it wasn't until 1858 that a body was appointed within the AMA to deal specifically with *Code* enforcement.[31]

Perhaps the most important development in physician self-regulation during the AMA's first 50 years was its decision to vest disciplinary powers in a Committee on Ethics (later renamed the Judicial Council and, in 1985, the current Council on Ethical and Judicial Affairs (CEJA)[32]). Although the function and effectiveness of the Committee changed substantially from its inception to its modern incarnation,[33] the intent of the physicians who voted to create it was to ensure that the *Code* served as more than just a suggestion. The Council confirmed that membership in the AMA was conditional on adherence with the *Principles*[34] and, importantly, regarded the *Principles* "as a *code of laws* governing the membership of this Association."[35] However, the Judicial Council's role as appellate body for individual physicians disciplined by a state and/or county medical society appears not to have become an important aspect of its duties until much later:

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[30] American Medical Association, *Transactions of the American Medical Association*, vol VIII (Philadelphia: TK and PG Collins, 1855) at 56 [American Medical Association, *Transactions, 1855*].
[31] American Medical Association, *Transactions of the American Medical Association*, vol XI (Philadelphia: Collins, 1858) at 39. This reference shows the appointment of members to the Committee on Ethics, but nothing in the *Transactions* of this or previous years provides the instant when the Committee was initially created.
[32] American Medical Association Council on Constitution and Bylaws, "Report A: Change of Name of Judicial Council" in American Medical Association, *Proceedings: House of Delegates, Annual Meeting, June 16-20, 1985* (Chicago: American Medical Association, 1985) at 172.
[33] The early years of the Committee were devoted mostly to sanctioning medical societies, medical schools and hospitals that associated with non-physician health practitioners, or seated non-physicians as delegates at AMA membership meetings. See Hirsch, *supra* note 28.
[34] American Medical Association, *Sixty-Third Annual Session, Held at Atlantic City, NJ, June 3-6, 1912--Minutes of the House of Delegates* (Chicago: American Medical Association, 1912) at 11.
[35] *Ibid*. at 5 [emphasis added]. The Council went on to warn "that unless some action is taken at this session, the Judicial Council will have no laws under which cases may be brought to its attention until the Association does frame some legal code." *Ibid*.

"[f]rom 1935 through 1979, the Judicial Council considered a total of 39 appeals from 16 states"[36] (note that today CEJA hears dozens of appeals per year[37]).

In 1903 the AMA determined that the *Code* needed to be revised to reflect modern practice. This demonstrated an understanding that medical ethics, like the law it originally sought to emulate, could not remain static: "[i]nflexibility…rendered the code so brittle that after the relatively short span of fifty years it snapped under the pressure of social change."[38] The most important changes in the 1903 revisions for a document that acted as law for physicians—now entitled *Principles of Medical Ethics*—was the removal of two articles that were the source of much of the criticism of the profession: "Obligations of Patients to Their Physicians", and "Obligations of the Public to Physicians".[39] This was not an admission that these issues were no longer important, just that it was difficult to explain their presence in a code of ethics *for physicians*. This represented a change in focus of the *Code* towards the patient-physician relationship, and away from the guild-like protectionism that the AMA was criticized for during its early years.[40]

The need to again revisit the structure and content of the AMA's ethics code was apparent by 1955[41] and in 1957 the HOD adopted a new *Principles of Medical Ethics* that greatly condensed

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[36] Hirsch, s*upra* note 28 at 16.
[37] See e.g. Council on Ethical and Judicial Affairs, "Judicial Function of the Council on Ethical and Judicial Affairs: Annual Report" in American Medical Association, *Proceedings of the 2012 Meeting of the House of Delegates* (Chicago: American Medical Association, 2012) at 147, online: American Medical Association <http://www.ama-assn.org/ama/pub/about-ama/our-people/house-delegates/meeting-archives/2012-annual-meeting.page> [CEJA, "Judicial Function"].
[38] Robert B Baker et al, eds, *The American Medical Ethics Revolution: How the AMA's Code of Ethics Has Transformed Physicians' Relationships to Patients, Professionals, and Society* (Baltimore: Johns Hopkins University Press, 1999) at xxx.
[39] AMA, "Proceedings, 1903", *supra* note 9 at 1379.
[40] However, some new additions to the *Code* appeared to be less about ethics than the power of the AMA within the organized medical profession. One called on every physician to "identify himself with the organized body of his profession as represented in the community in which he resides" while another required that "[a]ll county medical societies thus organized ought to place themselves in affiliation with their respective state associations, and these, in turn, with the American Medical Association." *Ibid*. at 1379-1380.
[41] American Medical Association, *Proceedings of the House of Delegates of the American Medical Association: The Clinical Meeting Held at Boston, Mass, Nov 29-Dec 2, 1955* (Chicago: American Medical Association, 1955) at

the content of the previous ethics codes to a preamble and 10 Principles.[42] Their focus was even more on the patient than the 1903 *Principles* and provided greater room for interpretation by the Judicial Council to address the changing ethical and practice environment of the profession. Rather than revising the *Principles* every time a new ethics issue needed to be addressed, the Council could publish an annotation to interpret the issue within the framework of the *Principles*. This new format, a set of brief Principles accompanied by annotations to examine specific issues,[43] has carried over to the modern arrangement of the AMA's *Code of Medical Ethics*.

These changes to the *Code* and *Principles* also expressed a shifting relationship between the profession and the State and how ethics were conceptualized as a self-regulatory tool. The 1957 *Principles* included a preamble clarifying that they "are not laws but standards by which a physician may determine the propriety of his conduct in his relationship with patients, with colleagues, with members of allied professions, and with the public."[44] Despite this, the new *Principles* continued to be the basis for evaluating individual physician behavior, the violation of which remained grounds for disciplinary action by the AMA and its constituent societies.[45]

113, 134. See also David J Rothman, *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making* (United States: Basic Books, 1991). Medical science exploded in the late 19th century and early to mid-20th century. The capacity to do things previously unimaginable likewise gave rise to ethical concerns previously unimagined. Much of the history of medical ethics in the 20th century relates to the failure of physicians and biomedical researchers to live up to ethical requirements. See also "Bioethics—Bioscience" (1972) 220 J Am Med Assoc 272; James H Ford, "A New Ethic for Medicine and Society" (1971) 114 Cal Med 46; Herbert M Swick, Charles S Bryan & Lawrence D Longo "Beyond the Physician Charter: Reflections on Medical Professionalism" (2006) 49 Perspective in Biol & Med 263; Jeff Blackmer, "Current Global Trends in Medical Professionalism" (2009) 1 World Med & Health Pol'y art 2.

[42] American Medical Association, *Proceedings of the House of Delegates, American Medical Association, 105th Annual Session, New York City, June 3-7, 1957* (Chicago: American Medical Association, 1957) at 26 [AMA, *Proceedings, 1957*].

[43] See e.g. Judicial Council, "Official Opinions of the Judicial Council" (1957) 163 J Am Med Assoc 1156.

[44] AMA, *Proceedings, 1957*, *supra* note 42 at 26.

[45] A 1960 resolution in the HOD reaffirmed the Judicial Council's role as appellate body from decisions of constituent associations. American Medical Association, *Proceedings of the House of Delegates, American Medical Association, 108th Annual Session, Miami Beach, Fla, June 13-17, 1960* (Chicago: American Medical Association, 1960) at 110.

More recent revisions to the *Principles* reflect further acquiescence to State authority, such as the 1980 revision's removal of the provision on pay and the prohibition on voluntary professional association with those who violate the principle of "healing founded on a scientific basis", both of which implicated State anti-trust law.[46] The 2001 *Principles* (still current) added two additional provisions.[47] The first requires physicians to "regard responsibility to the patient as paramount."[48] The second requires physicians to "support access to medical care for all people."[49] This addition emphasizes an issue that is "fundamental to the ethical practice of medicine and to the integrity of the profession but upon which the [1980] *Principles* were silent."[50] It might also be a response to negative public opinion of the medical profession stemming from the AMA's continual resistance to changes in the health care system.[51]

Another addition to the 2001 *Principles* is worth remark. Principle II now references reporting "physicians deficient in character or competence, or engaging in fraud or deception, *to appropriate entities*" (emphasis added).[52] This is another reaction of the greater role of the State in regulating the profession, and possibly the dissipation of the closeness between the profession and state medical boards. This presents a striking contrast with the 1957 *Principle*'s "self-imposed

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[46] Council on Ethical and Judicial Affairs, *Principles of Medical Ethics, June 1980*, online: American Medical Association < https://www.ama-assn.org/sites/default/files/media-browser/public/ethics/1980_principles_0.pdf>. The "scientific basis" issue was addressed in a judicial decision. *Wilk v American Medical Association*, 719 F 2d 207 (7th Cir 1983). This case was decided after the changes in the 1980 *Principles* but anti-trust concerns were doubtless one basis for the AMA's decision to change the *Principles*.
[47] American Medical Association, *House of Delegates Proceedings, 150th Annual Meeting, June 17-21, 2001* (Chicago: American Medical Association, 2001) at 66 [AMA, *Proceedings, 2001*].
[48] *Ibid*.
[49] *Ibid*.
[50] *Ibid*. at 65.
[51] A 1964 article in the *New England Journal of Medicine* details the ideological shift in the AMA with regards to social insurance, leading to the profession's official opposition to programs such as Medicare and Medicaid that were intended to aid those who might not otherwise be able to access the health care system. John Gordon Freymann, "Leadership in American Medicine: A Matter of Personal Responsibility" (1964) 270 N Eng J Med 710.
[52] AMA, *Proceedings, 2001*, *supra* note 47 at 66.

disciplines",[53] when self-regulation was still the primary means of physician discipline since physicians were at this time still in control of state medical boards.

The changes to the *Principles of Medical Ethics* in 1957 (which was a drastic change from 1903), 1980 and 2001 are important as a representation of changing norms within the profession, but currently represent only part of the equation. With the 1957 *Principles*, the use of annotations and, later, Opinions to elucidate the ethics of specific situations that physicians might find themselves in granted a much greater fluidity to medical ethics than was possible prior to 1957. Current AMA Bylaws only permit amendment to the Principles of Medical Ethics with two-thirds approval of HOD delegates present and voting;[54] yet adding to, amending, or deleting an ethics Opinion requires only a majority of the HOD.[55]

The core purpose of ethics codes continues to apply: they are intended to guide and control physician behavior, with tangible consequences for failure to do so. The vigor with which medical societies enforce ethics standards varies greatly both temporally and between the societies, but on paper codes of ethics are meant to be enforceable rules. The recognition in the current *Code of Medical Ethics* that it is not law does not mean it does not act as such within the profession. For decades, codes of ethics were the only way for the profession to regulate itself. The fact that today

[53] AMA, *Proceedings, 1957*, *supra* note 42 at 26.
[54] American Medical Association, *Constitution and Bylaws, July 2013* (Chicago, American Medical Association, 2013) at 71, Bylaw 12.20 [AMA, *Constitution and Bylaws*]. The AMA Bylaws were amended in 1956 to provide for amendments to the Principles. American Medical Association, *Proceedings of the House of Delegates of the American Medical Association: The Annual Session Held at Chicago, Ill, June 11-14, 1956* (Chicago: American Medical Association, 1956) at 53, 64.
[55] It is possible that CEJA can adopt a new Opinion without approval of the HOD, since its reports require HOD approval but Opinions do not. AMA, *Constitution and Bylaws*, *supra* note 54 at 25, Bylaw 2.6172. However, the political consequences for CEJA could negatively impact its ability to function and adopt future ethics policies, and this route is rarely if ever used.

the State has a much greater role in the regulation of medicine does not mean that the profession has given up entirely its own role.

The next subsection turns to another aspect of ethics of physicians and in health care. My focus in this Thesis is on codified and normalized ethics like the ones discussed in this subsection, but there exists other sources of ethics and guidance for physician behavior that do not have so concrete an application.

B. Other Sources of Medical Ethics

Codes of ethics are an important source of the medical ethics that serve to govern physician behavior. Although their roots are philosophical and theological, the form taken by these codes—as well as processes for their development—is traditionally much closer to that of State law than philosophy. Yet philosophy and theology continue to influence normative ethics, necessitating a brief examination of other sources of and influences on medical ethics aside from codes.

Religion has played an important role in the development of medical ethics for millennia. The commonly-cited origin of modern medical ethics, the Hippocratic Oath, is an oath to the Greek god Apollo.[56] In the predominantly Christian societies of the 19th century from which many modern ethics codes emerged, physicians in the UK and US viewed medical ethics through the lens of religious teachings and principles. The 1847 AMA *Code* is explicit in this: "[m]edical ethics, as a branch of general ethics, must rest on the basis of religion and morality."[57] In addition, although Percival did not make such overt connections between his *Medical Ethics* and religion,

[56] Goodfield, *supra* note 5 at 81.
[57] AMA, *Code of Medical Ethics (1847)*, *supra* note 4 at 83.

Pellegrino argued that Percival viewed philosophy and theology as "complimentary and not antagonistic as they were to many Enlightenment thinkers."[58]

Modern medical ethics within the profession remains dedicated to rules[59] but academic exposition of ethical issues has gained prominence of late, with the expansion of bioethics[60] as a field of academic study and along with it the growth of degree programs and non-medical professional experts who research, write about, and discuss a variety of moral quandaries raised by the modern practice of medicine and scientific/technological advancement in general. Those who work within this field have forwarded the conceptualization of medical ethics a great deal, and society has benefitted from their work and efforts to promote new thinking on such important issues as patient autonomy and research participant protections.[61]

However, this form of ethics—bioethics—has been criticized for its focus on the abstract at the expense of practicality and the real working conditions of practitioners (and researchers),[62] and its perceived status as "a kind of secular priesthood to which governments and other institutions look for guidance…."[63] Ethics theories and frameworks, though, often provide the background for analysis of many ethical issues that confront physicians daily—and sometimes with a distance from physicians and the practice of medicine that provides a new and beneficial perspective.

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[58] Edmund D Pellegrino, "Percival's *Medical Ethics*: The Moral Philosophy of a 19th-Century English Gentleman" (1986) 146 Arch Intern Med 2265 at 2266 [Pellegrino, "Percival's *Medical Ethics*"].
[59] This is essentially the "legalism" referred to by John Ladd, although he would call the medical ethics of codes "nonlegal" rules. See John Ladd, "Legalism and Medical Ethics" in John W Davis, Barry Hoffmaster & Sarah Shorten, eds, *Contemporary Issues in Biomedical Ethics* (Clifton, NJ: Humana Press, 1978) 1.
[60] Robert Baker, "Bioethics and History" (2002) 27 J Med & Phil 447 at 459. Bioethics is distinguished from medical ethics as the "interdisciplinary field…that emerged in the 1970s." *Ibid*. I use the term here to distinguish the more formalized rules of *medical* ethics from the more academic, theoretical and philosophical contributions of *bioethics*.
[61] See generally Rothman, *supra* note 41.
[62] As Baron notes, "it lacks the authority that comes from a single, coherent guiding theory in which practitioners are trained." Jonathan Baron, *Against Bioethics* (Cambridge, Mass: MIT Press, 2006) at 4.
[63] *Ibid*. at 4.

Rothman traced the evolution of medical ethics and how new capabilities in medicine gave rise to new moral challenges.[64] The general idea was that just because we *could* do something did not necessarily mean we *should* do it. Our historical legacy provides ample evidence of purely scientific pursuits overwhelming the humanity that should be implicit in any medical enterprise, which humanity was made explicit in the AMA's *Code*.[65] It was the voice of philosophers and theologians that helped to reign in medical and research excesses taking place throughout the 20th century and remind physicians of their self-imposed ethical obligations.

It was also these voices that led to the drafting of the *Belmont Report*, a seminal work in American bioethics and internationally.[66] The Report addressed ethics in research, but its impact extended into the clinical world as well. Its focus on three basic ethical principles—respect for persons, beneficence and justice—are mirrored in the clinical context. Shortly after the *Belmont Report* was published, another influential work was released: Beauchamp and Childress' *Principles of Biomedical Ethics* (Beauchamp was also a co-author of the *Belmont Report*).[67] This used a similar principles-based framework for examining ethical issues, but added a fourth principle of non-maleficence. Interestingly, the make-up of the committee that wrote the *Belmont Report* was majority non-physician, with many philosophers and attorneys, and non-physicians also wrote *Principles of Medical Ethics*. This is suggestive of the increasing role of non-physicians influencing the content of medical ethics from the 1970s onward.

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[64] Rothman, *supra* note 41.
[65] Beecher exposed medical research that violated the ethical constraints of the time. This article led to the *Belmont Report* and later the US Common Rule. Henry K Beecher, "Ethics and Clinical Research" (1966) 274 N Eng J Med 1354.
[66] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Washington, DC: US Government Printing Office, 1978).
[67] Tom L Beauchamp & James F Childress, *Principles of Biomedical Ethics* (New York: Oxford University Press, 1979).

The role of non-physicians in developing general ethics standards is now well established. Take, for example, McGill University's Centre of Genomics and Policy (CGP). The CGP researches and develops policy on a myriad of ethical and ethico-legal issues, primarily related to clinical and research genetics. While it works closely with physicians and biomedical researchers, the staff of the CGP consists primarily of attorneys, although many have science or other backgrounds relevant to genetics and medical research.[68] Once seen as taboo in medical ethics, the presence of non-physicians in organizations like the CGP that work in ethics—and there are many across the US as well—is now commonplace. Indeed, even the Ethics Group at the AMA consists almost entirely of non-physicians, although CEJA is made up of physicians and physicians-in-training.[69]

The importance of the numerous medical ethics and bioethics think tanks is not that they develop ethics rules or codes directly applicable to or enforceable on the medical profession, but rather that they influence the topics and direction of medical ethics within the profession. A brief reading of recent reports by CEJA clearly demonstrates this influence. The 2011 report "Deferral of Blood Donation by Men Who Have Sex with Men (MSM)" addresses a politically sensitive issue, rife with religious and cultural tension.[70] CEJA did not rely solely on the Principles of Medical Ethics contained within the *Code* to reach its conclusions. The references contain many citations to the bioethics literature in support of the policy proposed by the Council. Likewise, the report

[68] Centre of Genomics and Policy, "Our Team", online: Centre of Genomics and Policy <http://www.genomicsandpolicy.org/en/team>.

[69] The Vice-President, Ethics Group is a physician, as are most of the vice-presidents at the AMA in sections where a medical education is relevant. In addition, CEJA membership is entirely physicians, except for the medical student member. Although CEJA has final approval of any policy or report written by the Ethics Group that is to be submitted to the HOD or included in the *Code of Medical Ethics*, the Ethics Group staff has an important role in developing the policy. I was employed with the Ethics Group from 2006-2008.

[70] Council on Ethical and Judicial Affairs, "Report 2-I-11, Deferral of Blood Donation by Men Who Have Sex with Men (MSM)" in American Medical Association, *Proceedings of the American Medical Association House of Delegates, 65th Interim Meeting, November 12-15, 2011, New Orleans, Louisiana* (Chicago: American Medical Association, 2011) 95.

"Informed Consent in Research Involving Stored Human Biological Materials (Resolution 1-A-10)" contains many references to the ethics literature,[71] which is not surprising given the attention that this issue has received in recent years with the rise of biobanking and genetic research. There are many other examples of this integration of ethics literature into official ethics codes that was not apparent in the 1950s when CEJA began publishing annotations to the *Principles*. It was not until the late 1980s, when the Council began to submit formal reports to accompany its annotations and Opinions, that there was any indication of how CEJA members deliberated on the policies they put forward.

By this I do not imply that previous annotations and Opinions lacked any connection to the bioethics that was developing in the academic sphere, just that these connections were opaque. For example, euthanasia is an issue that evokes strong moral and religious opinions, and has been a part of the bioethics debate since the 1970s.[72] Yet, CEJA's 1988 report, "Euthanasia", makes no reference to any of the writings, debate or discussion taking place outside of the profession.[73] Contrast this report with one three years later, "Decisions Near the End of Life", which also addressed euthanasia.[74] The 1991 report refers to the literature, legal cases and informal guidelines in reaching its conclusions.

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[71] Council on Ethical and Judicial Affairs, "Report 6-A-11, Informed Consent in Research Involving Stored Human Biological Materials (Resolution 1-A-10)" in American Medical Association, *Proceedings of the American Medical Association House of Delegates, 160th Annual Meeting, June 18-21, 2011* (Chicago: American Medical Association, 2011) 223.

[72] See e.g. Rowine Hayes Brown & Richard B Truitt, "Euthanasia and the Right to Die" (1976) 3 Oh NUL Rev 615; Paul Marx "Abortion/Euthanasia" (1975) 2 Persona y Derecho 383; Bruce Vodiga, "Euthanasia and the Right to Die: Moral, Ethical and Legal Perspectives" (1974) 51 ITT Chicago-Kent L Rev 1.

[73] Council on Ethical and Judicial Affairs, "Report C-A-88, Euthanasia" in American Medical Association, *Proceedings: House of Delegates, Chicago, Illinois, June 26-30, 1988, 137th Annual Meeting* (Chicago: American Medical Association, 1988) 258.

[74] Council on Ethical and Judicial Affairs, "Report B-A-91, Decisions Near the End of Life" in American Medical Association, *House of Delegates, Proceedings, 140th Annual Meeting, Chicago, Illinois, June, 1991* (Chicago: American Medical Association, 1991) 245.

I have no concrete explanation for this shift, other than the growing prominence of bioethics or changes in CEJA membership and AMA staff. Any of these might have led to the recognition that the profession was no longer the sole arbiter of its work, even in the historically isolated sphere of medical ethics. Although bioethics does not claim the same outward influence over professional behavior as formal codes of medical ethics, it was certainly having an impact in other ways.

C. Concluding Thoughts on Ethics and the Law of the Profession

Medical ethics relies on a variety of approaches to resolve ethical ambiguities or conundrums, often taking the form of ethics codes and guidelines. These are intended to provide a tangible set of rules to address ethical problems that might arise in the practice of medicine. Codes, though, have been criticized for being merely protectionist of the profession[75] and for providing an easy out from difficult conversations (e.g. "this is what the codes says, so I'll do it").[76]

The more recent rise of bioethics as a companion to traditional medical ethics has changed how the profession responds to new ethical dilemmas,[77] how the State interacts with the profession and the health care system,[78] and how the public perceives the medical profession. The academic field of bioethics has removed much of the mystery of medicine and made physicians more accountable

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[75] Berlant, *supra* note 21; Waddington, *supra* note 20; Robert Baker, "Introduction" in Robert Baker, ed, *The Codification of Medical Morality*, *supra* note 25 at 2.

[76] See generally Maura Strassberg, "Taking Ethics Seriously: Beyond Positivist Jurisprudence in Legal Ethics" (1995) 80 Iowa L Rev 901. Strassberg examines legal analysis, but in the current legalistic atmosphere of medicine a similar analysis can be applied to medical ethics—that physicians often look to the rules for answers without considering the broader principles underlying the rules.

[77] Edmund D Pellegrino, "The Metamorphosis of Medical Ethics: A 30-Year Retrospective" (1993) 269 J Am Med Assoc 1158 [Pellegrino, "Metamorphosis"].

[78] For example, there is now the Presidential Commission for the Study of Bioethical Issues (formerly the National Bioethics Advisory Commission and then President's Council on Bioethics), which investigates bioethical issues and provides advice and guidance to the President, other arms of the State, and to a more limited extent the profession. Presidential Commission for the Study of Bioethical Issues, "History of Bioethics Commissions", online: Presidential Commission for the Study of Bioethical Issues <https://bioethicsarchive.georgetown.edu/pcsbi/history.html>.

to patients as philosophers, theologians, attorneys and others have cemented a place at the discussion table and broadened the perspective of ethics beyond myopic professional concerns.

Each conception of ethics has its place. The frameworks of bioethics can inform the provisions of ethics codes, and the establishment of codes can ground theory into practice. However, when considering what the "law" of the medical profession might consist of, ethics in its entirety presents a challenge. Applying a positivist conception of "law" to ethics, biomedical ethics generally fails to reach the threshold of something that imposes a duty.[79] Even under the much less proscriptive application of legal pluralism, biomedical ethics provides little from which to find a legal order, or even a semi-autonomous social field. Analyses can change based on the author, the more abstract cases or paradigms that might be used to determine a course of action (such as is done in casuistry) might have only a loose correlation to the facts under consideration,[80] and bioethics rarely results in something that looks normative. Furthermore, physicians likely only rarely engage with ethical theories to determine their course of action[81]—most physicians do not have formal philosophy or biomedical ethics training. This is the role of ethics committees, to provide an expertise at resolving ethical issues that individual physicians might not have. As Pellegrino, a reputable physician-ethicist, acknowledged 20 years ago, "[physicians'] medical expertise does not automatically equate with ethical authority or rectitude."[82]

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[79] This is Hart's definition of a primary rule. HLA Hart, *The Concept of Law*, 2d ed (Oxford: Oxford University Press, 1997) at 81.
[80] See e.g. Tom Tomlinson, "Casuistry in Medical Ethics: Rehabilitated, or Repeat Offender?" (1994) 15 Theoret Med 5.
[81] Ledermann wrote in 1970 that "[d]octors in the main believe that they carry on their practice without employing any general theory or philosophy, either in an overt or implicit way." E.K. Ledermann, *Philosophy and Medicine* (London: Tavistock Publications, 1970) at xiii.
[82] Pellegrino, "Metamorphosis", *supra* note 77 at 1158.

Ethics codes have more positivist characteristics than much of bioethics, more closely resembling the law of the State in both form and content than many examples of law provided by legal pluralists, which can be written *or* unwritten. They are at times vague, and at others very detailed and prescriptive. Some, such as the AMA's *Code of Medical Ethics*, retain broad ethical principles upon which the rules are based ("Opinions", in this instance), while others provide primarily straight-line rules without explicating the underlying theoretical foundation. Yet, even general principles such as are contained in the AMA's *Code* preserve a more rule-and-order appearance, and the *Code* makes no pretense to adhere to a specific ethical theory.[83]

Thus, for a consideration of the existence and place within the profession of a legal order, the next Section will focus on ethics codes and similar sets of rules, guidelines and norms intended to influence or order the behavior and actions of physicians. The perspectives provided by bioethics will be examined when called for, especially in later Chapters, but are not the focus of this analysis. Indeed, as will be discussed in greater detail below, it is the codes that are the backbone of medical ethics *as used by the profession itself*. It should be remembered that the development of ethics codes came from a much different place than bioethics—that of "concrete moral guidelines and an irenic spirit"[84]—and these differences will inform the remainder of this Chapter.

[83] Other ethics documents, such at Canada's *Tri-Council Policy Statement*, explicitly base their rules on principles or other theoretical foundations. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Ottawa: Interagency Secretariat on Research Ethics, 2010).
[84] Pellegrino, "Percival's *Medical Ethics*", *supra* note 58.

III. Codes of Ethics as Professionally-Sourced Law

A. Introduction

Codes of ethics remain an important source of norms for physicians, and the AMA's *Code of Medical Ethics* is easily the most detailed and comprehensive. The *Code* is based on nine brief ethical principles[85] that are the foundation for over 200 Opinions written by CEJA (often at the behest of or in conjunction with the House of Delegates or AMA Board of Trustees) on topics ranging from social policy issues to fees and charges to confidentiality to the patient-physician relationship.[86] The normative value of these Opinions varies from Opinion to Opinion and from topic to topic, but regardless the *Code* is a valuable source of ethics norms in medical practice due to its breadth.

Many medical societies have adopted their own ethics codes or guidelines for specific situations. In addition, governing documents such as organizational bylaws contain ethics provisions, or acknowledge external ethics codes or guidelines as governing the behavior of the organization's members. I gathered documents from these societies to determine the extent and nature of the use of medical ethics in the organized medical profession.

To attempt a comprehensive collection of these documents, I referred to the list of 121 medical specialty societies (which includes the American Osteopathic Association and the Council of Medical Specialty Societies) that are the constituent National Medical Societies with

[85] CEJA, *Code of Medical Ethics*, *supra* note 6 at xvii.
[86] The *Code* was modernized at the 2016 Annual meeting of the AMA House of Delegates. This has decreased the number of Opinions to 162 as similar Opinions are combined and outdated ones are removed. Council on Ethical and Judicial Affairs, "AMA Code of Medical Ethics: Concordance", online: American Medical Association <https://www.ama-assn.org/about-us/code-medical-ethics>. However, the version of the modernized *Code* available through the AMA's website is still listed as preliminary so I will continue to refer to the 2010-2011 version unless the Opinion has been amended or adopted more recently.

representation in the AMA House of Delegates and the 50 state medical societies plus the District of Columbia.[87] (See Table 1 for a list of these organizations.) There are other medical professional organizations that exist outside of this number,[88] but I chose this list because it provides a broad spectrum of medical specialties and the primary medical societies of each state, representing the mainstream of medicine in the US.

B. Methods

To identify relevant documents, I visited the website of each organization and did a basic search using the terms "bylaw", "constitution", "incorporation", "ethic", "code", and "principle" to locate the organization's bylaws and any principle or code of ethics as well as individual ethics policies. I also consulted websites' "About Us" or similar sections, as these commonly contained bylaws and ethics documents. For those organizations that did not place these documents on their websites or that I could not access without membership in the organization, I directly emailed relevant contacts as noted on the websites or used web-based contact forms if contact information was not available. Finally, I telephoned select organizations that did not respond to my email or contact request. The organizations contacted via telephone were chosen based upon state size (for the state societies), with larger states contacted, or perceived size and breadth (for specialty societies), with larger and broader societies contacted.

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[87] American Medical Association, "Member Organizations", online: American Medical Association <http://www.ama-assn.org/ama/pub/about-ama/our-people/house-delegates/the-delegates/member-organizations.page> .

[88] For example, the American Association of Physicians and Surgeons was formed to promote the private practice of medicine and oppose social health programs. It is not a constituent society of the AMA. American Association of Physicians and Surgeons, "About AAPS", online: American Association of Physicians and Surgeons <http://aapsonline.org/about-aaps/>.

I examined the documents collected for their ethics content and normative intent as well as indications of or mechanisms for enforcement or disciplinary actions. These will act as indicators of a legal order within my analysis: a set of rules and a means to sanction violations.

C. Results

1. General

Through website searches, I collected codes of ethics (46 specialty societies, 4 state societies) and individual ethics policies (37 specialty societies, 12 state societies), if available, as well as bylaws (70 specialty societies, 25 state societies), if available. For those societies that did not provide codes on their website I directly contacted each (specialty societies: 42 by email/webform, 6 by telephone; state societies: 28 by email/webform, 6 by telephone), requesting a code if the society had adopted its own or bylaws. An additional one code (specialty society) and 5 constitution/bylaws (2 specialty societies; 3 state societies) were obtained following correspondence with society representatives. Eight societies informed me that they do not provide ethics documents or bylaws to non-members (3 specialty societies; 5 state societies). Seven state societies informed me that they follow the AMA's Principles or *Code* in lieu of adopting their own ethics policy. One specialty society informed me that they have not adopted a disciplinary policy or procedures. In total, 52 codes[89] and 105 bylaws and/or constitutions were collected from 89 specialty societies and 33 state medical societies.[90]

A few societies made available on their websites independent disciplinary procedures or guidelines that provide detailed steps taken throughout the disciplinary process, including grounds for

[89] Not all documents were titled "code", as some used "principles", "codes of conduct", or similar language.
[90] A list of the documents obtained from each medical society is on file with the author.

disciplinary action. I obtained a total of 9 disciplinary policies, with 8 coming from specialty societies.

2. Enforcement of Conduct

The primary means of medical societies to enforce their ethics and professional standards is through a physician's status as a member. As voluntary organizations, medical societies have direct authority only over those who have joined. This authority is exercised through disciplinary provisions that enforce the society's ethical or other standards.

Of 123 total medical societies from which I obtained documents, 25 state medical societies and 64 specialty societies identify a specific body within the organization responsible for disciplinary actions against members. At times, the body is established to deal primarily with ethical or disciplinary issues, such as an ethics or professional standards committee or judicial council (36 specialty societies; 13 state societies). Otherwise, disciplinary duties are delegated to a general governing body such as a board of directors/trustees, executive committee or house of delegates (28 specialty societies; 12 state societies). One state society and 26 specialty societies provide for dual jurisdiction, often with the general governing body having appellate jurisdiction or acting on the recommendations of the specialized committee (e.g. the disciplinary action is not final until the general body rules).

Nearly all the societies that provide for a disciplinary process in their code of ethics, bylaws, or disciplinary procedure document also authorize specific disciplinary sanctions, such as censure, reprimand, probation, suspension and expulsion (65 specialty societies;[91] 18 state societies).

Important to the capacity to discipline members for their conduct is the outlining of what conduct, exactly, will be sanctioned. Although failure to pay dues is common grounds for membership termination (at least until the dues are paid), I focused on provisions that permit disciplinary action for unethical conduct. Forty specialty societies and 20 state societies include as grounds for discipline the breach of ethics standards—either the society's or another entity's.[92] Even if the breach of an applicable code of ethics or other ethics guideline is not specified as grounds for disciplinary action, some societies incorporate as grounds other behavior that could be interpreted to include such breaches or general unethical conduct (14 specialty societies; 1 state society). In total, 54 specialty societies and 21 state societies included as grounds for disciplinary action either a violation of ethical principles or a code of ethics, or other unethical or unprofessional behavior.

D. Discussion

1. Prominence of Ethics

The majority of state and specialty medical societies from which I obtained documents referred to ethics or ethical standards in some fashion as rules of behavior for their members. Although many state societies have adopted policies on specific ethical issues that might not exactly mirror the

[91] A few specialty societies specified disciplinary committees but not possible sanctions, and a few more specified sanctions without the disciplinary body, hence the fact that there is one more specialty society that specifies sanctions than societies that specify disciplinary bodies.

[92] This is almost always the AMA's *Code* or Principles, although a few societies that are more international in membership would allow a breach of the member's home country's applicable code of ethics to constitute grounds for action.

AMA's position, the majority of these societies (29) reference the AMA's Principles or *Code* as standards applicable to their members, demonstrating the importance of these documents to the profession and the role of state societies in the AMA.[93] Specialty societies, on the other hand, are more likely to adopt their own code or principles of ethics. Only 15 specialty societies reference the AMA's Principles or *Code* as the source, in whole or in part, of their own ethics standards in the documents that I collected.

One measure of the importance of ethics to medical societies, the specialty societies especially, is the decision to adopt one's own code of ethics versus reliance on the AMA. As noted previously, the AMA's *Code* is incredibly detailed, and could be the source of ethics standards for all the medical societies studied, as they are all constituent societies of the AMA. This is the case for the state societies, as none has adopted their own code—the 4 that provide a general ethics document on their website use the AMA's Principles. State societies' general nature essentially mirrors the AMA's, making the use of the AMA *Code* as expedient for them as it is for the AMA. Yet 46 specialty societies have chosen to create their own codes or ethics guidance. Many of these are based on the AMA's Principles or *Code*, but generally go farther to provide additional ethics guidance to the society's members.

The detail contained in some of these codes is striking. The American Academy of Child and Adolescent Psychiatry's *Code of Ethics* is an example of the practical need for some societies to provide greater clarification on specific issues that might not be covered very well in the AMA's

[93] In 1855, state medical societies were directed to adopt the AMA *Code* as a condition of representation in the AMA. American Medical Association, *Transactions, 1855*, *supra* note 30 at 56. The current AMA bylaws bind members to the Principles, but there is no provision requiring constituent societies to adopt the Principles or *Code*. AMA, *Constitution and Bylaws*, *supra* note 54.

Code.[94] Although the Academy "subscribes to the Principles of Medical Ethics of the American Medical Association and the Code of Ethics of the American Osteopathic Association",[95] the drafters of this code recognize that their particular field of practice "requires additional specific clarifications beyond those contained in the above-cited Principles, Code, and Annotations, because, unlike the majority of other medical specialties, patients of child and adolescent psychiatrists are predominantly dependent minors."[96] This is a particular problem for the Academy: the AMA's *Code* is generally broadly applicable to all patients, with only a few Opinions specific to pediatric practice where it has long been recognized that there are many ethical considerations that differ from those of the adult population.

Likewise, the American Psychiatric Association (APA) recognizes the shortcomings of the AMA *Code* and Principles for its members. The *Principles of Medical Ethics with Annotations Especially Applicable to Psychiatry* notes that the "general guidelines [of the AMA's Principles and CEJA opinions] have sometimes been difficult to interpret in psychiatry, so further annotations to the basic principles are offered" by the APA.[97] The APA is one of the few specialty societies to go even farther than adopting its own code of ethics, and has also published ethics opinions to address specific questions in much the same way as CEJA's ethics opinions, though in the form of question and answer.[98]

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[94] American Academy of Child & Adolescent Psychiatry, *Code of Ethics* (Washington, DC: American Academy of Child & Adolescent Psychiatry, 2014), online: American Academy of Child & Adolescent Psychiatry <http://www.aacap.org/App_Themes/AACAP/docs/about_us/transparency_portal/aacap_code_of_ethics_2012.pdf>.
[95] *Ibid*.
[96] *Ibid*.
[97] American Psychiatric Association, *The Principles of Medical Ethics with Annotations Especially Applicable to Psychiatry* (Arlington: American Psychiatric Association, 2013), online: American Psychiatric Association <http://www.psychiatry.org/practice/ethics/resources-standards>.
[98] *Ibid*.

A number of other specialty societies have adopted detailed ethics guidelines to complement the AMA's *Code*. The American Academy of Dermatology,[99] American College of Physicians,[100] American Academy of Neurology,[101] and the American College of Emergency Physicians[102] are some of the societies that provide ethics standards that extend beyond the AMA's. It should be noted that some societies provide only a short list of ethical principles to guide members, although these may have substantive differences from the AMA's Principles, for example the American Academy of Disability Evaluating Physicians,[103] American College of Preventive Medicine,[104] and American Society for Surgery of the Hand.[105]

In addition to codes and principles of ethics with society-specific content, many societies have also adopted ethics policies for certain topics, especially in the areas of conflicts of interest and expert witness guidelines. The AMA's *Code* has provisions dealing with both,[106] but specialty societies might want to reinforce the importance of these topics, address additional concerns by adopting their own guidance (especially if they have not formally adopted the AMA's *Code*), or fill in perceived gaps in AMA Opinions.

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[99] American Academy of Dermatology, *Professional and Ethical Standards for Dermatologists* (Schaumburg, Ill: American Academy of Dermatology, 2012), online: American Academy of Dermatology <http://www.aad.org/forms/policies/uploads/ar/1.%20professional%20and%20ethical%20standards%20for%20dermatologists%202012.pdf>.

[100] American College of Physicians Ethics, Professionalism, and Human Rights Committee, *supra* note 10.

[101] American Academy of Neurology, *Code of Professional Conduct*, *supra* note 10.

[102] American College of Emergency Physicians, *Code of Ethics for Emergency Physicians* (Dallas: American College of Emergency Physicians, 2016), online: American College of Emergency Physicians <http://www.acep.org/Clinical---Practice-Management/Code-of-Ethics-for-Emergency-Physicians/>.

[103] American Academy of Disability Evaluating Physicians, *Code of Ethical Guidelines* (Elk Grove Village, IL: American Academy of Disability Evaluating Physicians, 2012).

[104] American College of Preventive Medicine, *Code of Ethics* (Washington, DC: American College of Preventive Medicine, 2009), online: American College of Preventive Medicine <http://c.ymcdn.com/sites/www.acpm.org/resource/resmgr/committee/final_code_of_ethics_-approv.pdf>.

[105] American Society for Surgery of the Hand, *Code of Ethics and Professionalism for Hand Care Professionals* (Chicago: American Society for Surgery of the Hand, 2009), online: American Society for Surgery of the Hand <https://www.assh.org/Members/Ethics/Pages/CodeofEthics.aspx>.

[106] CEJA, *Code of Medical Ethics*, *supra* note 6 at 211, 337.

It is clear, considering the number of organizations that address ethics and professionalism in the bylaws or separate documents, that ethics remains an important aspect of professionalism and the professionalization of physicians. However, and as will be discussed in the next subsection, the adoption of these standards is a separate issue from intent and normativity.

2. Ethics and Normativity: The Importance of Words

In Chapter 3 I placed medical ethics in the world of law, identifying it as a legal order. This is by no means a reflection of the medical profession's own terminology or perception of the place of ethics in a legal system. The profession, the AMA specifically, has gone to great lengths to distinguish medical ethics from "law." However, its own usage is identifiable with Griffith's legal centralism.[107] Any idealization of medical ethics as law stems from the State rather than from the profession's own authority to enact rules that have the force of law: medical ethics as a source of "law" is "hierarchically subordinate to the law and institutions of the state."[108]

A brief recounting of the AMA *Code*'s disavowals is enlightening as to the profession's general view of the authority of medical ethics. Opinion 1.02 of the *Code* (prior to modernization in 2016) makes a clear distinction between ethics and law:

> Ethical values and legal principles are usually closely related, but ethical obligations typically exceed legal duties. In some cases, the law mandates unethical conduct. In general, when physicians believe a law is unjust, they should work to change the law. In exceptional circumstances of unjust laws, ethical responsibilities should supersede legal obligations
>
> The fact that a physician charged with allegedly illegal conduct is acquitted or exonerated in civil or criminal proceedings does not necessarily meant that the physician acted ethically.[109]

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[107] John Griffiths, "What is Legal Pluralism?" (1986) 24 J Legal Pluralism 1 at 3.
[108] *Ibid*.
[109] CEJA, *Code of Medical Ethics*, *supra* note 6 at 1-2.

This is an important statement, with a few components that should be further explored.

First, the Opinion notes that ethical obligations can "exceed legal duties."[110] This recognizes that the profession can regulate physician behavior more extensively than the State, and indeed often does, though there are examples where the State regulates more effectively than the profession (some of which will be discussed further in Chapter 7).

Second, this Opinion provides two options for when the State law is considered unjust. Physicians can work to change the law, as the organized profession does when it lobbies state and federal governments, acts as a party to litigation or as an *amicus*, or seeks to sway public opinion on a matter of public and ethical interest. Interestingly, the Opinion argues that in "exceptional circumstances of unjust laws" ethical responsibilities become more controlling.[111] This appears to advocate something akin to civil disobedience when the law is so unjust as to require violation rather than compliance.

Finally, the second paragraph of the Opinion implies that physicians who are acquitted or exonerated of an alleged violation of State law can still face penalties for ethics violations. This separates the disciplinary activities of the medical profession from those of the State.

These concepts live on in the modernized *Code*'s preamble, although slightly altered in terms of language and organization.[112] The modernized *Code* also contains a new preface that explains the use of certain language in the Opinions.[113] It reaffirms first that the Opinions in the *Code* "are not

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[110] *Ibid*.
[111] *Ibid*.
[112] Council on Ethical and Judicial Affairs, "Preamble to Opinions of the Council on Ethical and Judicial Affairs", online: American Medical Association <https://www.ama-assn.org/about-us/code-medical-ethics>.
[113] Council on Ethical and Judicial Affairs, "Preface to Opinions of the Council on Ethical and Judicial Affairs", online: American Medical Association <https://www.ama-assn.org/about-us/code-medical-ethics> [CEJA, "Preface to Opinions"].

laws or rules. They are guidance that identifies the essentials of ethical behavior for physicians."[114] It goes on to clarify the use of "*must*, *should*, and *may* in their common understandings to distinguish different levels of ethical obligation."[115] Much like State law, this preface views "must" as creating the greatest obligation to comply, and "may" the weakest. It also goes on to state that

> [t]he more stringent the ethical obligation, the stronger the justification required to deviate from it in any specific instance. Obligations indicated by *must* can be reversed or violated only in very rare circumstances, for example, when two or more core ethical values conflict in such a way that it is not possible for the physician to uphold both or all and the physician is forced to decide which value will prevail. Guidance introduced by *should* sets a general expectation for conduct, but permits more latitude for discerning alternative ways to meet the expectation. Obligations indicated by *may* call on the physician to confirm that qualifying conditions are met sufficiently to warrant taking the action addressed in guidance.[116]

Interestingly, the preface presents an internal inconsistency when considering medical ethics as a legal order for purposes of legal pluralism. The Opinions are not "laws or rules", but they are clearly intended to have the same impact. For those Opinions phrased in terms of "must" (or possibly "shall"), deviation is permissible "only in very rare circumstances". This is similar to the way that a law or rule operates, even one of the State. It is understandable that the AMA wishes to differentiate State law from its codified ethics, but it is almost (not quite, but almost) a distinction without difference.

Other medical societies also disclaim the status of medical ethics as law. The American College of Physicians *Ethics Manual*, for example, points out that conflicts may exist between "legal and ethical obligations….[w]e refer to the law in this Manual for illustrative purposes only; this should not be taken as a statement of the law or the legal consequences of actions, which can vary by state

[114] *Ibid*.
[115] *Ibid*.
[116] *Ibid*.

and country."[117] The American College of Radiology states that its "code is not a set of laws but rather a framework by which radiologists may determine the propriety of conduct in their relationship with patients, the public, colleagues, and members of allied professions."[118]

However, the internal structure of these codified ethics belies this differentiation because of how some societies characterize different parts of their ethics norms. Referring again to the American College of Radiology, the ethics contained in its Bylaws consists of two parts: Principles and Rules. Its Principles "serve as goals of exemplary professional conduct for which members of the College should constantly strive",[119] while its Rules of Ethics "are mandatory and directive of specific minimal standards of professional conduct for all members of the College."[120] This sounds suspiciously like how we expect State law to function.

Despite the appearance of similarity between medical ethics and State law in some circumstances, there remains a discomfort with the potential power of ethics as a regulatory tool. The American Academy of Neurology diminishes its own authority in its Code of Professional Conduct when it writes "[i]f any provision of this code conflicts with state or federal law, the state or federal laws will govern."[121] Unlike the AMA *Code*, which grants physicians the duty to place ethical

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[117] American College of Physicians Ethics, Professionalism, and Human Rights Committee, *supra* note 10.
[118] American College of Radiology, *2016-2017 Bylaws* (Reston, VA: American College of Radiology, 2016), online: American College of Radiology <http://www.acr.org/~/media/ACR/Documents/PDF/Membership/Governance/2016_2017%20Code%20of%20Ethics.pdf> at 28.
[119] *Ibid*.
[120] *Ibid*. at 30. See also American Academy of Ophthalmology, *Code of Ethics* (San Francisco: American Academy of Ophthalmology, 2016), online: American Academy of Ophthalmology <http://www.aao.org/ethics-detail/code-of-ethics> ("[t]he Principles of Ethics are not enforceable….The Rules of Ethics are enforceable" at 1-2); American Academy of Allergy, Asthma and Immunology, *Code of Ethics* (Milwaukee: American Academy of Allergy, Asthma and Immunology, 2016), online: American Academy of Allergy, Asthma and Immunology <http://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/About/AAAAI-Code-of-Ethics-review-and-approved-7-16.pdf> ("[t]hese General Principles of Ethics [are]….not enforceable rules as such….The Rules and Policies of Ethics…are enforceable by the AAAAI" at 2-3).
[121] American Academy of Neurology, *Code of Professional Conduct*, *supra* note 10.

obligations above unjust State law, the Academy makes no such exception. This does not mean that the Academy does not view its Code of Professional Conduct as having some normative value, but more clearly places it in a subordinate position to State law.

Many of the ethics documents used by medical societies have a directive nature akin to what is offered by the AMA *Code*. There are things that physicians can do;[122] things that physicians must do;[123] and things that physicians absolutely cannot do.[124] The use of terms such as "must", "shall", "should" and "may" indicate what behavior is expected, and the failure to conform can lead to disciplinary sanction.

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[122] See e.g. American Academy of Dermatology, *Code of Medical Ethics for Dermatologists* (Schaumburg, Ill: American Academy of Dermatology, 2014), online: American Academy of Dermatology <https://www.aad.org/forms/policies/uploads/ar/ar%20code%20of%20medical%20ethics%20for%20dermatologists.pdf> ("[g]ood relationship[s] among physicians, nurses, and other health care professionals are essential for good patient care. The dermatologist should promote the development of an expert health care team that will work together harmoniously to provide optimal patient care" at 5) [American Academy of Dermatology, *Code of Medical Ethics*]; American Academy of Otolaryngology – Head and Neck Surgery, *Code of Ethics* (Alexandria, VA: American Academy of Otolaryngology – Head and Neck Surgery, 2012) ("[p]hysicians should be allowed to patent devices, but the use of these devices must be in accordance with the patient's best medical interest, without regard to the physician's financial interests" at 2).

[123] See e.g. American Academy of Dermatology, *Code of Medical Ethics*, *supra* note 122 ("[i]f the dermatologist has a financial or ownership interest in a durable medical goods provider, imaging center, surgery center or other health care facility where the dermatologist's financial interest is not immediately obvious, the dermatologist must disclose this interest to the patient" at 4); American College of Cardiology, *Code of Ethics* (Washington, DC: American College of Cardiology, 2014), online: American College of Cardiology <http://www.acc.org/about-acc/our-bylaws-and-code-of-ethics/code-of-ethics> ("[i]n all dealings with patients, a members shall act fairly, in good faith, honestly, and with compassion and respect for a patient's dignity and rights").

[124] American Association for Thoracic Surgery, *Code of Ethics* (Beverly, MA: American Association for Thoracic Surgery, 2008), online: American Association for Thoracic Surgery <http://www.aats.org/AATSIMIS/AATS/Association/By-Laws_and_Policies/Code_of_Ethics/CODE_OF_ETHICS.aspx?WebsiteKey=81f79f5f-4a27-4146-913d-cffea0ac81f7> ("[m]embers must not discriminate on the basis of gender, race, national origin, sexual orientation, or any other basis that would constitute medically unjustified discrimination"); American College of Rheumatology, *Code of Ethics of the American College of Rheumatology, Inc., February 2015* (Atlanta: American College of Rheumatology, 2015), online: American College of Rheumatology <http://www.rheumatology.org/Portals/0/Files/Code%20of%20Ethics.pdf> ("[m]embers shall not engage in advertising or any other form of public communication, including electronic communication, which is false, fraudulent, deceptive or misleading" at 3); American College of Obstetricians and Gynecologists, *Code of Professional Ethics of the American College of Obstetricians and Gynecologists* (Washington, DC: American College of Obstetricians and Gynecologists, 2015), online: American College of Obstetricians and Gynecologists <http://www.acog.org/About-ACOG/ACOG-Departments/Committees-and-Councils/Volunteer-Agreement/Code-of-Professional-Ethics-of-the-American-College-of-Obstetricians-and-Gynecologists> ("[i]t is unethical to prescribe, provide, or seek compensation for therapies that are of no benefit to the patient" at 2).

The content of some societies' ethics documents makes clear that violation is sanctionable. The American Academy of Allergy, Asthma and Immunology informs members that its Code of Ethics "is enforceable solely by the AAAAI", and further that its "Code authorizes the AAAAI to invoke its enforcement and disciplinary procedures in connection with a wide range of violations and the AAAAI reserves the right to exercise such authority in the event that it determines that doing so is in its best interests or that of its members."[125] Similarly, the American Academy of Dermatology warns members that "[v]iolations may be subject to disciplinary action pursuant to the procedures set forth in the Academy's Administrative Regulations."[126]

These modern ethics codes and standards have taken medical ethics to a level foreign to the practitioners of the 19th and early 20th centuries. Any suggestion that ethics codes served a monopolistic role or only as rules for etiquette are (hopefully) waylaid by the clear intent that ethics act as normative rules with a consequence for violation. Despite the regular disclaimer by societies that medical ethics is not law it is at the very least structurally similar, and the stated intent in some ethics codes that violations will be sanctioned increase the parallels between medical ethics and State law.

A perhaps greater shift in medical ethics than an improved normativity began with the evolution of the AMA to appoint a body explicitly charged with enforcing its *Code* in the 19th century. This cemented the enforceability of at least some aspects of codified medical ethics. The next subsection will explore the mechanisms used to sanction physicians who violate ethics norms.

[125] American Academy of Allergy, Asthma and Immunology, *supra* note 120 at 3.
[126] American Academy of Dermatology, *Code of Medical Ethics*, *supra* note 122 at 1.

3. Assessing Normativity: Enforcement and "Law"

Assessing the normativity of the various documents—whether they can be considered part of a legal order—creates a difficult question: how should normativity be measured? The mere existence of codes of ethics or other ethics standards is indicative of the intent to guide physician behavior, as codes were historically the only way to regulate physicians, even if ineffectually. Modern ethics codes and other ethics guidance furthers this regulation by claiming authority over the ethical comportment of member physicians—they "must," "should" or "may" do certain things. However, making statements about how physicians should act in specific situations might be insufficient to create a legal order. In many of the examples of legal pluralism addressed in the previous Chapter, there might have been something to back up a rule. Moore's example of the garment industry focused on the economic impact of not cooperating within the system used by the industry.[127] A more abstract and broad example of law is the authority exercised by parents over their children, which would rely on some sort of negative outcome for a failure to comply.[128] The common thread of these examples is that the semi-autonomous social field in question has "the means to induce or coerce compliance."[129] Griffiths recognized this implicitly when he defined law as "the *self-regulation* of a 'semi-autonomous social field'" (emphasis added).[130]

Turning back to medical ethics, we are faced with the question of when should a code or other ethics standard be considered part of a legal order for purposes of legal pluralism, and when should

[127] Sally Falk Moore, "Law and Social Change: The Semi-Autonomous Social Field as an Appropriate Subject of Study" (1973) 7 L & Soc'y Rev 719. Moore noted that these obligations were not legally enforceable, but rather were encouraged by "extra-legal sanctions." *Ibid*. at 726.
[128] Brian Z Tamanaha, "The Folly of the 'Social Scientific' Concept of Legal Pluralism" (1993) 20 JL & Soc'y 192 ("[r]eligion and the family are believed to be outside state law, not because state law affirmatively says so, but because many people simply believe that to be the case, as residual cultural notions based upon natural law or natural rights" at 213 n 21).
[129] Moore, *supra* note 127 at 720.
[130] Griffiths, *supra* note 107 at 38.

it not. As the AMA found in its early history, a code of ethics with no teeth did not allow for effective governance of the profession, hence the establishment of the Judicial Council[131] and the connection of violations with punishment. Here the profession recognized that there must be some mechanism of enforcement for an operative ethics code, and some form of sanction.

Being a member of a medical society subjects physicians to the society's rules, policies and procedures, including any means used by the society to enforce its rules. As discussed in the previous subsection, the language used in many ethics codes indicates intent that they be treated as enforceable rules. The presence of disciplinary provisions in ethics codes, society bylaws, or other society documents give force to this intended normativity. Earlier in this Chapter I indicated that many state and specialty medical society documents contain provisions directed specifically towards ethics violations, and others contain more general language that could include a violation of professional ethics as grounds for disciplinary action (e.g. "unprofessional conduct").[132] The need for the threat of disciplinary action to ensure physician compliance with medical ethical standards is clear: "[i]f these simple maxims [basic principles of ethics] were routinely observed by physicians in their care of patients and in all else they do professionally, the enunciation of ethical principles in medicine would be little more than an academic exercise."[133] Simply put, physicians do not always follow the rules, and when they do not there must be consequences.

This is a common refrain in legal pluralism, and although the penalty for non-compliance varies depending on the circumstance, the semi-autonomous social field, and the legal order at issue, there must be some incentive, positive or negative, to encourage behavior that is acceptable to the

[131] The Judicial Council was initially established in 1873 to "decide all questions of an ethical or judicial character that may arise in connection with the Association." American Medical Association, *The Transactions of the American Medical Association,* vol XXVI (Philadelphia: American Medical Association, 1873) at 35.
[132] See above § III(C)(2).
[133] American Academy of Dermatology, *Code of Medical Ethics*, *supra* note 122.

group. The authority of the semi-autonomous social field must be clearly defined for it to be effective against members, and against challenge from members.[134] For the medical profession, non-compliance with medical ethics can lead to loss of membership in the society or lesser penalties (reprimand, probation or suspension).

The normative value of ethics varies amongst the societies. Drawing from the documents I obtained, many societies with their own ethics codes do not make violations actionable (19 of the 50 specialty societies that have adopted their own code of ethics). Some societies distinguish between actionable portions of their ethics standards and those that are merely aspirational. As noted in the previous subsection, societies like the American Academy of Ophthalmology have both Principles and Rules of Ethics as part of their ethics codes. The "Principles of Ethics are not enforceable" while the "Rules of Ethics are enforceable."[135]

The majority of state medical societies from which I obtained documents (20 of 33) will potentially assess a penalty for violation of ethics standards. Sanctions can range from the minor letter of censure to the ultimate penalty of expulsion from the society. A greater number specify an internal body to address disciplinary issues (25 of 33), even if unethical behavior is not specifically included in the grounds for action. This is not very surprising, considering that these societies have a history and purpose similar to the AMA and represent the profession generally within their respective states.

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[134] See e.g. HLA Hart, "Positivism and the Separation of Law and Morals" (1958) 71 Harv L Rev 593. Hart's conception of the law involves more than just the commanded and the commander, although this resembles the criminal law. One important aspect of law that falls outside of the "gunman situation writ large" are legal rules that "provide facilities more or less elaborate for individuals to create structures of rights and duties for the conduct of life within the coercive framework of the law." *Ibid*. at 604.

[135] American Academy of Ophthalmology, *supra* note 120 at 1-2.

Amongst specialty medical societies, the size and function of the society can correlate with its explicit recognition of the actionability of ethics violations. As Jacob noted, "it can be said that professional ethics will be the more developed, and the more advanced in their operation, the greater the stability and the better the organization of the professional groups themselves."[136] Large specialty societies catering to a specific area of practice, especially if the society represents physicians directly involved with patient care, are more likely to have a complex organizational structure and include sanctions for unethical behavior in bylaws or codes of ethics. Secondary medical societies[137]—those whose members likely belong to one or more other societies for their specific discipline—are less likely to have their own disciplinary procedures. The American Academy of Psychiatry and the Law, for example, states that it "does not adjudicate complaints that allege unethical conduct by its members or nonmembers….such complaints will be returned to the complainant for referral to the local district branch of the American Psychiatric Association (APA), the state licensing board, and/or the appropriate national psychiatric organization of foreign members."[138] Some of these secondary societies have a smaller membership than the broader umbrella organizations for the various specialties,[139] and this combined with their specific function might limit their perceived need to address medical ethics independent of larger medical societies.

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[136] Jacob, *supra* note 7 at 127.

[137] In this number I include societies such as the American Academy of Psychiatry and the Law, American College of Medical Quality, American Medical Directors Association, and Association of Military Surgeons of the United States.

[138] American Academy of Psychiatry and the Law, *Ethics Guidelines for the Practice of Forensic Psychiatry* (Bloomfield, CT: American Academy of Psychiatry and the Law, 2005), online: American Academy of Psychiatry and the Law <http://www.aapl.org/docs/pdf/ETHICSGDLNS.pdf> at 4.

[139] For example, the Radiological Society of North America boasts over 53,000 members, while the American Society for Radiation Oncology claims over 10,000. Radiological Society of North America, "About RSNA", online: Radiological Society of North America <http://www.rsna.org/AboutRSNA.aspx>; American Society of Radiation Oncology, "About ASTRO: Membership Demographics", online: American Society of Radiation Oncology <https://www.astro.org/About-ASTRO/Membership-Demographics/Index.aspx>.

Available resources are likely a component of any decision by a society to adopt an independent ethics agenda as well as to enforce it. Some of the larger specialty societies, such as the American Society of Anesthesiologists, American Academy of Neurology, American Psychiatric Association, and the American Congress of Obstetricians and Gynecologists[140] have more detailed ethics codes and disciplinary procedures (the American Academy of Neurology is one of the eight societies from which I obtained an independent disciplinary procedure document). Accompanying their comparably large membership is presumably more funding from both membership dues and activities such as CME programs, journal subscriptions (and advertising) and other sources of revenue. Given the potential costs of maintaining a committee, staff and administrative support for disciplinary proceedings, it is sensible that societies with fewer resources do not take the same steps as those with greater membership and financial resources. However, this is also indicative of potential problems arising from the splintering of the medical profession into a large number of medical societies, wherein ethical accountability of members declines as the size and resources of the medical society decreases.

Many medical societies undoubtedly rely on the State to determine the eligibility of members or applicants. The individual states are responsible for licensing, and membership in a society is commonly based on maintaining a valid license and practice.[141] For many societies suspension or

[140] Respectively, these societies claim over 52,000 members, 27,000 members, 33,000 members, and 55,000 members. American Society of Anesthesiologists, *American Society of Anesthesiologists 2015 Annual Report* (Schaumburg, Ill: American Society of Anesthesiologists, 2015), online: American Society of Anesthesiologists <http://www.asahq.org/resources/publications/annual-reports>; American Academy of Neurology, "Membership", online: American Academy of Neurology <https://www.aan.com/membership/>; American Psychiatric Association, "About APA & Psychiatry", online: American Psychiatric Association <http://www.psychiatry.org/about-apa--psychiatry>; American Congress of Obstetricians and Gynecologists, "The American College of Obstetricians and Gynecologists", online: American Congress of Obstetricians and Gynecologists <http://www.acog.org/About_ACOG/Leadership_and_Governance>.

[141] Some categories of membership, such as medical student or resident members, honorary, and international members do not have this requirement, but the privileges of membership for these might be different, for example they cannot hold leadership positions within the society (other than, say, as a member of a committee made up of fellow members of the category).

revocation of a medical license is grounds for automatic suspension or termination of membership, regardless of whether the society otherwise specifies grounds for disciplinary action. In addition, licensing board, medical society and hospital disciplinary actions, as well as medical malpractice actions, must be reported to the National Practitioner Data Bank[142] and societies can rely on negative reports to deny membership.

More problematic are those societies that do not mention member discipline in any document obtained, or that only cite failure to pay dues as grounds for membership suspension or termination. It is possible that these societies have other documents or procedures that I could not access permitting action based on ethics violations, but if not the constraints of State law might prohibit any disciplinary action taken that is not provided for in governance documents. If the society's bylaws or other documents do not sanction unethical behavior, and the society has not adopted or referenced a code of ethics or other ethics standards that might imply the capacity to regulate physician conduct, that society could be left with the inability to outline and enforce expected ethical behavior of their members.

What does it mean to be sanctioned by a medical society? Membership in a medical society is not required for licensure by the State, but it has the effect of strengthening a physician's credentials. It provides a physician with (potentially cheaper) access to continuing medical education programs, a typical requirement for license renewal, and it indicates a physician's acceptance of and into the mainstream of the profession in the eyes of patients. It also provides a physician with an additional certificate to demonstrate his or her professionalism and competence. On the more abstract side, membership in a medical society can impact physicians' self-conception as a

[142] 45 CFR pt 60 (2016).

professional and their sense of belonging. Losing these things does not impact a physician's ability to *legally* practice medicine, but it can affect how they view themselves as well as how their colleagues view their professionalism.

Clearly, many medical societies view ethics violations of members as actionable. Although some provide disciplinary procedures for these violations, others are more general and do not specify violations of an ethics code or even the broader "unethical behavior" as grounds for action. However, the capability of societies to rely on external bodies for disciplinary decisions, even mirroring the actions of those bodies, indicates a willingness to consider ethics violations as grounds for discipline even if not otherwise specified in relevant documents. For the medical profession, enforcement of rules of conduct and ethics standards cannot lead to imprisonment or financial penalties (these remain the province of the State), but medical societies do retain some powers to ensure that their rules are followed.

E. Limitations

The limitations of the above analysis of medical society codes, bylaws, constitutions, and disciplinary procedures are based primarily on documents accessible to me. Although I obtained documents of one kind or another from well over half of the specialty and state societies that are the constituent societies of the AMA, not all documents were of equal value, and some provided no insight into how the society addresses ethical or disciplinary issues. Those societies from which I did not obtain any documents likely have at least governance documents such as bylaws or constitutions that might shed light on how ethics and disciplinary issues are addressed.

A secondary limitation relates to the text of the collected documents versus the reality of medical ethics within the individual societies. Due to confidentiality policies of medical societies, I was

not able to collect data regarding whether and how individual medical societies react to the ethics violations of their members, other than what is published in publicly accessible society newsletters[143] or similar materials and the reports of the AMA Council on Ethical and Judicial Affairs,[144] which provides information only on the number of physicians disciplined by the Council and the type of discipline meted out. Thus, while I can state the content of relevant medical society documents and their relation to medical ethics and self-regulation, I have no basis upon which to assess whether the medical societies follow through with the directives of their bylaws, constitutions and ethics codes other than my experience working for CEJA and the evidence provided by the limited documentation available on enforcement actions.[145]

IV. Conclusions

Medical ethics remains a cornerstone of modern medical practice. It was a foundation upon which the US profession organized and trained from the early 19th century onward, and even though it is no longer the primary means of professional regulation—state medical boards now serve this function—it is still an important component within the profession, especially for activities that fall outside the boundaries of State regulation. The past century and a half has seen a dramatic shift in the locus of power in medicine, but not a complete absorption of authority by the State. The capacity and desire of the profession to retain some control over its members is strong, as represented in part by the vibrant discourse about the contours and content of medical ethics by physician, ethicists, lawyers and others who have an stake in it.

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[143] See e.g. Society of Thoracic Surgeons, "STSNews", vol 18 issue 4 (2013) at 9. This issue notes only a single physician who was disciplined for violation of the Society's expert witness policy.
[144] See e.g. CEJA, "Judicial Function", *supra* note 37.
[145] As will be discussed in the next Chapter, State licensure actions are accompanied with more publicly available documentation because of transparency and open record requirements that medical societies, as private organizations, are not required to have.

Important here, though, is not just the significance of ethics to the medical profession but its status as a legal order and the implications that this might have on the relationship between the medical profession and the State. In modern medicine, the assertion that ethics acts as a kind of law applied by the profession to its members is not made easily: the profession itself no longer explicitly equates ethics with the force of law. Societies are correct that medical ethics is not the same as the law *to which they are referring*; that is, the law of the State. These disavowals by medical societies are reasonable when considering the doctrine of legal centralism[146] and the theory of professionalism, but these disavowals are only as good as the objective reality of medical ethics as a normative system within the profession. How are ethics codes and other ethics documents structured? What do they say about the expected adherence to ethics norms? How do they address alleged violations of these norms? These are important questions that shed light on the nature of medical ethics as they are intended to be used, not just how the medical profession characterizes them.

The language of ethics codes and standards shows clear intent that they act as rules for physician behavior, and many societies explicitly link violation of ethics to sanctions. The language of ethics norms mirror that of State law, with "must," "should" and "may" distinguishing different levels of behavioral expectations. The modernized AMA *Code*'s exposition on these terms further supports this notion.[147]

The efforts of many medical societies to provide disciplinary procedures and rules also solidifies medical ethics as a legal order. Ethics norms are rules backed up by the force of sanction: if a

[146] Griffiths, *supra* note 107.
[147] CEJA, "Preface to Opinions", *supra* note 113.

physician violates his or her ethical obligations there are mechanisms for accountability *within* the profession, not only from outside of it.

Granted, the existence of rules and mechanisms for enforcement does not an effective legal system make. As I will detail in the next Chapter, the State has positioned itself as the primary regulator of physicians through its use of licensure and other laws that affect whether and how physicians practice medicine. The medical profession's *actual use* of ethics as a normative tool—separate from how ethics are *intended* to be used—does not rise to the level of the State's capabilities. This does not mean, though, that medical ethics cannot be considered a legal order. Physicians are made to understand through these documents that medical ethics governs their behavior as physicians and oftentimes their personal lives.[148] Societies continue to proclaim the capability to act against physicians who violate relevant ethics guidance, and although action often follows decisions by other organizations (state licensing boards, health facilities, judicial decisions) it remains their intent that is a crucial determination of a legal order for the purposes of legal pluralism.

Medical ethics exists with the primary purpose of delineating acceptable practice and behavior of physicians. It is not entirely about patients, nor is it entirely about the profession. It is meant to inform the entirety of medical practice. It is also meant to be fluid in its development and application, and in the past century especially organized medicine has demonstrated a willingness to reconsider ethics norms in light of changing societal norms and technological advances. In sum, ethics was and remains the primary means of the profession to ensure that the needs of patients are the first focus of physicians. Pecuniary and personal interests take second seat to the patient, and

[148] For example, prohibitions against sexual relationships with patients. CEJA, *Code of Medical Ethics*, *supra* note 6 at 297.

a system of ethics codes and disciplinary procedures and policies reflect the seriousness with which the profession takes its responsibility. Ethics as a legal order is not perfect, and its imperfections will be explored in Chapters 6 and 7, but it is a field in which physicians have exercised their authority as a self-regulating profession. The status of medical ethics as "law" is not claimed by the profession, but its actions and intents clearly demonstrate its function as such.

To conclude this Chapter, I leave you with the sentiments expressed by the President of the AMA in 1961.

> I regard self-discipline as a vital responsibility which we as physicians must exercise vigorously and openly if we are to preserve our free practice of medicine.
>
> Because it is a privilege to practice medicine, we as physicians are duty-bound to keep medical practice free from impurities or flaws. Medicine must not tolerate anything less than the best.
>
> I don't think it will ever be repetitious for the medical profession to restate its creed on this matter. *WE SHALL DISCIPLINE OURSELVES*.
>
> This statement not only means that we don't want outsiders trying to assume our own responsibilities, but it also means that we pledge [to] our colleagues and our patients that we shall not tolerate anything but the finest quality medical care and the highest standards of professional ethics known to science.
>
> Of course, it is difficult to express a dogmatic philosophy on this vital subject, since ours is an ever-changing, ever-discovering science, and one which cannot be hamstrung by purely traditional restrictions.
>
> To me, the entire question of medical discipline can be summarized thus: We must do everything to encourage progress and knowledge, yet also fight fiercely against regression and stagnation….
>
> To be specific, what we must concern ourselves with in the matter of self-discipline is improper practice, incompetent practice, and unethical actions of every nature.[149]

[149] Leonard W Larson, "House of Delegates Report" (1961) 177 J Am Med Assoc 71 at 73.

TABLE 1. State and Specialty Medical Societies

State Medical Societies
Alaska State Medical Association
Medical Association of the State of Alabama
Arkansas Medical Society
Arizona Medical Association
California Medical Association
Colorado Medical Society
Connecticut State Medical Society
Medical Society of the District of Columbia
Medical Society of Delaware
Florida Medical Association
Medical Association of Georgia
Hawaii Medical Association
Idaho Medical Association
Illinois State Medical Society
Indiana State Medical Association
Iowa Medical Society
Kansas Medical Society
Kentucky Medical Association
Louisiana State Medical Society
Maine Medical Association
Med Chi: Maryland State Medical Society
Massachusetts Medical Society
Michigan State Medical Society
Minnesota Medical Association
Mississippi State Medical Association
Missouri State Medical Association
Montana Medical Association
Nebraska Medical Association
Nevada State Medical Association
New Hampshire Medical Society
Medical Society of New Jersey
New Mexico Medical Society
Medical Society of the State of New York
North Carolina Medical Society
North Dakota Medical Association
Ohio State Medical Association
Oklahoma State Medical Association
Oregon Medical Association
Pennsylvania Medical Society
Rhode Island Medical Society
South Carolina Medical Association
South Dakota State Medical Association
Tennessee Medical Association
Texas Medical Association
Utah Medical Association
Vermont Medical Society
Medical Society of Virginia
Washington State Medical Association
West Virginia State Medical Association
Wisconsin Medical Society
Wyoming State Medical Society

Specialty Medical Societies
Academy of Physicians in Clinical Research (Affiliated with Association of Clinical Research Professionals)
Aerospace Medical Association
American Academy of Allergy, Asthma and Immunology
American Academy of Child and Adolescent Psychiatry
American Academy of Cosmetic Surgery
American Academy of Dermatology
American Academy of Disability Evaluating Physicians
American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Family Physicians

American Academy of Hospice and Palliative Medicine
American Academy of Insurance Medicine
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Orthopaedic Surgeons
American Academy of Otolaryngic Allergy Inc.
American Academy of Otolaryngology-Head and Neck Surgery
American Academy of Pain Medicine
American Academy of Pediatrics
American Academy of Physical Medicine and Rehabilitation
American Academy of Psychiatry and the Law
American Academy of Sleep Medicine
American Association for Hand Surgery
American Association for Thoracic Surgery
American Association of Clinical Endocrinologists
American Association of Clinical Urologists, Inc.
American Association of Gynecologic Laparoscopists
American Association of Hip and Knee Surgeons
American Association of Neurological Surgeons
American Association of Neuromuscular & Electrodiagnostic Medicine
American Association of Plastic Surgeons
American Association of Public Health Physicians
American Clinical Neurophysiology Society
American College of Allergy, Asthma and Immunology
American College of Cardiology

American College of Chest Physicians
American College of Emergency Physicians
American College of Gastroenterology
American College of Legal Medicine
American College of Medical Genetics and Genomics
American College of Medical Quality
American College of Mohs Surgery
American College of Nuclear Medicine
American College of Occupational and Environmental Medicine
American College of Phlebology
American College of Physician Executives
American College of Physicians
American College of Preventive Medicine
American College of Radiation Oncology
American College of Radiology
American College of Rheumatology
American College of Surgeons
American Congress of Obstetricians and Gynecologists
American Gastroenterological Association
American Geriatrics Society
American Institute of Ultrasound in Medicine
American Medical Directors Association
American Medical Group Association
American Orthopaedic Association
American Orthopaedic Foot and Ankle Society
American Osteopathic Association (“Other Groups”)
American Psychiatric Association
American Roentgen Ray Society
American Society for Aesthetic Plastic Surgery, Inc.
American Society for Clinical Pathology

American Society for Dermatologic Surgery
American Society for Gastrointestinal Endoscopy
American Society for Radiation Oncology
American Society for Reproductive Medicine
American Society for Surgery of the Hand
American Society of Abdominal Surgeons
American Society of Addiction Medicine
American Society of Anesthesiologists
American Society of Bariatric Physicians
American Society of Cataract and Refractive Surgery
American Society of Clinical Oncology
American Society of Colon and Rectal Surgeons
American Society of Cytopathology
American Society of Echocardiography
American Society of General Surgeons
American Society of Hematology
American Society of Interventional Pain Physicians
American Society of Maxillofacial Surgeons
American Society of Neuroimaging
American Society of Neuroradiology
American Society of Ophthalmic Plastic and Reconstructive Surgery
American Society of Plastic Surgeons
American Society of Retina Specialists
American Thoracic Society
American Urological Association
Association of Military Surgeons of the United States
Association of University Radiologists
College of American Pathologists
Congress of Neurological Surgeons
Contact Lens Association of Ophthalmologists

Heart Rhythm Society
Infectious Diseases Society of America
International College of Surgeons - US Section
International Society of Hair Restoration Surgery
International Spine Intervention Society
National Association of Medical Examiners
National Medical Association (“Prof Interest Med Association”)
North American Spine Society
Radiological Society of North America
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society for Investigative Dermatology, Inc.
Society for Vascular Surgery
Society of American Gastrointestinal
Endoscopic Surgeons
Society of Critical Care Medicine
Society of Hospital Medicine
Society of Interventional Radiology
Society of Laparoendoscopic Surgeons
Society of Medical Consultants to the Armed Forces
Society of Nuclear Medicine and Molecular Imaging
Society of Thoracic Surgeons
The Endocrine Society
The Triological Society
Undersea and Hyperbaric Medical Society
United States and Canadian Academy of Pathology

CHAPTER 5: THE LAW OF THE STATE

I. INTRODUCTION **166**

II. WHO CAN BE A DOCTOR? **168**

A. Introduction *168*

B. Physician Licensure and Discipline *169*

1. Medical Licensing Acts 169

2. Medical Board Disciplinary Action 173

a. What constitutes grounds for action? 173

b. How are physicians disciplined? 179

III. THE WIDE WORLD OF HEALTH LAW **183**

A. Introduction *183*

B. State and Federal Health Care Programs and Provision of Care *184*

C. Medical Emergencies and Active Labor *187*

D. Fraud and Conflicts of Interest *189*

E. Privacy and Confidentiality *191*

F. Contract Law and Insurance Regulation *192*

IV. AN EXTENSIVELY REGULATED PROFESSION **195**

TABLE 2. STATE MEDICAL LICENSING DISCIPLINARY PROVISIONS—UNETHICAL OR UNPROFESSIONAL CONDUCT SPECIFIED AS ACTIONABLE BY MEDICAL BOARD **198**

I. Introduction

State law is vast. A perusal of the United States (US) Code (all 54 volumes) provides a vague idea of the breadth and scope of federal law, which exists in addition to the statutes of each individual state. Below these are regulatory compilations that often provide more detail than their corresponding statute. Given the quantity of statutory and regulatory State law, not to mention the law created by the judiciary through opinions and orders, it should not be surprising that the practice of medicine falls within their pages. What might be surprising is the very wide variety of State law pertaining to health care covering a very wide variety of medical and physician practices as well as the practices of other health care-related occupations, facilities and funders.

Likely very few physician activities are not covered in some way by some form of State law. Much like other areas of life and vocation, the State claims jurisdiction to regulate—a kind of legal centralism or monism. Looking back to Chapter 2, there is a very specific reason for this in the practice of medicine: the State has a role in protecting the public, and the regulation of physicians is an important way of expressing this. So important, in fact, that the organized medical profession encouraged the adoption of licensing laws by states to protect the public from those whom they considered charlatans.[1]

State regulation grew from these limited laws to widespread and general regulation that we have today. The profession's experience is not an isolated example of increased State regulation, but is

[1] The AMA approved a report by the Committee on Uniform Legislation in 1889 advocating for the "enactment of efficient medical legislation in every State in the Union." American Medical Association, "Society Proceedings, American Medical Association: Official Report of the Fortieth Annual Meeting" (1889) 13 J Am Med Assoc 97 at 102. There were other reasons as well for the profession's support of licensing, including its economic protection, but public safety loomed large in the State's reasoning for eventually adopting licensure laws. See also Paul Starr, *The Social Transformation of American Medicine* (New York: Basic Books, 1982) at 102-112; Elton Rayack, *Professional Power and American Medicine: The Economics of the American Medical Association* (Cleveland: World Publishing Company, 1967) at 5.

reflective of the overall increase in governmental regulation that took place early in the 20th century and vastly expanded with the introduction of State-funded welfare programs. As the federal government began spending more money on health care and health-related activities, it sought greater regulatory control over the economic beneficiaries of its spending—physicians, health facilities, insurers and others who received State funds. Although regulation of physicians was initially the sole responsibility of the states pursuant to their police powers, the so-called "power of the purse" (and interstate commerce) gave the federal government a greater role in this regulation.

Federal and state law is now intimately connected to modern medicine. It attempts to ensure the safety of the medications we are prescribed (as well as those available without prescription), the proper functioning of our health facilities, the availability and fairness of health insurance,[2] and the proper training of licensed physicians. It does not do so perfectly, but the State has developed a complex and at times incomprehensible web of laws, regulations, and jurisprudence to regulate medicine more than almost any other single field.

My primary focus in this Chapter will be the state regulatory schemes that set forth the requirements to become a licensed physician and mechanisms to ensure competence and patient safety. In the broad structure of State regulation of physicians and the medical profession these licensing acts are only a small part, but all other laws depend on the physician's status granted by the individual states. Following an accounting of state licensing acts, I will briefly delve into other areas of state and federal law that impact the medical profession and its legal order. A more

[2] Although health insurance regulation is limited compared to other forms of medical regulation, the 2010 Patient Protection and Affordable Care Act attempts to provide some check on insurers' harmful practices. *Patient Protection and Affordable Care Act*, Pub L No 111-148, 124 Stat 119 (2010) [*PPACA*]. The Trump administration and a Republican-dominated Congress have promised to "repeal and replace" this legislation, but as yet have done neither.

detailed exploration of different forms of State regulation of the profession and physicians will take place in Chapters 6 and 7, as applicable to the specific topics discussed in those Chapters.

II. Who Can Be a Doctor?

A. Introduction

The answer to the question of who can be a doctor has changed greatly since the mid-19th century. Initially, there were few enforceable standards, and the profession was mostly left to its own means to determine education and training. At the same time, individuals without the training that medical societies attempted to impose could also claim to be health practitioners, and the lack of State regulation permitted them to claim the title "physician" with little resistance except from the profession—which anyway had no real power to prevent this.

The organized medical profession promoted a particular ideal of who could and should be a physician, one that eventually was adopted into state licensing acts. Despite challenges from other types of health practitioners—or physicians who ran or graduated from substandard medical colleges[3]—the professional descendants of physicians who had formed the AMA and its constituent medical societies were the victors. It became their standards that determined who could be licensed.

Early licensing laws might have included graduation from a medical college as the criterion for licensure, without any control over the quality of that education and training.[4] As medical practice became more complex, standardized testing became a consideration. Today it is a combination of education and testing that determines basic competency to become a physician: graduation from

[3] *Dent v West Virginia*, 129 US 114 (1889); *State ex rel. Johnston v Lutz*, 38 SW 323 (Mo Sup Ct 1896).
[4] Starr, *supra* note 1 at 104-106.

an accredited medical school, completion of a post-graduate training program (residency), and sufficient scores on the United State Medical Licensing Examination (USMLE).[5]

State regulation of the medical profession evolved as the relationship between physicians and the State evolved. Health care as a subject of states' police power provided the impetus for states' intervention in medical practice, but health care as a complex and expensive system is also correlated with changes in how the State regulated health care and the medical profession. With each decade, the balance between State regulation and professional self-regulation has tipped more and more in favor of the State. The profession's monopoly over licensing boards has ended, judicial interpretation of anti-trust law limits the ability of the profession to promote its economic interests, and legislative and judicial restraints on a variety of medical practices has changed both the profession's financial outlook and physicians' ability to practice freely. All of these, and the myriad other physician and medical regulation stem from the same basic consideration: who is a physician, and how does he or she become one?

B. Physician Licensure and Discipline

1. Medical Licensing Acts

Today, every state has a medical licensing law, all of which are comparable although not identical. In order to become and remain a practicing physician, physicians must comply with the requirements of these laws in each state where they wish to practice.[6] The Federation of State Medical Boards (FSMB) publishes its *Essentials of a State Medical and Osteopathic Practice Act*

[5] See e.g. Federation of State Medical Boards, *Essentials of a State Medical and Osteopathic Practice Act, April 2015* (Washington, DC: Federation of State Medical Boards, 2015) at 10-12.

[6] An exception to this is the Interstate Medical Licensure Compact, which creates a multi-jurisdictional medical license. This is not yet active in many states. Interstate Medical Licensure Compact Commission "Interstate Medical Licensure Compact", online: Interstate Medical Licensure Compact <http://www.licenseportability.org/>.

as a model law,[7] and while states are free to design their licensing laws however they want the FSMB's model is an important baseline, thus there are many commonalities amongst the states' solutions for medical licensing.

First, it is useful to assess what the State thinks the practice of medicine is, something that is highlighted in the *Essentials*. In the FSMB's view, the practice of medicine consists of many things, including prescribing drugs and devices, "offering or undertaking to prevent or to diagnose, correct, and/or treat in any manner or by any means, methods, or devices any disease, illness, pain, wound, fracture, infirmity, defect, or abnormal physical or mental condition of any person, including the management of pregnancy and parturition", and performing any surgical procedure.[8] The practice of medicine also includes holding oneself out as a physician and using the title of doctor or physician (or Dr. or MD) in the context of providing any services otherwise considered the practice of medicine.[9] Importantly, especially in the topics to be examined in the next Chapter, the practice of medicine includes "rendering a determination of medical necessity or a decision affecting the diagnosis and/or treatment of a patient…."[10]

Second, if a person is engaged in the practice of medicine, what must they do to do so legally? According to Tennessee, "no person shall practice medicine…unless and until such person has obtained a license from the [Board of Medical Examiners]."[11] This is the usual requirement, but raises the follow-up question of how one qualifies for a license. The *Essentials* and state laws generally set forth minimum educational qualifications. Illinois, for example, requires graduation

[7] Federation of State Medical Boards, *supra* note 5.
[8] *Ibid*. at 5.
[9] *Ibid*. This would not prevent an individual holding a doctorate in another field from using the title "Dr." so long as this person is not also trying to practice medicine.
[10] *Ibid*.
[11] Tenn Code Ann § 63.6.201(a) (2016).

from a medical or osteopathic college (inside or outside of the US), two years of previous liberal arts education, and at least a year of postgraduate clinical training (residency).[12] Texas has similar requirements, except that post-medical school training for individuals educated and trained outside of the US and Canada is two years instead of one.[13] Interestingly, and unlike Texas, Illinois and similar jurisdictions, the *Essentials* suggests that applicants for a medical license have *three* years of post-graduate clinical training rather than one.[14] The AMA notes that medical residencies typically extend from three to seven years depending on specialty and program.[15]

In addition to formal medical education and clinical training, license applicants are expected to have passed an examination as specified by the state, generally the USMLE,[16] although state law might not specify the particular exam. Texas, like many states, requires only that the applicant have "passed an examination administered or accepted by the board…."[17] In these instances, medical boards are given flexibility to change requirements as need arises, but might still specify the USMLE in medical regulations (rather than statutes) like Texas,[18] Illinois[19] and Maryland[20] all do.

These basic requirements for licensure are only nominally controlled by the individual states. Recall that the primary reason the medical profession advocated for medical licensing acts by the late 19th century was to ensure a certain quality of physician and type of training, but at that time

[12] 225 Ill Comp Stat 60/11(A) (2016). There are slightly different requirements for graduates of foreign, non-Canadian medical schools.
[13] Tex Occ Code Ch 3 §155.003(a) (2016). Texas' requirements are much more concise than those in Illinois.
[14] Federation of State Medical Boards, *supra* note 5 at 12.
[15] American Medical Association, "Requirements for Becoming a Physician", online: American Medical Association <http://www.ama-assn.org/ama/pub/education-careers/becoming-physician.page?>.
[16] *Ibid*.
[17] Tex Occ Code Ch 3 §155.003(a) (2016).
[18] 22 Tex Admin Code § 163.6 (2016).
[19] Ill Admin Code tit 68 §1285.60 (2016).
[20] Md Code Regs § 10.32.01.03 (2016).

medical education was in the hands of the profession—or at least the education that the organized profession wanted recognized as sufficient for licensure. This aspect of licensure remains true today: the Liaison Committee on Medical Education is the primary accreditation resource for US medical schools, and "is jointly sponsored by the Association of American Medical Colleges (AAMC) and the American Medical Association (AMA)."[21] Neither of these entities is controlled by the State, giving the profession and the medical schools themselves substantial influence over medical education. Likewise, the primary licensing examination, the USMLE, is developed by the Federation of State Medical Boards and the National Board of Medical Examiners (NBME).[22] The FSMB represents the interests of state medical licensing agencies, and therefore to some extent the State, but the NBME is an independent assessment organization.

In addition to granting initial licenses, states also require physicians to maintain competency through continuing medical education (CME).[23] Yet here again the State defers to non-State entities to develop appropriate programs. California, for example, accepts programs approved by the California and American Medical Associations and American Academy of Family Physicians, although it also accepts "[p]rograms offered by other organizations and institutions acceptable to the division [of Licensing]."[24] Rather than design CME programs itself, the State delegates this to others who are better positioned to design appropriate educational programs to meet the needs of a wide variety of medical specialties.

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[21] Liaison Committee on Medical Education, "Frequently Asked Questions", online: Liaison Committee on Medical Education <http://lcme.org/faqs/>.
[22] Federation of State Medical Boards & National Board of Medical Examiners, "What is USMLE?", online: United States Medical Licensing Exam <http://www.usmle.org/>.
[23] See e.g. Cal Bus & Prof Code § 2190 (2016).
[24] Cal Code Regs tit 16 § 1337(a)(3) (2016).

The requirements for licensure and for maintaining a medical license are sensibly closely connected to the medical profession. Given the national nature of health care and the chaos that would occur if each state had its own requirements for CME, examination and education, as used to be the case, it makes sense that national bodies are primarily responsible for determining these standards. Furthermore, the State has never been in the business of designing the content of education, other than primary and secondary. There is a long history of the medical profession's involvement in education, and until a time when the current structure is no longer effective there is little chance that states will take a more active role in designing education programs, not least because of the cost and expertise required to do so.

All the above indicate that states hold the ultimate responsibility for licensing physicians. The content of medical licensing acts, though, also illustrate the reliance of the State on the medical profession to determine appropriate standards. The profession might be answerable to the State, but it also retains substantial power to determine the fitness of members. This is a successful implementation of the original vision of a unified medical profession represented by the establishment of the AMA in 1847. The State might be the muscle, but the profession remains the brain.

2. Medical Board Disciplinary Action

a. What constitutes grounds for action?

A second core function of state medical licensing authorities is their capacity to act against licensees who act in contravention of established norms. Physicians must not only meet basic educational and competency requirements; they must also comport themselves in a specific manner in order to retain their status as licensed physicians. State licensing laws generally contain

a long list of grounds for disciplinary action, and violation can lead to probation, suspension, revocation or other similar actions against a physician's license.[25] The FSMB's *Essentials* provides a useful compilation of the possible grounds, although individual states differ on the exact content. Many of the provisions relate to fraud, deception or dishonesty of some sort or another, such as misrepresentations in applying for a license, "conduct likely to deceive, defraud or harm the public", or making inaccurate statements to patients about the capacity to cure a condition.[26] Activities that would be illegal for non-physicians can also constitute grounds for licensure action, including drug abuse and conviction of a felony unrelated to the practice of medicine.[27]

Many the provisions in *Essentials* have direct corollaries in medical ethics. "Willfully or negligently violating the confidentiality between physician and patient" is prohibited, as it is by the AMA's *Code* and virtually every medical society statement on the matter.[28] Other prohibitions that are common both to the *Essentials* and medical ethics include false, fraudulent or deceptive testimony provided as an expert witness, failing to report physical or mental disability that impacts the physician's ability to practice medicine, and sexual misconduct.[29]

In all, the *Essentials* lists 59 grounds for disciplinary action against physicians, including a violation of professional ethics (a "national code") as acknowledged by the state Board, which would bring "the medical profession into disrepute…."[30] This potentially incorporates the AMA's

[25] Depending on the physician's action, licensure sanction can be preceded by or accompanied with criminal or civil monetary penalties.
[26] Federation of State Medical Boards, *supra* note 5 at 17-22.
[27] *Ibid*.
[28] *Ibid.* See also Council on Ethical and Judicial Affairs, *Code of Medical Ethics: Current Opinions with Annotations, 2010-2011* (Chicago: American Medical Association, 2010) at 160 [CEJA, *Code of Medical Ethics*].
[29] Federation of State Medical Boards, *supra* note 5 at 19.
[30] *Ibid*. at 21.

Code of Medical Ethics as the law of the state if a state's medical act were to contain this or a similar provision.

In the area of physician discipline, the lack of uniformity amongst state medical practice acts makes state laws difficult to reconcile despite the availability of a model act representing the opinion of the medical boards themselves. In reviewing the laws, it is clear that all share the same concerns with physicians who are convicted of crimes (including of "moral turpitude"), are disciplined by other states (who wants to license a physician who has been stripped of his or her license in another state?), have sexual relations with patients, or prescribe medications illegally. The number of provisions that are shared amongst the states is large—the above are just a few—but the variation is also substantial.

This is apparent by the use or lack thereof of "unprofessional conduct" and the reference to professional codes of ethics, or even ethics at all. The *Essentials* puts a wide range of behaviors under the umbrella of "unprofessional conduct", including ethics violations.[31] The individual states, though, often make neither "unprofessional conduct" nor ethics violations quite so clear. Many states refer to the broad and potentially limiting (from an ethics viewpoint) unprofessional conduct in their licensing statutes, but fewer refer to ethics, unethical behavior, or professional ethics codes or codes of conduct (see Table 1). Five make no reference to unprofessional or unethical conduct at all. This represents a disconnect between the profession and the legislatures that regulate it, especially if the FSMB's own model act is not influential enough to have greater impact in the legislative process.[32]

[31] *Ibid*.

[32] It is possible that the lobbying efforts of medical societies has led to the modification of various aspects of the *Essentials*, but it is unlikely that medical societies, especially the state societies and the AMA, would lobby against

This variation between states in how they address unprofessional or unethical conduct has implications for the profession as well as for individual physicians. For example, a physician in Kentucky, which has adopted the AMA's *Code*,[33] could have his or her license revoked or suspended for ethical misconduct, while a physician in Florida would not because the Florida *Medical Practice Act* makes no mention of unethical behavior as grounds for action.[34]

The clear implication for individual physicians is that acceptable conduct might differ greatly between states, where the adoption of the AMA's *Code* or even the less specific inclusion of "unethical behavior" as a basis for licensure action provides for a broad range of conduct to which the physician must conform. This is important because medical boards are unable to take action against a physician for grounds not included within the statute or related regulations, and even the general phrase "unethical behavior" might not provide sufficient specificity to put physicians on notice that there is an expectation that a certain type of ethic is to be respected.

For the profession as a whole, the inconsistent manner in which ethics norms are incorporated or referred to in state licensing acts sends the signal that ethics is not really all that important to states, or at least not to the states that have yet to adopt the *Code* or make some other effort to incorporate ethics as a foundation for practice. There is no explanation as to whether the omission is intended as a way to maintain State control over the activities of physicians;[35] however, the inclusion of a provision referencing ethics in the FSMB's *Essentials of a Modern Medical and Osteopathic*

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the reference to the AMA's *Code* in medical practice acts. As well, model acts for any type of law are rarely enacted without modification, as the needs, traditions, and capacities of each state are different.

[33] Ky Rev Stat § 311.597 (2014).

[34] Fla Stat § 458.331 (2014). Surprisingly, the only place that the term "ethical" appears in the Medical Practice Act is in a section related to medical assistants. Fla Stat § 458.3485 (2014).

[35] A Georgia court made clear that the AMA has no role in legislating ethics for the state. *Zitrin v Georgia Composite State Board of Medical Examiners*, 2005CV103905 (Fulton County Superior Ct, 31 July 2005).

Practice Act is indicative that the state medical boards themselves find no difficulty with using medical ethics violations as grounds for discipline.

An additional topic of note under the general umbrella of state licensing laws is the way some states regulate specific practices through disciplinary provisions. This is closely related to politics and public awareness of certain medical procedures and will be detailed more in the next Chapter, but these deserve mention here due to their incongruity within the context of the grounds for discipline that are otherwise provided by law.

Disciplinary rules regarding abortion are the most common of these practice-specific grounds. These are interesting in part because often the actions prohibited are implied by other parts of the law. For example, Mississippi law prohibits "[p]rocuring, or attempting to procure, or aiding in, an abortion that is not medically indicated."[36] This is the only place in the section that refers to a specific medical procedure. As well, this would likely also constitute unprofessional conduct[37] and would certainly fall within medical malpractice statutes (performing an unnecessary medical procedure). Alabama's provisions for abortion within the disciplinary law are even more detailed, prohibiting most abortions during the third trimester and restricting abortions prior to the third trimester to certain facilities and by physicians with the necessary training.[38] Much like Mississippi's law, these provisions stand out in a statute that otherwise contains general disciplinary grounds without reference to specific practices.

[36] Miss Code § 73-25-29(5) (2014).
[37] Miss Code § 73-25-29(8)(d) (2014).
[38] La Rev Stat § 1285(8)-(9), (27)-(28) (2014).

Like abortion, breast cancer is a matter of substantial public interest. Although it is much less common to have standards for breast cancer and mammography in disciplinary provisions of licensing acts and regulations, Utah has a very detailed provision in its regulations:

> "Unprofessional conduct" includes:…(9) supervising the providing of breast screening by diagnostic mammography services or interpreting the results of breast screening by diagnostic mammography to or for the benefit of any patient without having current certification or current eligibility for certification by the American Board of Radiology. However, nothing in this subsection shall be interpreted to prevent a licensed physician and surgeon from reviewing the results of any breast screening by diagnostic mammography procedure upon a patient for the purpose of considering those results in determining appropriate care and treatment of that patient if the results are interpreted by a physician and surgeon qualified under this subsection and a timely written report is prepared by the interpreting physician and surgeon in accordance with the standards and ethics of the profession;….[39]

This is a very detailed requirement for a specific procedure, and the only such instance in this section. Interestingly, board certification is not required to obtain a medical license although it provides an additional qualification. Further, a physician who does the acts listed in this provision and is unqualified to do so would certainly be subject to discipline through other provisions of the disciplinary statute as well as through medical malpractice liability if a patient was harmed.

Medical licensing acts are the backbone of State physician regulation, and determine who can practice medicine in a given jurisdiction. Despite this importance, states' treatment of medical ethics—the backbone of physician self-regulation—create doubt in most states as to the capacity of medical boards to regulate physician behavior based upon ethical standards promulgated by medical societies. This does not necessarily impact the capacity of medical societies to do so, but since medical boards are also a form of self-regulation (albeit as creatures of State law) the role of ethics in the modern profession might be circumscribed by the lack of recognition or even

[39] Utah Admin Code r 156-67-502(9) (2014).

acknowledgement in states' laws.

b. How are physicians disciplined?

Grounds for disciplinary action are backed up by laws and rules that provide physicians with due process and fair hearings in the state's deliberation of claims against them. As with any State judicial or administrative process, individuals are guaranteed that the State will not act without procedural protections in place.

For the most part, and like medical societies, state medical boards do not initiate action against licensees without some kind of external complaint, whether it be from a patient or a colleague, or knowledge of a court order or other civil or criminal action. If the information proves reliable and following a hearing, boards are empowered by medical practice legislation to suspend or revoke physicians' licenses or take lesser actions such as censure or probation (much like medical societies).[40] Given the greater due process requirements placed on the State compared to voluntary societies, judicial processes are generally strictly adhered to.[41] Boards take evidence and depending on the circumstances might hear from witnesses, and their decisions, like those of other state administrative bodies, are appealable to the general courts.[42]

State boards make available the names of those physicians who have had action taken against their licenses. Some states also provide greater information to the public about the action taken, either

[40] See e.g. Ga Code § 43-34-5(c)(10) (2014).
[41] See e.g. Ga Code § 43-34-9 (2014); 225 Ill Comp Stat 60/22 (2014); Neb Rev Stat ch 38 (2016). See also William P Gunnar, "The Scope of a Physicians' Medical Practice: Is the Public Adequately Protected by State Medical Licensure, Peer Review, and the National Practitioner Data Bank?" (2005) 14 Ann Health L 329.
[42] One challenge by licensees to state disciplinary laws is that they are ambiguous or vague, a constitutional challenge. However, this argument is difficult to prove. See e.g. *Finucan v Maryland Board of Physician Quality Assurance*, 846 A 2d 377 (Md Ct App 2004); *Haley v The Medical Disciplinary Board*, 818 P 2d 1062 (Wash Sup Ct 1991).

by providing full documents,[43] summaries,[44] or a list of specific cases.[45] This is more than most medical societies do (see Chapter 4), but states are also bound by open records law to disclose non-confidential information to the public upon request.[46]

A brief survey of available state licensing board disciplinary records[47] demonstrates that medical ethics are not a common basis for a board taking disciplinary action, at least not directly. Much of the available information indicates that substance abuse (alcohol and illegal or prescription drugs), prescribing, and patient relationship issues lead to many of the disciplinary actions.[48] Although state records do not commonly reference the AMA *Code*[49] or other ethical foundations

[43] Maryland Board of Physicians, "Disciplinary Alerts", online: Maryland Board of Physicians <http://www.mbp.state.md.us/pages/disciplinary.html>; North Carolina Medical Board, "Immediate Disciplinary Notices", online: North Carolina Medical Board <http://www.ncmedboard.org/disciplinary_reports> (this page links to licensee information pages for the individual physicians, where more documents are available).

[44] For example, Alaska provides a list of disciplinary actions with a "reason for action" category, although this is not very enlightening in many instances as summaries often refer to actions or investigations in other states or withdrawal of applications for "unspecified reasons." Alaska State Medical Board, "Board Actions", online: Alaska State Medical Board <https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/StateMedicalBoard/BoardActions.aspx>. Washington State provides a more detailed summary in the medical board's newsletter, which is available electronically. Washington State Medical Commission, "Publications by the Commission", online: Washington State Medical Commission <http://www.doh.wa.gov/LicensesPermitsandCertificates/MedicalCommission/MedicalResources/Publications>. The public can also search for specific licensees and if there has been disciplinary action taken against him or her it might be available on the Commission's website. Iowa provides detailed summaries in a monthly disciplinary newsletter. Iowa Board of Medicine, "Discipline Press Releases and Agency News Releases", online: Iowa Board of Medicine <http://www.medicalboard.iowa.gov/Press/index.html>.

[45] Alabama lists recent actions without providing information as to why the physician was disciplined, although the public can request copies without fee of "public disciplinary documents." Alabama Board of Medical Examiners & Medical Licensure Commission of Alabama, "Disciplinary Actions", online: Alabama Board of Medical Examiners <http://www.albme.org/actions.html>.

[46] For example, the Kentucky Board of Medical Licensure permits the public "to make a written request pursuant to Kentucky Open Records" for more detailed information about a disciplinary case. Kentucky Board of Medical Licensure, "Board Action Reports", online: Kentucky Board of Medical Licensure <http://kbml.ky.gov/board/Pages/Board-Action-Reports.aspx>. See Ky Rev Stat § 61.872 (2014).

[47] Many states provide public access through licensing board websites to either a list of physicians who have been disciplined or detailed orders or other documents providing information about the grounds for action. A detailed study of these documents is beyond the scope of this Thesis, but would provide interesting data as to how and why physicians as a whole are disciplined.

[48] See e.g. Darren Grant & Kelly C Alfred, "Sanctions and Recidivism: An Evaluation of Physician Discipline by State Medical Boards" (2007) 32 J Health Pol'y 867.

[49] CEJA, *Code of Medical Ethics*, *supra* note 28 at 297, 302.

for the legal prohibitions of these activities, professional ethics have long addressed physician substance abuse and inappropriate patient relationships.

In addition to state medical boards making disciplinary actions publicly available, the federal government also collects information on disciplinary actions, malpractice awards, credentialing decisions and medical society membership actions. The National Practitioner Data Bank (NPDB) was created as part of the Health Care Quality Improvement Act of 1986.[50] The US Congress found that "(1) The increasing occurrence of medical malpractice and the need to improve the quality of medical care have become nationwide problems that warrant greater efforts than those that can be undertaken by any individual State [and] (2) There is a national need to restrict the ability of incompetent physicians to move from State to State without disclosure or discovery of the physician's previous damaging or incompetent performance."[51] The NPDB was intended to address the problem alluded to above: the lack of investigation or cooperation between states.

The federal government does not itself discipline physicians in the same manner as state medical boards. Its primary means of sanctioning physician behavior or activity is through exclusion from federal programs or civil or criminal prosecution pursuant to federal law, although none of these directly impacts a physician's medical license since the federal government is not empowered to revoke it.[52] The creation of the NPDB provided an additional mechanism to ensure that physicians' misdeeds are communicated to appropriate parties. However, one flaw in this system—if one chooses to consider this a flaw—is that the public cannot access information contained in the data

[50] *Health Care Quality Improvement Act of 1986*, Pub L 99-660, 100 Stat 3784 at Title IV.
[51] 42 USC § 11101 (2014).
[52] However, an action that leads to federal or judicial sanctions can also lead to state medical board sanctions.

bank, aside from general statistics.[53] Thus, while medical boards, health facilities and medical societies are all required to report actions to the NPDB[54] and are generally required to consult the data bank before credentialing or granting a license,[55] patients cannot consult the databank for information on their physician despite this being a potentially more complete source of information than anything available from individual states.[56]

The creation of the NPDB also highlights the continuing challenges of a state-by-state method of licensing and discipline. Generally, physicians must apply to each state where they want to practice to obtain a separate license from each state. This is no different from attorneys, and like attorneys there are exceptions to the requirement to have an unrestricted license if the physician is already licensed in another state.[57] Unlike the practice of law, though, there is no difference in how medicine is (or should be) practiced across the US. Each state has its own peculiar laws—and certainly peculiar ways of organizing them—but the purpose of a general curriculum and a nationally recognized licensing examination is to create uniformity across the profession so that a physician educated in Oregon has the same knowledge and can practice in the same manner as one educated in Maine.

Much of the difference in medical practice across states comes from how each state regulates what physicians can and cannot do. As noted above, states might regulate medical procedures

[53] 45 CFR § 60.13 (2016). Under this provision, the only time an individual can request identifiable information is in relation to a medical malpractice action or claim. Otherwise, access to information by the public is limited to "statistical information, in a form which does not permit the identification of any individual or entity." 45 CFR § 60.13(a)(1)(vii) (2016).
[54] 42 USC §§ 11132-11133 (2014); 45 CFR §§ 60.9-60.11 (2014).
[55] 42 USC § 11135 (2014); 45 CFR §§ 60.12, 60.13 (2014).
[56] 45 CFR § 60.15 (2014) ("[i]nformation reported to the NPDB is considered confidential and shall not be disclosed outside the Department of Health and Human Services, except as specified in §§ 60.12, 60.13, and 60.16").
[57] See e.g. Ky Rev Stat § 311.560(2) (2016); Or Rev Stat § 677.060 (2016); Rev Code Wash § 18.71.030 (2016). A common and interesting exception is for licensed physicians from another state accompanying a sports team for an event in the state.

differently from each other, and the examples of abortion and physician-assisted suicide will be discussed in next Chapter. There have been efforts to promote a national licensure, but so far these are in their infancy and do not otherwise displace state disciplinary rules.[58] Even the FSMB, which supplies model provisions for a medical practice act, has been unable to create uniformity in the face of political considerations that regularly take precedence over typical regulatory considerations. Despite the vast similarity in how states attempt to regulate physicians, there are still some differences and a resistance to uniformity across the country.[59] Yet, states' licensing continues to serve as the most effective way to ensure that physicians meet basic training requirements and, to a more limited extent, behave in a manner befitting a "professional."

III. The Wide World of Health Law

A. Introduction

Medical licensing and disciplinary actions are the primary means the State has to control the entry into and practice of medicine. As shown in the previous Section this is not solely a State-directed endeavor, as the medical profession has always had a strong role since the reintroduction of medical licensing laws in determining medical education and clinical training requirements. However, there are many other laws aside from licensing that influence directly and indirectly how

[58] The Interstate Medical Licensure Compact is one example, and is promoted as a way to permit physicians to practice across multiple states, and potentially ease patient access issues in rural areas. Robert Steinbrook, "Interstate Medical Licensure: Major Reform of Licensing to Encourage Medical Practice in Multiple States" (2014) 312 J Am Med Assoc 695. Roughly 17 states have enacted Compact statutes, mostly in 2015, so it is too early to know how effective these will be in accomplishing the purposes of the Compact. Interstate Medical Licensure Compact Commission, *supra* note 6. See also *Interstate Medical Licensure Compact Act*, 45 Ill Comp Stat 180/ (2016); Wyo Stat § 33-26-701 et seq (2016).

[59] See e.g. Association of American Physicians and Surgeons, "Help Stop the MOC Trojan Horse, the Interstate Medical Licensure Compact", online: Association of American Physicians and Surgeons <http://aapsonline.org/help-stop-the-moc-trojan-horse-the-interstate-medical-licensure-compact/>. This organization is a conservative physician group that regularly opposes the AMA and regulatory actions by the State. See also Lisa Frappier, "New Medical Licensure Plan a Bad Idea", *Providence Journal* (19 May 2016) online: Providence Journal <http://www.providencejournal.com/article/20160519/opinion/160519189>.

and whether physicians can practice medicine. These range from facilities and insurance regulation to exacting standards for medical practices or procedures. Some relate to states' responsibilities to protect public health, and others are authorized by the State's power to control its spending.[60] I will not cover these in detail here, but will provide an overview of the variety of ways in which the State regulates physicians in addition to its basic licensing functions.

B. State and Federal Health Care Programs and Provision of Care

Money is at the core of our health care system. I do not mean this in a negative way, although there are certainly negative aspects to money in health care (see conflicts of interest, Chapter 7). What I mean is that because they are paid for their services, physicians can be at the mercy of whomever is paying them. Before the widespread use of health insurance by the mid-20th century, physicians were paid by patients or by barter. With some exception for charity care, if a patient could not pay in some way physicians were under no obligation to treat them. With the expansion in both the use and cost of technology and health facilities, the individual patient is no longer the primary source of payment.

The State has become an important payor in the US health care system, exceeding the expenditures of private insurance.[61] In this expansive role, the State uses laws and regulations to set limits or attach conditions to payment.[62] For the federal Medicare program especially, laws and regulations have served as vehicles to define the boundaries of appropriate care and what will be paid for.

[60] The State is the single largest financier of health care in the US, outpacing spending by private sources and giving it significant leverage over medical practices. David U Himmelstein & Steffie Woolhandler, "The Current and Projected Taxpayer Shares of US Health Costs" (2016) 106 Am J Pub Health 449.
[61] *Ibid*.
[62] Most of the laws and regulations discussed in this Section were enacted on the basis of the State's role as payor, especially for the federal government, which otherwise has little constitutionally-based jurisdiction over matters of health care or insurance aside from the sometimes-tenuous interstate commerce clause.

This control is at times necessary to avoid duplicitous or unnecessary services, and hence save money for other uses. Decisions by payors also determine exactly what care is provided (unless an individual pays for his or her care directly); thus, if a payor will not pay for a service it generally will not be provided.

One way that Medicare (and private insurance) attempted to control costs and the risks of waste and fraud was through the development of procedure codes and diagnostic-related groups (DRGs) for use primarily in the hospital environment.[63] DRGs group all services used for a particular treatment or procedure into one reimbursement.[64] The intent is to provide a single payment for a particular service, rather than multiple payments for the various components of the service, which created potential for fraud and abuse.[65] In addition to providing more consistency in payment, DRGs generated a new form of control over physicians, in part by changing coding habits and encouraging hospitals and other health facilities to pay closer attention to reimbursement practices.[66]

The federal government has also instituted a program for review of the utilization and quality of health care, intended to ensure that services provided to Medicare beneficiaries are both medically necessary and of high quality.[67] This program empowers "quality improvement organizations" contracted with the Department of Health and Human Services to review care provided by physicians and hospitals and determine "whether payment shall be made for services…."[68]

[63] Mirella Cacace & Achim Schmid, "The Role of Diagnosis Related Groups (DRGs) in Health Care System Convergence" (2009) 9 BMC Health Serv Res A5.
[64] Kevin Quinn, "After the Revolution: DRGs at Age 30" (2014) 160 Ann Intern Med 426.
[65] *Ibid*.
[66] *Ibid*.; Cacace & Schmid, *supra* note 63.
[67] 42 USC § 1320c et seq. (2016).
[68] 42 USC § 1320c-3(a)(2) (2016). Physicians (and health facilities and patients) are entitled to a hearing if they want the organization's determination of non-payment to be reconsidered. 42 USC § 1320c-4 (2016).

Programs like this and similar ones instituted by private insurers are intended to promote cost savings and a better quality of care, but are charged with investigating beneficiary quality and service complaints.[69]

While DRGs represent regulation of physicians through payment formulas and quality improvement organizations through external review of services and charges, other regulation developed because of the State being a high-volume payor for health services, having "skin in the game," so-to-speak. Certainly, some of these laws and regulations were intended to protect patients and inhibit the translation of money into actionable conflicts of interest, and have served to this effect.[70] Yet other laws that outline the specific procedures eligible for payment, their value,[71] and their medical validity have also had important effect. Only recently has the federal government recognized the importance of primary care as a means of preventing higher costs later.[72] Given the expansiveness of Medicare rules and payment mechanisms, it has influenced private insurance practices as well.

Medicaid, on the other hand, can be viewed as the black sheep of the State health care programs. Its payment scales are set by individual states and the federal government provides only a broad outline of what these programs must do and cover.[73] There can be wide disparities between states, which in turn effects the kind of amount of care that citizens of each state can receive. Its lower

[69] 42 USC § 1320c-3(a)(14) (2016).
[70] Both the Emergency Medical Treatment and Active Labor Act and Stark Laws are examples of this, and will be discussed briefly below.
[71] Herzlinger argued that insurer and State determinations of high payment levels for some forms of care has worsened the effects of self-referral. Regina E Herzlinger, "Specialization and Its Discontents: The Pernicious Impact of Regulations Against Specialization and Physician Ownership on the US Healthcare System" (2004) 109 Circulation 2376.
[72] See *PPACA*, *supra* note 2 at tit 1 § 1001(5); 42 USC § 300gg-13 (2016).
[73] 42 USC § 1396a (2016). The Patient Protection and Affordable Care Act expanded Medicaid coverage, but the US Supreme Court held that the federal government could not require states to accept the expansion. Many states have not, forgoing the additional funding provided by the federal government. *National Federation of Independent Business v Sebelius*, 132 S Ct 2566 (2012).

reimbursement—compared to Medicare—also influences the direction of physician practice, as it can deter physicians from taking Medicaid patients or from ordering otherwise expensive care that is not reimbursed (which might be for the benefit of the patient, who would otherwise be liable for payment).[74] For physicians and the medical profession, Medicaid creates a conundrum: the profession supports access to health care and health justice,[75] but the program most likely to improve access and individual health is also not very popular politically, pays poorly compared to other programs, and an easy target for claims of waste and abuse.[76] In addition, the cost of providing care to un- and underinsured patients[77] has led to dubious practices by health facilities to avoid providing care, necessitating the federal government to enact a law to address the actions of emergency rooms.

C. Medical Emergencies and Active Labor

Some statutes are linked to encouraging behavior by physicians and health facilities that is desirable from both the State's and the profession's perspective. The federal Emergency Medical Treatment and Active Labor Act (EMTALA) is one of these, and requires hospitals with emergency departments to examine and stabilize a patient presenting with an emergency condition

[74] In an Illinois case, a physician informed a Medicaid patient that the state's Medicaid program would not pay for genetic testing to determine risk for breast cancer, but did not inform her that grants were available to cover the costs. *Downey v Dunnington*, 895 NE 2d 271 (Ill Ct App 2008). The physician argued that he was merely stating the fact that the patient would be liable for any costs not covered by her health program.

[75] The AMA's Principle of Medical Ethics IX states "[a] physician shall support access to medical care for all people." CEJA, *Code of Medical Ethics*, *supra* note 28 at xvii. Opinions in the *Code* address such topics as civil rights and health care, and gender, racial and ethnic disparities in health care. *Ibid*. at 320, 352, 354.

[76] Josh Levin, "The Welfare Queen", *Slate* (19 December 2013) online: Slate <http://www.slate.com/articles/news_and_politics/history/2013/12/linda_taylor_welfare_queen_ronald_reagan_made_her_a_notorious_american_villain.html>; John Blake, "Return of the 'Welfare Queen'", *CNN* (23 January 2012) online: CNN <http://www.cnn.com/2012/01/23/politics/weflare-queen/>.

[77] The vagaries of state Medicaid qualifications means that in some states even being well below the poverty level does not mean you qualify for Medicaid if you are single or childless. In some circumstances children can be covered by state health programs, but their parents are not. See e.g. 42 USC § 1396u-1(b)(3) (2016). States also have separate programs providing health care just to children, the State Children's Health Insurance Program (SCHIP), which can insure children even if their parents are not covered by Medicaid or other health insurance. 42 USC § 1397aa et seq (2016).

or in active labor prior to transferring the patient.[78] Although the requirement to stabilize is not phrased in terms of the hospital's participation in Medicare, the penalty section is.[79] This combined with EMTALA's placement in Title 42 of the US Code related to Medicare implies that it is the federal government's role in administering Medicare that authorizes it to require these services.

Although EMTALA creates obligations for hospitals this requirement filters down to physicians who have privileges at or are employed by the hospital, as it is these individuals who must treat patients admitted pursuant to EMTALA. This act was passed to address the problem of "patient dumping," where a hospital would refuse to treat or would release a patient still in need of care due to the patient's inability to pay.[80] The role of physicians in this practice is not well-explored, but certainly such practices violate ethical duties to treat patients once a relationship begins and to provide emergency treatment.[81]

EMTALA creates a basic standard that patients presenting with emergency conditions (or in active labor) must be stabilized—that a hospital must "provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility…."[82] This standard still allows for physician discretion, but creates a high barrier to patient

[78] 42 USC § 1395dd(a)-(c) (2014).
[79] 42 USC § 1395dd(a) & (d) (2014).
[80] See generally United States Government Accountability Office, *Emergency Care: EMTALA Implementation and Enforcement Issues, Report to Congressional Committees* (Washington, DC: Government Accountability Office, 2001). The patient may be poor but ineligible (or unenrolled) for Medicaid, or have some financial means but has not purchased private insurance.
[81] CEJA, *Code of Medical Ethics*, *supra* note 28 at 278, 383. Principle of Medical Ethics VI also states that physicians are free to decide whom to treat, except in cases of emergency. *Ibid*. at xvii.
[82] 42 USC § 1395dd(e)(3)(A) (2014).

dumping.[83] The meaning of "stabilized" is "purely contextual or situational,"[84] and if a medical basis for failure to stabilize (such as inadequate facilities for the condition) can be shown liability can be avoided.

While this legislated attempt to address the problem of discriminatory treatment of poor or uninsured patients is laudable, it does create some uncertainty for physicians. The creation of a standard of care to "stabilize" means that hospitals and their physicians are open to lawsuits for transferring patients without stabilizing them, leaving the physicians and hospitals to prove that their decisions were based on medically valid reasons.[85] However, the concept that physicians provide treatment to patients rather than placing them at risk is well-grounded in medical ethics ideals.

D. Fraud and Conflicts of Interest

While EMTALA was intended to address the problem of too little care provided, other federal and state statutes address the problem of too much or the wrong kind of care. There is an intrinsic public interest in government money being well-spent, with a minimum of waste and corruption. It is safe to say that waste and corruption remain endemic to all of government,[86] much of it based

[83] See e.g. *Cherukuri v Shalala*, 175 F 3d 446 (6th Cir 1999) (anesthesiologist allowed to refuse to provide anesthesia that would have allowed operation because it would have been, in his opinion, too risky) [*Cherukuri*]. See also *Roberts v Galen of Virginia*, 525 US 249 (1999) (no requirement to show improper motive to establish a violation of EMTALA).
[84] *Cherukuri*, *supra* note 83 at 449.
[85] See e.g. *ibid*.; *Morin v Eastern Maine Medical Center*, 780 F Supp 2d 84 (D Me 2010). See *contra Matter of Baby K*, 16 F 3d 590 (4th Cir 1994) (court held that EMTALA must be interpreted to require stabilizing care, even if that care exceeds the general standard of care for like patients).
[86] See e.g. Transparency International, "Corruption Perceptions Index 2013", online: Transparency International <http://cpi.transparency.org/cpi2013/results/>. Under the measures used in this study, the US was ranked 19th of 177 countries analyzed. Of course, this is not an absolute measure of public corruption, but rather a study of public perception. Concrete examples of corruption include the 2010 conviction of Illinois Governor Rod Blagojevich, the trial of Former Virginia Governor Bob McDonnell in 2014 (his conviction was later overturned: although he accepted gifts and other things, these did not fit the definition of illegal activity he was convicted of), and the 2014 indictment of Texas governor Rick Perry.

on charges to the government for services provided, and not only in the field of medicine. However, various federal statutes attempt to address much of this, from the broad False Claims Act (FCA) to the more health care-relevant Stark Law.

The authority of the federal government to legislate in these areas is linked to its payment for health services. False Claims Act lawsuits are based on the premise that individuals and entities fraudulently bill the government for services presumably provided.[87] The allegation might be that the billed services were never provided, or that services actually provided were of lesser value than charged.[88] In addition, individuals are entitled to bring charges on behalf of the federal government and share in any recovery, encouraging whistleblower actions.[89] This is not a direct regulation of medical practices, but serves to provide a check on behavior that can have negative consequences for patients.

Anti-kickback and self-referral laws are more directed towards the medical profession than the FCA. These will be discussed in more detail in Chapter 7, but like the FCA they are intended to prevent financial and other relationships that pit physician economic interests against patient interests. Individual states have enacted these laws based on their general ability to regulate the practice of medicine,[90] but federally these laws are based primarily on the government's role as payor.[91] Anti-kickback and self-referral laws—and their exceptions[92]—provide a great amount of detail about what types of financial and investment relationships physicians can enter into.

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[87] 31 USC §§ 3729-3730 (2016) (civil penalty; right of private individuals to bring *qui tam* actions); 18 USC § 287 (2016) (criminal penalty).
[88] The statute's use of "false" provides a broad umbrella under which to prosecute a variety of claims. 31 USC § 3729(a)(1) (2016).
[89] 31 USC § 3730(b)-(d) (2016).
[90] See e.g. Cal Bus & Prof Code § 650.01 (2016); Fla Stat § 456.053 (2016); 225 Ill Comp Stat 47/ (2016).
[91] See e.g. 305 Ill Comp Stat 5/8A-2.5, 8A-3, 8A-3.5, 8A-13, 8A-14, 8A-15 (2016); 42 USC § 1320a-7b(b) (2016).
[92] There are exceptions to the general prohibition on self-referral, and these will be discussed in Chapter 7.

E. Privacy and Confidentiality

Medical privacy and the confidentiality of patient records are basic requirements in our health care system. Only in rare instances are physicians permitted to disclose medical information outside of the care context.[93] Common law and statutory law both dictate this, a requirement made even more formal by the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).[94] Individual states each have their own requirements for confidentiality as well as when this can be breached (e.g. gunshot and stabbing wounds), and the expansive federal law has provided additional detail and has incidentally caused a massive change in formal methods for ensuring and notifying of confidentiality rights (the widespread use of the HIPAA notice).[95]

Confidentiality and privacy are not new concepts in medicine. They have been a part of medical ethics since the advent of the Hippocratic Oath[96] and early and current iterations of the AMA *Code* continue to place confidentiality at the fore of physician ethical obligations.[97] What the State has added, though, is a level of detail not seen in ethics sources. The *Code*'s confidentiality provision is brief.[98] The federal HIPAA privacy rule, on the other hand, is voluminous and covers the gamut of situations where medical information might be used or is at risk.[99] State medical practice acts make the illegal breach of confidentiality an actionable offense; that is, if a physician discloses medical information without falling within an exception then he or she can be disciplined by the

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[93] *Tarasoff v Regents of the University of California*, 551 P 2d 334 (Cal Sup Ct 1976) (created the now generally-accepted standard that psychologist (and physicians) are required to warn third-parties of specific danger posed by patients); Mass Gen L ch 112 § 12A (2016); Rev Code Wash § 70.41.440 (2016).
[94] *Health Insurance Portability and Accountability Act*, Pub L No 104-191, 110 Stat 1936 (1996).
[95] 45 CFR pt 164 (2016).
[96] See e.g. June Goodfield, "Reflections on the Hippocratic Oaths" (1973) 1 Hastings Center Studies 79.
[97] CEJA, *Code of Medical Ethics*, *supra* note 28 (Principle of Medical Ethics IV requires physicians to "safeguard patient confidences and privacy within the constraints of the law" at xvii).
[98] *Ibid*. at 160.
[99] 45 CFR Pt 164 (2016).

medical board (on top of any other civil or criminal penalty provided by law).[100] Thus, the primary contribution of State law to confidentiality and privacy is to provide additional detail to what is and is not permitted over and above the generally vague and broad ethics standards and the ability to penalize violations more stringently than the profession can.

F. Contract Law and Insurance Regulation

The topics of contract law and insurance regulation are not directly related to the practice of medicine and the regulation of physicians, but physicians' existence within a health care market economy connects them to these forms of regulation. Freedom to contract is an immutable characteristic of our current economic system. The State regulates at the edges to ensure a minimally level playing field (e.g. age at which one can sign a contract; union laws) but overall adults of contracting capacity are left to themselves to compete within this system. The general rules for contract set forth in statutory and common law generally require adherence to contracts, with rare exception, creating the potential for civil action for violation.

Contracts also drive our health care system. Physicians sign contracts to work for health facilities and in group practices; they sign contracts for supplies and services; they sign contracts to become part of insurance panels and to receive reimbursement from State health programs. These contracts can determine what a physician is permitted to do, and include review mechanisms for quality and cost control—at times these types of provisions can be used to limit the types of care physicians

[100] See e.g. NY Edu Law § 6530(23) (2016) ("[r]evealing of personally identifiable facts, data, or information obtained in a professional capacity without the prior consent of the patient, except as authorized or required by law…"); Ohio Rev Code Ann § 4731.22(B)(4) (2016) ("[w]illfully betraying a professional confidence"); Federation of State Medical Boards, *supra* note 5 at 18 ("[w]illfully or negligently violating the confidentiality between physician and patient except as required by law..."). Interestingly, many state licensing acts do not include a violation of confidentiality as a specific basis for disciplinary action. Presumably, this would be covered under the broad "unprofessional conduct" or other provision.

provide if the insurer does not give approval.[101] Physicians who provide care in contravention contractual terms, including utility or quality control mechanisms, or who spend more on care than the contract envisions (e.g. capitation provisions), might be financially penalized. Contract terms might also be designed specifically to comply with (or skirt) the prohibitions of federal and state civil and criminal law, such as safe harbors for kickback and self-referral regulation.

Historically, the organized profession attempted to control fees to ensure fair pay and prevent physicians from undercutting the prices offered by competitors.[102] It also attempted to limit the impact of insurance and contracted health care under the guise of ensuring that physicians were paid appropriately for care actually provided and limiting incentives for substandard care.[103] The profession's attempts to control price and contracting were greatly curtailed by the federal government's pursuit of anti-trust charges against the American Medical Association and other medical societies.[104] Today, medical societies have no real control over prices or contracts, and even groups of physicians in a particular locale might face anti-trust scrutiny when negotiating *en masse* for insurance contracts. This has implications for the ability of physicians to increase reimbursement and remove contractual provisions that might be inimical to the ethical practice of medicine.

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[101] See J Scott Andresen, "Is Utilization Review the Practice of Medicine? Implications for Managed Care Administrators" (1998) 19 J Legal Med 431; Robert I Field, "New Ethical Relationships Under Health Care's New Structure: The Need for a New Paradigm" (1998) 43 Vill L Rev 467; Natalie L Regoli, "Insurance Roulette: The Experimental Treatment Exclusion and Desparate Patients" (2004) 22 Quinnipac L Rev 697.

[102] See Bureau of Economics, Federal Trade Commission, *Competition in the Health Care Sector, Past, Present, and Future: Proceedings of a Conference Sponsored by the Bureau of Economics, Federal Trade Commission*, Warren Greenberg, ed (Washington, DC: Federal Trade Commission, 1978) at 57-131.

[103] See Medical Economics, "Contract Practice" (1907) 49 J Am Med Assoc 2028; Medical Economics, "Contract Practice" (1911) 57 J Am Med Assoc 145; Carey P McCord, "The Economics of Industrial Medicine" (1932) 98 J Am Med Assoc 1238.

[104] *American Medical Association v United States*, 317 US 519 (1943); *American Medical Association v Federal Trade Commission*, 638 F 2d 443 (2nd Cir 1980).

State regulation of health insurers provides some bulwark against the negotiating power that these companies often wield, as well as some of the more problematic practices that have raised eyebrows over the years. Individual states are generally empowered to regulate insurance, including health insurance. They can require insurers to retain a certain amount in assets and certain structural features to ensure solvency.[105] States also regularly require insurers to cover certain procedures or treatments as bare minimum coverage to insured individuals.[106] Other features of states' insurance regulation advances the provision of care, such as prompt payment rules.[107]

Federally, there is no direct authority for health insurance regulation. This is achieved, though, by the regulation of insurers providing insurance through federal health programs such as Medicare and Medicaid,[108] as well as pursuant to the Constitution's Commerce Clause that permits Congress to "regulate commerce…among the several states…."[109] It is through this second mechanism that Congress has regulated many aspects of health insurance with the Patient Protection and Affordable Care Act.[110] However, the federal government has also interfered in states' insurance regulation via the Employee Retirement Income Security Act (ERISA), a law designed to protect employees' pensions but which also included the protection of other employment benefits as well. Judicial interpretation of this statute has led to a situation where many employer-run health plans

[105] See e.g. *Illinois Health Maintenance Organization Act*, 215 Ill Comp Stat 125/ (2016); Conn Gen Stat § 38a-41 et seq. (2016).
[106] Insurers are generally empowered to deny claims for things not covered in the insurance contract, and state requirements for certain procedures and treatments guarantees that at least these will be covered. Given the complexity of insurance contracts and the generally unexpected nature of health care needs, this is an important protection for insureds.
[107] See e.g. Nev Rev Stat § 683A.0879(1) (2016); RI Gen L § 27-18-61 (2016); W Va Code § 33-45-2 (2016).
[108] 42 USC § 1396u-2 (2016); 42 USC ch 7, subch XVIII, pt C (2016).
[109] US Const art I, § 8, cl 3.
[110] *PPACA*, *supra* note 2.

are exempted from many facets of states' insurance law.[111] Particularly important is the determination that certain decisions made by the insurer are not reviewable under state tort law (i.e. malpractice cases).[112] The implication here is that the physician is potentially liable for a decision made by an insurer, while the insurer might be liable only for the cost of care not provided.[113] This creates additional imbalance in the physician-insurer relationship, and can be reflected in health care decision making.

IV. An Extensively Regulated Profession

The regulation of health care and medical practice in the US is a vast and complex system. Much of the law regulating health care does not directly regulate physicians, but by implication often determines how and where physicians can practice. Then again there is a significant set of laws that have a direct impact.

Primary among these are physician licensing statutes. One cannot practice as a physician without having a license, irrespective of education and medical society membership. This basic barrier to entry is controlled exclusively by the individual states, although the medical profession has substantial influence through medical education and the development of licensing examinations and continuing education programs. So, one can say that while the State controls who can be a

[111] 29 USC § 1144 (2016).
[112] See e.g. *Pegram v Herdrich*, 530 US 211 (2000); *Rush Prudential HMO v Moran*, 536 US 355 (2002); *Sawyer v USAA Insurance Company*, 912 F Supp 2d 1118 (D N Mex 2012).
[113] 29 USC § 1132(a)(1) (2016). ERISA civil enforcement provisions permit beneficiaries "to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan…." Patients/beneficiaries who are injured due allegedly to decisions made by their benefit plans are more likely to receive greater compensation through state tort law systems, but depending on the nature of the decision and the structure of the health plan state claims might be entirely preempted. 29 USC § 1144 (2016).

licensed and practicing physician, the medical profession continues to control the content of medicine and the meaning of professionalism.

Even though the content of medical education and the intricacies of medical practice remain under professional control pursuant to the terms of licensing statutes, there are many other sources of physician regulation by the State that tend to negate aspects of physician autonomy. Some of these, such as confidentiality laws and EMTALA, reinforce the profession's legal orders. Others, such as self-referral prohibitions, tend to fill in gaps in how the profession regulates itself (see Chapter 7). Some forms of State regulation, especially that related to abortion procedures and health facilities, might supplant entirely what the profession views as the appropriate and ethical practice of medicine (see Chapter 6). Finally, there is a body of law that is directed at non-physicians but still has a substantial impact on the profession, as the regulation of insurance does.

What this shows is that the regulation of physicians and the medical profession is not a narrow thing. When medicine was essentially self-contained and able to regulate itself—before technology and the places and methods of practice grew beyond professional control—self- and then State regulation did not have much to regulate beyond the basic requirements of becoming a physician in the eyes of the State. With the development of complex medical technology, the establishment of insurance as a primary method of payment, and the establishment of health facilities as primary points of service the State had much more to regulate.

There are large areas of regulation that I did not touch on in this Chapter that have an impact on physicians as much as those that I did discuss. Health facility regulation sets requirements for safe

facilities but might also link approval or funding to the provision of specific services.[114] Recent state abortion regulation has attempted to impose strict and expensive facilities regulations on providers, but was struck down by the US Supreme Court.[115] Peer review regulation (e.g. the Health Care Quality Improvement Act of 1986) attempts to protect legitimate peer review while permitting legal action for reviews that are primarily economic or vindictive in nature.[116]

With these different forms of regulation in mind, there are very few areas of health care that the State cannot regulate. The sum of legislative, executive and judicial law and regulation, and the potential for its expansion, is incredibly large. The medical profession retains authority through its associations, many accreditation organizations, medical education, and the basic complexities of medical practice, but the expansion of State regulation demonstrates at the very least that it is conceivable for legislators, regulators and judges to identify a problem (real or not) and determine that the only way to solve it is for State intervention. As in other areas of State law, health care law is ever changing.

The next two Chapters will consider the medical profession's legal order established in Chapter 4 and the State's established above. The constantly evolving nature of State law and medical ethics creates interesting, sometimes harmonious, and sometimes troubling intersections between State and professional legal order. How these intersections are handled determines the kind of care patients receive and the kind of practitioners physicians can be.

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[114] See e.g. VM Hoge, "The Hospital Survey and Construction Act" (1946) 9 Soc Sec Bull 15. The Hospital Survey and Construction Act, also known as the Hill-Burton Act, links funding for the construction of hospitals to the provision of charity care as well as non-discrimination.
[115] *Whole Woman's Health v Hellerstedt*, 579 US __, 136 S Ct 2292 (2016).
[116] See e.g. 42 USC §§ 11111-11112 (2016).

TABLE 2. State Medical Licensing Disciplinary Provisions—Unethical or Unprofessional Conduct Specified as Actionable by Medical Board

State	Specifies Unethical Conduct	Specifies Unprofessional Conduct	References Ethics Code, Specifically or Generally	No Reference to Unethical or Unprofessional Conduct or Reference to Ethics Code (5)
1. Alabama		X		
2. Alaska		X	X (AMA: adopted by Board Regulation)	
3. Arizona		X		
4. Arkansas	X (included in definition of "unprofessional conduct")	X		
5. California		X		
6. Colorado		X		
7. Connecticut				X
8. Delaware	X (included in definition of "unprofessional conduct")	X		
9. Florida				X
10. Georgia	X	X		
11. Hawaii			X (Hawaii Medical Association or AMA standards of ethics)	
12. Idaho				X
13. Illinois	X	X		
14. Indiana				X (however, 844 IAC 5 provides specific standards for conduct that

State	Specifies Unethical Conduct	Specifies Unprofessional Conduct	References Ethics Code, Specifically or Generally	No Reference to Unethical or Unprofessional Conduct or Reference to Ethics Code (5)
				are similar to ethics code provisions)
15. Iowa	X		X (regulations reference AMA Code as guiding principles)	
16. Kansas		X		
17. Kentucky	X	X	X (AMA Principles)	
18. Louisiana		X	X (AMA Principles incorporated by medical board regulation)	
19. Maine		X	X Board of Licensure policy that the AMA Code "is one of the primary sources in defining ethical physician and physician assistant behavior.")	
20. Maryland		X	X (AMA Principles incorporated by regulation, but Principles "are not binding on the Board.")	
21. Massachusetts				X
22. Michigan	X ("unethical business practices")	X		
23. Minnesota	X	X		
24. Mississippi		X	X (regulations reference AMA Principles but only for physicians who	

State	Specifies Unethical Conduct	Specifies Unprofessional Conduct	References Ethics Code, Specifically or Generally	No Reference to Unethical or Unprofessional Conduct or Reference to Ethics Code (5)
			perform medical expert activities)	
25. Missouri	X	X		
26. Montana		X		
27. Nebraska	X (unprofessional conduct includes failure to conform to "the ethics of the profession")	X	X (regulations reference AMA Code)	
28. Nevada			X (statute allows State Board of Medical Examiners to adopt a code of ethics based on a national code of ethics, but the Board has not done so)	
29. New Hampshire		X	X (regulations reference AMA Code; Regulation also specifies that the version of the Code applicable to the physician is the one in force at the time of the conduct)	
30. New Jersey		X		
31. New Mexico		X	X (regulations reference "latest published version" of the AMA Code)	
32. New York		X ("professional misconduct")		

State	Specifies Unethical Conduct	Specifies Unprofessional Conduct	References Ethics Code, Specifically or Generally	No Reference to Unethical or Unprofessional Conduct or Reference to Ethics Code (5)
33. North Carolina	X ("ethics of the medical profession")	X		
34. North Dakota	X	X		
35. Ohio			X (AMA Code)	
36. Oklahoma	X	X		
37. Oregon		X		
38. Pennsylvania	X (unprofessional conduct includes violation of "ethical standards of the profession")	X		
39. Rhode Island		X		
40. South Carolina			X (misconduct includes violation of "code of medical ethics adopted by the board" but no code yet adopted; regulations contain "Principles of Medical Ethics that are similar to AMA Principles)	
41. South Dakota		X		
42. Tennessee	X	X	X (regulations reference AMA Code to the extent that it does not conflict with other state law, rules or position statements)	
43. Texas		X		
44. Utah	X	X		

State	Specifies Unethical Conduct	Specifies Unprofessional Conduct	References Ethics Code, Specifically or Generally	No Reference to Unethical or Unprofessional Conduct or Reference to Ethics Code (5)
45. Vermont		X		
46. Virginia	X (unprofessional conduct includes violating "standards of ethics of his branch of the healing arts")	X		
47. Washington		X		
48. West Virginia	X (in regulations)	X (in regulations)	X (regulations reference AMA Principles)	
49. Wisconsin		X		
50. Wyoming		X		

CHAPTER 6: POLITICS, MORALITY, MEDICAL ETHICS AND LAW

I. INTRODUCTION 204

II. THE IMPACT OF POLITICS ON MEDICAL ETHICS 206

A. Ethics in the Shadow of Politics 206

B. Abortion 208

1. Introduction 208

2. Abortion as a Medical Procedure 209

3. *Planned Parenthood v Casey* and the New Informed Consent 213

4. *Gonzales v Carhart*, Medical Procedures and Medical Necessity 220

a. Partial-Birth Abortion 220

b. Mandatory Ultrasound 223

5. Abortion and a Growing Distrust Between the State and Profession 230

C. Gun Safety Speech Laws 231

III. "PROTECTING THE INTEGRITY AND ETHICS OF THE MEDICAL PROFESSION," SOMETIMES 241

A. Introduction 241

B. Physician-Assisted Suicide 241

C. Physicians' Role in Capital Punishment 247

IV. MEDICAL ETHICS, POLITICS, MORALITY AND LAW 260

> The most strategic and treasured characteristic of the profession—its autonomy—is…owed to its relationship to the sovereign state from which it is not ultimately autonomous.[1]

I. Introduction

The previous two Chapters showed two different sources of physician regulation: the medical profession's legal order of medical ethics and the State's legal order. Neither is necessarily dependent on the other for validation; however, the nature of health care, medical practice and medical ethics creates a unique situation in the world of legal pluralism. The profession has created its own legal order for use within its semi-autonomous social field, but the interrelationships between the profession and the State that *are* necessary—and there are many—require coordination, understanding and acceptance of the role that each play for an effective framework of physician regulation. The purpose of this Chapter is to examine in more detail specific issues in medicine, medical ethics and State law and how they speak to this effectiveness and the health of the relationship between the profession and the State. It is a contrast to what happens on paper, which was the focus of Chapters 4 and 5, and reflects the reality of what happens when the profession's legal order encounters the State's.

The next Section will address abortion statutes and accompanying legal challenges, and "gun gag" laws. These topics were chosen because they are examples of the State clearly disregarding well-established medical ethical obligations towards patients—and even general legal obligations—for political and "moral" ends, and in the face of professional protest. They also represent politically and socially sensitive topics that receive almost continual attention in the media, perhaps

[1] Eliot Freidson, *Profession of Medicine: A Study of the Sociology of Applied Knowledge* (New York: Dodd, Mead & Co, 1970) at 23.

contributing to the political decision-making giving rise to the relevant legislation and judicial decisions.

The third Section of this Chapter will examine two topics where the State has explicitly addressed professional ethics. These include end-of-life issues, such as physician-assisted suicide and euthanasia, which will be contrasted with lethal injection and physician participation in the execution of incarcerated individuals.

One important item to note before continuing is the common theme of all the issues addressed in this Chapter. Each conflict between medical ethics and State law arises, except for capital punishment, not directly between the State and the medical profession, but rather in how the State defines the issue in relation to the rights of individuals and patients. The profession is often only a tangential consideration even though the patient-physician relationship is central to what the State is regulating. Despite the State's focus on the rights of the individual—the right (or not) to have assistance in suicide, the right (or not) to have a physician to ensure the most painless execution possible (and one that comports with constitutional requirements), the right to own a firearm without question, and the right (or not) to terminate a pregnancy—the patient is only one half of the patient-physician relationship.

A final note before continuing to the substantive matters of this Chapter. New statutes, regulations and court decisions regularly transform most of the issues discussed below, so some of what is contained within is subject to change rather quickly. The materials used are up to date as of early 2017, but given the volume of legislation regularly introduced by state legislatures, especially on abortion, these topics should be considered very fluid.

II. The Impact of Politics on Medical Ethics

A. Ethics in the Shadow of Politics

Politics is a familiar thing in medicine, as the organized medical profession is itself political in nature.[2] The internal organization and processes of many medical societies mirror those of political structures at the local, state and federal levels. Policy decisions, including ethics development, are often based on political considerations of the profession and segments within the profession (i.e. what is best for its membership). The organized profession also lobbies governments to obtain favorable laws or diminish the impact of unfavorable ones, inserting the profession into federal and state political activities.[3]

Politics of the State also influence the direction of State policy regulating health care and the medical profession. Legislators, executives and some state judges are popularly elected[4] so to some extent the policies enacted by the State reflect the electoral calculations of these officials, sometimes at the expense of facts and practicality. Policy organizations or lobbying groups that focus on a few issues might "score" or endorse legislators (or judges) based on their perceived

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[2] I use politics here as defined in the Merriam-Webster dictionary: "activities that relate to influencing the actions and policies of a government or getting and keeping power in a government; the work or job of people (such as elected officials) who are part of a government; the opinions that someone has about what should be done by governments; a person's political thoughts and opinions". Merriam-Webster, "Politics", online: Merriam-Webster <http://www.merriam-webster.com/dictionary/politics>.

[3] See e.g. Wesley Lowery, "For 17th Time in 11 Years, Congress Delays Medicare Reimbursement Cuts as Senate Passes 'Doc Fix'", *Washington Post* (31 March 2014) online: Washington Post <http://www.washingtonpost.com/blogs/post-politics/wp/2014/03/31/for-17th-time-in-11-years-congress-delays-medicare-reimbursement-cuts-as-senate-passes-doc-fix/>.

[4] However, the role that financial contributions play in judicial elections has come under scrutiny of late, given that we expect judges to be impartial and the acceptance of large donations from interest groups creates at the very least the appearance of partiality. See e.g. Alicia Bannon et al, *The New Politics of Judicial Elections, 2011-2012* (Washington, DC: Justice at Stake, 2013); Debra Erenberg & Matt Berg, "The Dark Night Rises: The Growing Role of Independent Expenditures In Judicial Elections After Citizens United" (2013) 49 Willamette L Rev 501; Editorial Board, "A Messy Supreme Court Case Shows Why Judges Should be Appointed, Not Elected", *Washington Post* (21 January 2015) online: Washington Post <http://www.washingtonpost.com/opinions/a-messy-supreme-court-case-shows-why-judges-should-be-appointed-not-elected/2015/01/21/dab54610-a0f6-11e4-9f89-561284a573f8_story.html>.

support for these issues, and might call for their reelection or defeat depending on this support, pressuring elected officials to endorse policies not necessarily garnering widespread support amongst their constituencies.[5]

Even appointed judges (including federal judges) are not fully separated from the political discourse that goes on around them. For one, their appointments are generally based on their political affiliations; that is, the individual or group that is charged with nominating judges typically nominate based on the nominee's ideological consistency with their own. President George W Bush nominated conservative judges, and President Barak Obama nominated liberal judges. In turn, the judges' decisions often reflect their political leanings despite proclamations that appointed judges are impartial. Really, no one is truly impartial. As well, tremendous political pressure can be brought to bear on judges who do not perform as expected, with the most obvious instance being United States (US) Supreme Court justices who vote against what their affiliated political party advocates.[6]

Political considerations in government processes can lead to law that does not meet with the reality of medicine, or forces the profession to abrogate its ethical obligations in the face of political resistance. The topics discussed in this Section, abortion and gun gag laws, represent just two examples of politics coming into conflict with professionalism and medical expertise.

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[5] See e.g. National Rifle Association Political Victory Fund, online: National Rifle Association Political Victory Fund <https://www.nrapvf.org/> (past election candidate grades available to NRA members only); National Right to Life, "Legislative Action Center: NLRC Vote Scorecards", online: National Right to Life <http://www.capwiz.com/nrlc/home/>; Susan B Anthony List, "Candidate Fund", online: Susan B Anthony List < https://www.sba-list.org/candidate-fund>; Heritage Action for America, "Scorecard", online: Heritage Action for America <http://heritageactionscorecard.com/>.

[6] A good example is current Chief Justice Roberts (appointed by conservative president George W Bush), who voted to uphold most of the Patient Protection and Affordable Care Act despite the strong opposition of Republicans to the law. *National Federation of Independent Business v Sebelius*, 132 S Ct 2566 (2012).

B. Abortion

1. Introduction

The political history of abortion in the US is complicated. For a long time in the country's early history, abortion was tacitly approved. It was not prosecuted and not publicly discussed. However, as medicine changed, so did the social implications and resistance to abortion, leading states to prohibit it and the American Medical Association (AMA) to speak against it.[7] Following US Supreme Court decisions approving other areas of reproductive rights,[8] states continued to criminalize abortion and the Court was asked to address these laws in the case of *Roe v Wade*.[9] The Court documented one basis for states' regulation of abortion and why they often took such strong positions: morality. Arguments underlying Texas' position in *Roe* and that continue to appear in state statutes and judicial decisions even today highlight the moral implications of aborting a fetus. In opposition to this, and strengthened by *Roe*, is the right of the woman to choose not to carry a fetus to term and be free of State interference in this decision. The moral questions underlying abortion are unlikely to be settled any time soon,[10] even though many other western, industrialized nations (including Canada) do not have the same heated debate over abortion as the

[7] See e.g. American Medical Association, "Report on Criminal Abortions" in *Transactions of the American Medical Association*, vol XII (Collins: Philadelphia, 1859) at 73; American Medical Association, *Transactions of the American Medical Association*, vol XIII (Collins: Philadelphia, 1860) at 58; American Medical Association, *Digest of Official Actions, 1846-1958* (Chicago: American Medical Association, 1959) at 68-69. It is possible that in addition to a moral opposition to abortion (and a misunderstanding of women's health issues in general), the profession opposed abortion because of the role given to midwives in the procedure.

[8] See e.g. *Griswold v Connecticut*, 381 US 479 (1965); *Eisenstadt v Baird*, 405 US 438 (1972).

[9] *Roe v Wade*, 410 US 113 (1973) [*Roe*].

[10] As one federal district court aptly put it, "[t]oday there is no issue that divides the people of this country more than abortion. It is the most divisive issue to face this country since slavery. When compared with the intensity, emotion, and depth of feeling expressed with regard to abortion, the recent arguments on affordable healthcare, increasing the debt ceiling, and closing the government retreat to near oblivion. Sincere and caring persons of good will are found on both sides of the issue, but neither side will ever change the position of the other. Legislatures and courts will continue to be confounded by the issue for the foreseeable future. No ruling of this court will sway the opinion regarding abortion held by anyone." *Planned Parenthood of Greater Texas v Abbott*, 951 F Supp 2d 891 at 896 (WD Tex 2013).

US. The issues that I raise about abortion in this Thesis, though, have little to do with the morality of the procedure itself and speak more to *how* the State regulates abortion.

I start from the premise that abortion was legalized in 1973 with the Supreme Court's decision in *Roe*. Once states could no longer prohibit abortion, their focus turned to regulating the procedure and those who perform it. Physicians, as a part of a state-regulated profession, were caught up in regulatory schemes that had less to do with actual patient safety, and more to do with the moral and political influence that shapes our legislatures, executive officers and courts. The decisions made by these institutions and individuals since *Roe* continue to make abortion a moral and political question rather than a medical and medical ethical one.

2. Abortion as a Medical Procedure

Modern abortion jurisprudence began with the conceptualization of abortion as primarily a medical procedure, with the *Roe* majority attempting to strip away the moral debate as part of its decision, although it could not ignore this entirely. The Court found that until "the state interests provide *compelling justification* for intervention….the abortion decision in all its aspects is inherently, and primarily, a *medical* decision, and basic responsibility for it must rest with the physician".[11] In structuring a woman's right to an abortion, the Court created a hierarchy of corresponding State and women's rights, wherein during the first trimester the State is severely limited in the regulations it can impose on abortion;[12] after the first trimester "the State, in promoting the interest and health of the mother, may, if it chooses, regulate the abortion procedure in ways that are reasonably related to maternal health";[13] and after fetal viability the State can regulate or even

[11] *Roe*, *supra* note 9 at 166 [emphasis added].
[12] *Ibid*. ("the abortion decision and its effectuation must be left to the medical judgment of the pregnant woman's attending physician" at 163).
[13] *Ibid*. at 164.

prohibit abortion "except where it is necessary, *in appropriate medical judgment*, for the preservation of the life or health of the mother."[14]

Abortion was a relatively safe medical procedure by 1973 when performed in the proper setting. The regulatory restrictions placed on states by *Roe* accepted the medical over the moral, but still allowed some room for states to regulate abortion to ensure that it

> is performed under circumstances that insure maximum safety for the patient. This interest obviously extends at least to the performing physician and his staff, to the facilities involved, to the availability of after-care, and to adequate provision for any complications or emergency that might arise.[15]

Thus, abortion should theoretically be treated like any other medical procedure, with appropriate regulations ensuring health and safety but not so oppressive as to infringe on the woman's right to choose it.

For nearly 20 years following *Roe v Wade*, the Supreme Court met attempts to more strictly regulate various aspects of abortion by continuing to uphold the basic precepts of *Roe*. In 1976, *Planned Parenthood of Central Missouri v Danforth* invalidated a prohibition on an abortion procedure after the first trimester, primarily because *the procedure was accepted within the population of physicians performing abortions* and was used in the majority of post-first trimester abortions.[16] Far from being a regulation intended to promote women's health, "it forces a woman

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[14] *Ibid*. at 165 [emphasis added].

[15] *Ibid*. at 150. These areas of permissible regulation have become important in recent abortion regulation, as states use very restrictive means that they claim fit within these boundaries. See *Planned Parenthood of Greater Texas Surgical Health Services v Abbott*, 748 F 3d 583 (5th Cir 2014) ("[v]iewed from the proper perspective, the State's articulation of rational legislative objectives, which was backed by evidence placed before the state legislature, easily supplied a connection between the admitting-privileges rule and the desirable protection of abortion patients' health" at 594); *Isaacson v Horne*, 716 F 3d 1213 (9th Cir 2013) ("[t]he stated purpose of the Act is to '[p]rohibit abortions at or after twenty weeks of gestation, except in cases of a medical emergency, based on the documented risks to women's health and the strong medical evidence that unborn children feel pain during an abortion at that gestational age'" at 1218).

[16] *Planned Parenthood of Central Missouri v Danforth*, 428 US 52 at 77 (1976) [*Danforth*].

and her physician to terminate her pregnancy by methods more dangerous to her health than the method outlawed."[17]

In 1983, *Akron v Akron Center for Reproductive Health* invalidated a host of regulations requiring second trimester or later abortions to be performed in hospitals; parental consent for abortions for children under 15 years (except with a court order); the provision of a variety of information about the abortion to the woman, including the developmental stage of the fetus and the physical and emotional complications of an abortion; and a 24-hour waiting period following consent before the abortion could be performed.[18] The Court found that "[c]ertain regulations that have *no significant impact* on the woman's exercise of her right may be permissible where justified by important state health objectives",[19] but also that the state could not "adopt abortion regulations *that depart from accepted medical practice*."[20]

Turning to informed consent requirements, the Court recognized that an explicit requirement for informed consent was upheld in *Danforth* because of the importance and stressfulness of the decision to have an abortion.[21] However, "[t]his does not mean…that a State has unreviewable authority to decide what information a woman must be given before she chooses to have an abortion. *It remains primarily the responsibility of the physician to ensure that appropriate information is conveyed to his patient, depending on her particular circumstances*."[22] The Court found that much of the information required to be disclosed to patients was designed to persuade her to forego abortion, including a "'parade of horribles' intended to suggest that abortion is a

[17] *Ibid*. at 79. Those two primary methods, hysterotomy and hysterectomy, were viewed as significantly more dangerous.
[18] *Akron v Akron Center for Reproductive Health*, 462 US 416 (1983).
[19] *Ibid*. at 430 [emphasis added]. This reflects states' general ability to regulate in matters of public health.
[20] *Ibid*. at 431 [emphasis added].
[21] *Ibid*. at 442, citing *Danforth*, *supra* note 16 at 67.
[22] *Ibid*. at 443 [emphasis added].

particularly dangerous procedure" when, in reality, it was not.[23] These informed consent requirements represented an "intrusion upon the discretion of the pregnant woman's physician…. Akron unreasonably has placed 'obstacles in the path of the doctor upon whom [the woman is] entitled to rely for advice in connection with her decision.'"[24]

In its final major case before a change in juriprudential direction, the Court again addressed abortion requirements similar to those decided in *Danforth*, *Akron* and other Supreme Court cases after *Roe*.[25] *Thornburgh v American College of Obstetricians and Gynecologists* deemed that requiring physicians to provide information designed primarily to deter women from obtaining an abortion "makes him or her in effect an agent of the State in treating the woman and places his or her imprimatur upon both the materials and the list."[26] More so than in previous cases, the *Thornburgh* decision found the required provision of information to be potentially destructive of the patient-physician relationship, especially for patients with a life-threatening pregnancy who had the option of aborting or risking their own lives.[27]

Supreme Court decisions for the first nearly two decades of post-*Roe* jurisprudence recognized the importance of physician independence in obtaining informed consent as well as in determining appropriate medical procedures. However, beginning in 1992 with the case of *Planned Parenthood of Southeastern Pennsylvania v Casey* the Supreme Court has taken drastically different positions on substantially the same questions answered in previous cases.

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[23] *Ibid*. at 445.
[24] *Ibid*., citing *Whalen v Roe*, 429 US 589 at 604 (1977).
[25] *Thornburgh v American College of Obstetricians and Gynecologists*, 476 US 747 (1986) [*Thornburgh*].
[26] *Ibid*. at 763.
[27] *Ibid*.

3. *Planned Parenthood v Casey* and the New Informed Consent

From *Roe* in 1973 through *Thornburgh* in 1986, the Supreme Court was careful to analyze state laws considering medical appropriateness and the ethical obligations of physicians. States could regulate abortion, but were subject to more than a facial examination of motives and interests. This link between abortion, medicine and ethics was greatly weakened starting with *Casey*.[28]

Before *Casey*, the Court tended to view specific and onerous informational requirements negatively, but *Casey* and later cases were much more accepting of detailed requirements and states' (often flimsy) justifications for their inclusion. The reasons for this change are explained by the plurality opinion in *Casey* as a better reflection of the State's interest in health and safety and fetal life and a better adherence to *Roe* than the previous 20 years of jurisprudence.[29] *Casey* and subsequent decisions by the Supreme Court and lower courts loosened the leash that *Roe* had placed on states, and therefore substantially revised the role that the medical profession plays in regulating abortion and the attendant patient-physician relationship.

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[28] See *Casey v Planned Parenthood of Southeastern Pennsylvania*, 505 US 833 (1992) [*Casey*]; *Gonzales v Carhart*, 550 US 124 (2007) [*Gonzales*]. See also *Webster v Reproductive Health Services*, 492 US 490 (1989). This decision was handed down prior to *Casey*, but I do not discuss it in detail here because its focus on parental consent and mechanisms to obtain consent when parental consent is not appropriate is not something that is of great importance in this Thesis (although it is, in general, an important issue). I will note, though, that this case is probably the first to limit the breadth of *Roe*, and reflected the gradual change in the ideological makeup of the Supreme Court that resulted in the shift in abortion jurisprudence since *Casey*.

[29] *Casey*, *supra* note 28 ("[n]ot all of the cases decided under [*Roe*'s] formulation can be reconciled with the holding in *Roe* itself that the State has legitimate interests in the health of the woman and in protecting the potential life within her. In resolving this tension, we choose to rely upon *Roe*, as against later cases" at 871). The makeup of the Court is a reasonable explanation for this change. Justice Blackmun, who wrote the majority opinion in *Roe*, authored an opinion in *Casey* concurring and dissenting in part, disagreeing with much of the plurality opinion. Of the 6 other Justices who joined or concurred with the majority in *Roe*—Brennan, Burger, Douglas, Marshall, Powell and Stewart—none remained on the court at the time of *Casey* although a Republican appointee, Stevens, filed an opinion in *Casey* concurring and dissenting in part in which he stated his belief that *Akron* and *Thornburgh* should have controlled the Court's decision in *Casey*. The two dissenters in *Roe*, White and Rehnquist, remained on the Court for *Casey* and were joined by Republican appointees Kennedy, O'Connor, Scalia, Souter and Thomas, with a plurality opinion written by O'Connor. Kennedy, Scalia and Thomas were not on the Court at the time of *Thornburgh*.

Casey addressed statutory informed consent and other provisions substantially similar to those ruled upon and mostly invalidated six years earlier in *Thornburgh*.[30] Failure to comply with these informed consent provisions subjected physicians to misdemeanor charges, placing the burden on the physician to prove "by a preponderance of the evidence that he or she reasonably believed that furnishing the information would have resulted in a severely adverse effect on the physical or mental health of the patient."[31]

Contrary to prior cases such as *Akron* and *Thornburgh*, the Court in *Casey* upheld most of the Abortion Control Act, invalidating only the requirement that a woman notify her spouse prior to obtaining an abortion.[32] By upholding the Act, the Court modified the role of physicians and the medical profession in abortion and abortion regulation. *Thornburgh* had concluded that "[i]t remains primarily the responsibility of the physician to ensure that appropriate information is conveyed to his patient, depending on her particular circumstances".[33] The Court in *Casey* expressly overruled this decision,[34] finding that so long as the information is truthful and not misleading it is permissible for the State to require specific information to be disclosed, as this is a "reasonable measure to ensure an informed choice, one which might cause the woman to choose childbirth over abortion."[35]

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[30] *Thornburgh*, *supra* note 25 at 762-764 (provision of printed material describing fetal development at 2-week intervals; listing of agencies that can assist the woman; information that medical assistance is available and the father has financial responsibilities; information about detrimental physical and psychological effects).
[31] *Casey*, *supra* note 28 at 904.
[32] *Ibid*. (this requirement is "likely to prevent a significant number of women from obtaining an abortion….for many women, it will impose a substantial obstacle" at 893-894).
[33] *Ibid*.
[34] O'Connor presented a lengthy discussion of the concept of stare decisis in arguing that the essentially holding of *Roe* was being upheld in line with this doctrine. However, it is clear when comparing the law in *Casey* to those at issue in *Akron* and *Thornburgh* that stare decisis played a minimal role.
[35] *Casey*, *supra* note 28 at 883. The *Roe* decision did not envision the State's attempt to persuade against having an abortion as a legitimate exercise of power, especially in the early stages of pregnancy. It focused on the State's interest in the life and health of the mother and fetus and even then, the State's rights to limit abortion was relegated to the period after the first trimester. See *Roe*, *supra* note 9 at 164-165.

With regards to the impact on the patient-physician relationship and its inherent privacy, the Court took note of the exception in the law permitting a failure to comply if there is a "preponderance of evidence" that disclosure presents a risk of physical or mental harm.[36] Yet the Court did not explain why the additional provisions in the Pennsylvania law were either necessary or prudent given *Roe*'s restrictions on State regulation of abortion, which were upheld in subsequent Court decisions, other than its assertion that *Roe* gave too little credit to State interests.[37]

The Court went on to argue that "a requirement that a doctor give a woman certain information as part of her consent to an abortion is, for constitutional purposes, no different from a requirement that a doctor give certain specific information about any medical procedure."[38] This is a specious argument, because requiring that *specific* information be provided to patients as part of informed consent is almost never done, for the reason that the medical profession is much better situated to know what information is accurate, useful and not harmful.[39] The Court in *Casey* compared the statute's regulation of physicians as merely an expression of "reasonable licensing and regulation by the State",[40] but this reasonable sounding statement represented a shift in how the State

[36] *Casey*, *supra* note 28 at 883-884. The importance of provisions like this cannot be understated. Rather than requiring the State to prove that the physician acted without a reasonable belief that providing the information could harm the patient, the physician is now shouldered with the burden of proof. In this situation it is likely that the decision is very subjective, so it would be difficult for a court to find a consistent rule of what is sufficient to create the "reasonable belief."
[37] *Ibid*. at 873.
[38] *Ibid*. at 884.
[39] The requirement to provide specific information about a medical procedure is still not done today except with more general informational requirements in the context of end-of-life care and decision-making. See Sonia M Suter, "The Politics of Information: Informed Consent in Abortion and End-of-Life Decision Making" (2013) 39 Am JL & Med 7. Suter notes the qualitative difference between abortion disclosure statutes and end-of-life statutes, specifically that abortion statutes generally require more and more detailed (and at times incorrect or misleading) information.
[40] *Casey*, *supra* note 28 at 884.

previously viewed the relationship between it and the medical profession, and the purpose of its professional regulation.[41]

The strength of women's rights afforded under *Roe* was also significantly lessened by *Casey*. Rather than using a heightened scrutiny approach favored by *Roe*, the *Casey* decision determined that

> a law which serves a valid purpose, one not designed to strike at the right itself, [but] has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidated it. Only where state regulation poses an *undue burden* on a woman's ability to make this decision does the power of the State reach into the heart of the liberty protected by the Due Process Clause.[42]

This, of course, greatly changed the degree to which courts will scrutinize laws, as "undue burden" is a significantly lower standard than that set by *Roe*, and is also a significant departure from the standards that other fundamental rights are found to have. The renewed balancing of the rights of the State and woman granted more weight to the State than *Roe* envisioned, and accordingly permitted a much wider array of regulation to be constitutionally permissible—regulations that had previously been found to violate the rights set forth in *Roe* and that consequently impact physicians' ability to practice in accordance with ethical obligations.

Since *Casey*, many states have enacted similar abortion informed consent statutes that continue to push requirements past the boundaries of what *Thornburgh* found repugnant.[43] Kansas provides a

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[41] See e.g. *Dent v West Virginia*, 129 US 114 (1889). In *Dent*, the Supreme Court indicates that the purpose of state licensing laws was "to secure such skill and learning in the profession of medicine that the community might trust with confidence those receiving a license under the authority of the state." *Ibid*. at 128. Much had changed in State regulation of medicine by the time of *Casey*, but at core the State's responsibility was to ensure that physicians had the requisite education and skill, not micromanage medical practices.

[42] *Casey*, *supra* note 28 at 874 [emphasis added]. Justice Blackmun, the author of the *Roe* majority, noted his continued belief that the trimester framework of *Roe* was "far more administrable, and far less manipulable, than the 'undue burden' standard adopted by the joint opinion." *Ibid*. at 930.

[43] The Guttmacher Institute compiles and updates the types of statutes adopted and the states that have adopted them, and I will not reproduce this work here. Guttmacher Institute, "An Overview of Abortion Laws", online: Guttmacher Institute <http://www.guttmacher.org/sections/abortion.php>. This organization advances sexual and

good example of the kind of informed consent provisions that are now tolerated. Much of the information mandated for disclosure falls less within the category of promoting patient safety and informed decision-making, from the medical perspective, and seems designed to make the procedure more psychologically difficult for women to undergo (thus supposedly promoting the State's interest in protecting the unborn, which under *Roe* did not take priority until later in pregnancy).[44] In addition to direct disclosures from health care provider to patient, the statute requires that patients be provided with the informational booklet *If You Are Pregnant*.[45] This handbook provides detailed information on abortion, the development of the fetus, and the risks of abortion, pregnancy in general, and natural childbirth.

Some of the information contained in the Kansas Handbook is misleading at best. Take, for instance, the assertion that "[a]fter having an abortion, some women suffer from a variety of psychological effects ranging from malaise, irritability, difficulty sleeping, to depression and even posttraumatic stress disorder. The risk of negative psychological experiences may increase if a woman has previously suffered from mental health problems."[46] Justice Ginsburg confronted this claim in her *Gonzales v Carhart* dissent: "The Court is surely correct that, for most women, abortion is a painfully difficult decision. But 'neither the weight of the scientific evidence to date nor the observable reality of 33 years of legal abortion in the United States comports with the idea that having an abortion is any more dangerous to a woman's long-term mental health than

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reproductive health rights, so in general skews in favor of abortion rights. However, the document cited here is factual in nature and merely lists and categorizes the wide variety of state laws regulating abortion.

[44] The information includes "the woman is free to withhold or withdraw her consent to the abortion at any time prior to invasion of the uterus" and "the abortion will terminate the life of a whole, separate, unique, living human being". Kan Stat Ann § 65-6709 (2014) [emphasis added].

[45] Kan Stat Ann § 65-6709(d) (2014). This subsection requires the provision of the materials at least 24 hours before the procedure, while subsection (b)(2) requires only that the woman be informed that the materials are available. It is unclear why both provisions appear.

[46] Kansas Department of Health and Environment, "If You are Pregnant", online: Kansas Department of Health and Environment <http://www.womansrighttoknow.org/> at 27.

delivering and parenting a child that she did not intend to have'" (citations omitted).[47]

Ginsburg's argument did not prevent an federal appellate court, in 2012, from upholding a requirement to disclose "to patients seeking abortions…an '[i]ncreased risk of suicide ideation and suicide'"[48] based on medical studies (from 1996 and 2006) finding an increased risk of suicide in women who have undergone an abortion, despite statements from the American Psychological Association and American Psychiatric Association that the risk might be from other factors and causation was not established.[49] According to this court, the increased risk was truthful information even if the root cause of the increase was not well established because construction of the statute did not require causation.[50]

Another "risk" contained in the Kansas handbook is the link between abortion and breast cancer.[51] Not all the information contained in this section is incorrect: the link between childbirth and a reduction of risk of breast cancer has been demonstrated, although there are also factors of

[47] *Gonzales*, *supra* note 28 at 183 n 7.
[48] *Planned Parenthood of Minnesota, North Dakota, South Dakota v Rounds*, 686 F 3d 889 at 892 (8th Cir 2012) [*Rounds*].
[49] APA Task Force on Mental Health and Abortion, *Report of the APA Task Force on Mental Health and Abortion* (Washington DC: American Psychological Association, 2008); American Psychiatric Association, "Abortion and Women's Reproductive Health Rights", online: American Psychiatric Association <www.psych.org>.
[50] *Rounds*, *supra* note 48 at 896. In one study cited by the court, the authors wrote "[t]he relation between suicide, mental disorders, life events, social class, and social support is a complex one. Abortion might mean a selection of women at higher risk for suicide because of reasons like depression. Another explanation for the higher suicide rate after an abortion could be low social class, low social support, and previous life events or that abortion is chosen by women who are at higher risk for suicide because of other reasons. Increased risk for a suicide after an induced abortion can, besides indicating common risk factors for both, result from a negative effect of induced abortion on mental wellbeing. With our data, however, it was not possible to study the causality more carefully. Our data clearly show, however, that women who have experienced an abortion have an increased risk of suicide, which should be taken into account in the prevention of such deaths." Mika Gissler, Elina Hemminki & Jouko Lonnqvist, "Suicides After Pregnancy in Finland, 1987-94: Register Linkage Study" (1996) 313 Brit Med J 1431. Another study cited by the court provided stronger conclusions as to the moderate increase of risk of concurrent or subsequent mental health problems, but the authors stated, after considering contextual factors that might have confounded the results, that "it is our view that the issue of whether or not abortion has harmful effects on mental health remains to be fully resolved" thus diminishing the utility of the study as a grounds for inclusion of the risk as part of the informed consent process. David M Fergusson, L John Horwood & Elizabeth M Ridder, "Abortion in Young Women and Subsequent Mental Health" (2006) 47 J Child Psychology & Psychiatry 16 at 23.
[51] Kansas Department of Health and Environment, *supra* note 46 at 26.

childbirth that might increase risk.[52] However, the link between induced abortion and breast cancer has not been established. Although early studies showed a possible correlation between abortion and breast cancer,[53] more recent studies, including the National Cancer Institute review referred to in the Kansas handbook, have found no such link.[54]

The change in *Casey* to the undue burden standards and the acceptance of "truthful and not misleading" informational requirements[55] provides a much lower standard for courts, and one where they can obfuscate science, ideology and medical practice. No longer are states prohibited from requiring information that is intended primarily to persuade women against abortion. At least for abortion, physicians are no longer the arbiters of appropriate information to provide in order to obtain an informed consent.

Informed consent is only one area where pre-*Casey* abortion cases that gave physicians and the medical profession at least some deference and autonomy have been essentially overturned. The next subsection addresses the similar result for medical procedures.

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[52] National Cancer Institute, "Reproductive History and Breast Cancer Risk", online: National Cancer Institute <http://www.cancer.gov/cancertopics/factsheet/Risk/reproductive-history>.

[53] See e.g. Joel Brind et al, "Induced Abortion as an Independent Risk Factor for Breast Cancer: A Comprehensive Review and Meta-Analysis" (1996) 50 J Epid & Community Health 481. This study found the risk increase to be low, but given the high incidence of abortion there was concern at the overall increase in breast cancer linked to the procedure.

[54] See e.g. American College of Obstetricians and Gynecologists Committee on Gynecologic Practice, "Induced Abortion and Breast Cancer Risk" (2009) 113 Obstetrics & Gynecology 1417; David H Brewster et al, "Risk of Breast Cancer After Miscarriage or Induced Abortion: A Scottish Record Linkage Case-Control Study" (2005) 58 J Epid & Community Health 283; Collaborative Group on Hormonal Factors in Breast Cancer, "Breast Cancer and Abortion: Collaborative Reanalysis of Data from 53 Epidemiological Studies, Including 83,000 Women with Breast Cancer from 16 Countries" (2004) 363 The Lancet 1007; Mads Melbye et al, "Induced Abortion and the Risk of Breast Cancer" (1997) 336 N Eng J Med 81.

[55] *Casey*, *supra* note 28 at 882.

4. *Gonzales v Carhart*, Medical Procedures and Medical Necessity

a. Partial-Birth Abortion

In 2003 Congress passed the Partial-Birth Abortion Ban Act, banning a procedure sometimes used by physicians for abortions: intact dilation and evacuation (intact D & E), also called dilation and extraction (D & X).[56] This statute was challenged by physicians, leading to the 2007 decision of *Gonzales v Carhart*.

Under *Casey*, attempts to restrict abortions after fetal viability were subject to "exceptions for pregnancies which endanger the woman's *life or health*" even after viability.[57] This standard persists, but the Court in *Gonzales* greatly limited it by asserting that medical uncertainty about the need for D & X made this specific procedure *never* necessary, even for a woman's health.[58] The Court based its interpretation on previous decisions granting legislatures "wide discretion to pass legislation in areas where there is medical and scientific uncertainty."[59]

However, the testimony by the plaintiffs' witnesses at the district court level categorically rejected the assertion that medical consensus was against the use of this procedure.[60] Although the experts presented by the federal government in support of the prohibition "concluded that the alleged

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[56] The title "partial-birth abortion" is a political term and not usually ascribed to by physicians. *Gonzales*, *supra* note 28 at 136. The majority opinion does not provide an exact number, but they state that second trimester abortions are roughly 10-15 percent of the total number of abortions, so D & X is likely a small percentage of this number. *Ibid*. at 134.

[57] *Casey*, *supra* note 28 at 846 [emphasis added]; *Roe*, *supra* note 9 at 163-164.

[58] The Court seems to promote something akin to the "beyond a reasonable doubt" standard, an odd choice for medical science, which is constantly changing and often filled with uncertainty.

[59] *Gonzales*, *supra* note 28 at 163. The majority cited a litany of cases supporting this proposition. However, none address a situation quite like that of abortion and this specific procedure, given the weight placed on a woman's rights pre-viability and on her health even after fetal viability is reached.

[60] Although the three district courts involved in this decision heard testimony from both physicians' and government experts, all ruled in favor of the physicians and thus did not find a consensus against the use of the procedure. See *Planned Parenthood Federation of America v Ashcroft*, 320 F Supp 2d 957 (ND Cal 2004) [*Planned Parenthood Federation*]; *National Abortion Federation v Ashcroft*, 330 F Supp 2d 436 (SD NY 2004) [*National Abortion Federation*]; *Carhart v Ashcroft*, 331 F Supp 2d 805 (D Neb 2004) [*Carhart*].

health advantages were based on speculation without scientific studies to support them,"[61] this conclusion was inaccurate. The research exploring the comparative safety of D & E and D & X by Chasen, referred to in *National Abortion Federation*,[62] demonstrated that D & X was at least as safe as D & E and concluded that "[a]ttempts to regulate intact D & X on the basis of concern for maternal well-being cannot be supported by available evidence."[63] Even the discomfort of the AMA[64] and American College of Obstetricians and Gynecologists (ACOG)[65] with D & X was tempered by the acknowledgment that there might be instances when it was medically necessary and physicians should retain discretion to determine when to use it.

There are a number of questionable assertions in the reasoning of this opinion. First, the *Gonzales* majority interpreted the need in some circumstances to use D & X as a matter of "convenience".[66] However, given the belief of many testifying physicians that D & X, regardless of the distaste that the Court or the public may have, is the safest procedure given the medical presentation of some patients, the Court should not have so quickly discarded the potential implications of the ban for women's health.[67] Other than granting the government's witnesses opposing the procedure greater

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[61] *Gonzales*, *supra* note 28 at 162. I should note first that rigorous controlled studies of medical procedures are not that common when compared to trials of medical devices or pharmaceuticals. See e.g. Robin S McLeod, "Issues in Surgical Randomized Controlled Trials" (1999) 23 World J Surg 1210; Forough Farrokhyar et al, "Randomized Controlled Trials of Surgical Interventions" (2010) 251 Ann Surg 409.

[62] *National Abortion Federation*, *supra* note 60 at 461.

[63] Stephen T Chasen et al., "Dilation and Extraction at ≥ 20 Weeks: Comparison of Operative Techniques" (2004) 190 Am J Obstetrics & Gynecology 1180 at 1183.

[64] "The AMA recommends that the procedure not be used unless alternative procedures pose materially greater risk to the woman. The physician must, however, retain the discretion to make that judgment, acting within standards of good medical practice and in the best interest of the patient." American Medical Association, "H-5.982 Late-Term Pregnancy Termination Techniques", online: American Medical Association <https://searchpf.ama-assn.org/SearchML/searchDetails.action?uri=%2FAMADoc%2FHOD.xml-0-4533.xml>.

[65] American College of Obstetricians and Gynecologists, "Abortion Policy", online: Physicians for Reproductive Rights <http://www.physiciansforreproductiverights.org/wp-content/uploads/2013/03/ACOG-abortion-policy.pdf>.

[66] *Gonzales*, *supra* note 28 at 166.

[67] The three district court decisions leading to the Supreme Court's decision all ruled in favor of the physicians due to the evidence that in some circumstances intact D & X is safer than regular D & E and therefore should be considered medically necessary in those instances. *Planned Parenthood Federation*, *supra* note 60; *National Abortion Federation*, *supra* note 60; *Carhart*, *supra* note 60.

credibility—something none of the lower courts did—the majority provided no explanation for this.[68]

Second, the Court also considered the Congressional findings supporting the passage of the D & X ban, which were severely flawed. Two of the reasons that Congress banned the procedure were that it was not taught in any US medical school and that there was a medical consensus that there were no instances when it was necessary to preserve the health of the mother.[69] The Court majority acknowledged that, whether these were true or not at the time of the Act's passage, they were no longer true and therefore reliance on Congress' findings to uphold the law was not warranted.[70] The Court reasonably noted that "[u]ncritical deference to Congress' factual finding in these cases is inappropriate",[71] but still deferred to Congress on its decision to ban D & X procedures *despite medical evidence* and Congressional inaccuracies and untruths.

Finally, the Court's determination that the Act protected the ethics of the medical profession[72] is also questionable, since major medical organizations opposed the absolute ban. Specifically, the AMA and ACOG opposition should have led to the opposite conclusion: if these organizations oppose the ban, and are also quite active in developing and policing ethics for their members, should we not give them credibility and authority in the field of ethics?

As an indication of ongoing attempts to restrict access to abortion through regulating the medical

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[68] See *Gonzales*, *supra* note 28, Ginsburg J, dissenting, citing *Salve Regina College v Russell*, 499 US 225 (1991) ("[i]n deference to the unchallenged superiority of the district court's factfinding ability, Rule 52(a) commands that a trial court's findings of fact 'shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses'" at 179). See also Caitlin E Borgmann, "Appellate Review of Social Facts in Constitutional Rights Cases" (2013) 101 Cal L Rev 1185.
[69] *Gonzales*, *supra* note 28 at 165-166.
[70] *Ibid*.
[71] *Ibid*. at 166.
[72] *Ibid*. at 157, citing *Washington v Glucksberg*, 521 US 702 at 731 (1997). This assertion also smacks of State paternalism, implying that by the profession approving the use of D & X it was not capable of monitoring its own integrity.

profession, in April, 2015, the Kansas legislature passed and the Governor signed the Unborn Child Protection From Dismemberment Abortion Act.[73] The legislation appears to outlaw the dilation and evacuation (D & E) method of abortion and provides no exception for the health of the mother, although if her life is at risk or she is at risk of "substantial and irreversible physical impairment of a major bodily function" she may still receive the procedure.[74] This is the most common abortion procedure in the second trimester[75] and is also considered the safest.[76] The statute was challenged and enjoined by a Kansas district court, which was upheld by an equally divided court of appeals.[77] This decision is currently under review.

b. Mandatory Ultrasound

Gonzales was the first time the Supreme Court upheld the prohibition of a medical procedure in the face of medical expert opposition. Other recent state regulation, rather than *banning* a procedure, has taken the unusual step of *requiring* physicians or other health professionals to perform a medical procedure: ultrasounds. These statutes raise questions of legitimate State interests, patient privacy, and the patient-physician relationship, as well as bodily integrity and patient autonomy which were so important in decisions like *Casey* and *Roe*.

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[73] US, SB 95, *Unborn Child Protection from Dismemberment Abortion Act*, 2014-2015, Reg Sess, Kan, 2015, (enacted); Kan Stat Ann § 65-6743 (2016). See also US, HB 257, 2016, Reg Sess, Ky, 2016, (introduced); US, HB 1714, 98th Gen Assem, Reg Sess, Mo, 2016, (introduced).
[74] Kan Stat Ann § 65-6743(3)(a) (2016).
[75] Bonnie Scott Jones & Tracy A Weitz, "Legal Barriers to Second-Trimester Abortion Provision and Public Health Consequences" (2009) 99 Am J Pub Health 623; Erik Eckholm & Frances Robles, "Kansas Limits Abortion Method, Opening a New Line of Attack", *New York Times* (7 April 2015) online: New York Times <http://www.nytimes.com/2015/04/08/us/kansas-bans-common-second-trimester-abortion-procedure.html?_r=0>.
[76] Amy M Autry et al, "A Comparison of Medical Induction and Dilation and Evacuation for Second-Trimester Abortion" (2002) 187 Am J Obstetrics & Gynecol 393.
[77] *Hodes & Nauser, MDs v Schmidt*, 368 P 3d 667 (Kan Ct App 2016).

The Guttmacher Institute has compiled a list of those states requiring ultrasounds prior to abortion.[78] Six (Kentucky, Louisiana, North Carolina, Oklahoma, Texas and Wisconsin) require an ultrasound *and* require the physician to display and describe the image, although the laws of North Carolina and Oklahoma have been permanently enjoined.[79] In all, 16 states have adopted some requirement that a sonogram or ultrasound be performed prior to the abortion procedure, most of which are still in effect.[80]

Courts asked to address the constitutionality of these statutes have come to opposing conclusions. The 5th Circuit Court of Appeals heard a challenge to Texas' Woman's Right to Know Act, which requires a physician, at least 24 hours prior to an abortion, "to perform and display a sonogram of the fetus, make audible the heart auscultation of the fetus for the woman to hear, and explain to her the results of each procedure."[81] The woman can decline to view the sonogram and hear the heartbeat, but can only refuse to hear the explanation in a few circumstances.[82] The appellate court very clearly supported the law, foreshadowing the remainder of its opinion at the very beginning: "[t]he amendments challenged here *are intended to strengthen the informed consent* of women who choose to undergo abortions."[83]

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[78] Guttmacher Institute, "State Policies in Brief: Requirements for Ultrasound", online: Guttmacher Institute <http://www.guttmacher.org/statecenter/spibs/spib_RFU.pdf> [Guttmacher Institute, "Requirements for Ultrasound"].

[79] Texas law provides that the woman has the "option" to view the sonogram image and hear the heartbeat, but she must hear an explanation of the sonogram images except for women pregnant due to assault, minors who obtain an abortion via judicial bypass, and women whose fetus has an irreversible medical condition or abnormality. Tex Health and Safety Code § 171.012(a)(4)-(5) (2014). Wisconsin law likewise permits a woman to decline to view an ultrasound image or listen to a heartbeat, but appears to require the physician to describe what he or she sees without providing an opportunity for the woman to opt-out of hearing the description. Wis Stat § 253.10(3g) (2014).

[80] Guttmacher Institute, "Requirements for Ultrasound," *supra* note 78.

[81] *Texas Medical Providers Performing Abortion Services v Lakey*, 667 F 3d 570 at 573 (5th Cir 2012) [*Lakey (5th Cir)*].

[82] *Ibid*.

[83] *Ibid*. [emphasis added].

The physicians challenged the requirements on the grounds of freedom of speech, claiming that the state compelled them to provide its ideological message without any medical purpose.[84] The 5th Circuit in *Lakey* disposed of the physicians' arguments by noting that the state was permitted to regulate the provision of truthful, nonmisleading and relevant information,[85] which does not rise to the level of compelled ideological speech necessitating a First Amendment analysis.[86] In addition to the state's authority to regulate professional conduct in this manner, it can also show a "'profound respect for the life within the woman.'"[87] The court found that not providing the information to the woman "is more of an abuse to her ability to decide than providing the information."[88] It viewed the physicians' arguments as an attempt to trump the balance between "women's rights and states' prerogatives"[89] and instructed the district court to maintain the sonogram, audio and verbal description requirements.[90]

On remand from the 5th Circuit, the district court granted summary judgment to the state defendants as ordered by the appellate court (it was bound to do so) but registered its objection to the appellate court's reasoning and its directive to the district court.[91] The Judge noted that the principles enunciated by the 5th Circuit finding that the required sonogram and description did not violate physicians' free speech rights, "taken together, describe a remarkable scope of state power in the

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[84] *Ibid*. at 574.
[85] *Ibid*. at 575.
[86] *Ibid*. at 576.
[87] *Ibid*. citing *Gonzales*, *supra* note 28 at 128.
[88] *Ibid*. at 579. This decision did not address the psychological harm that could result from requiring a woman to hear the description of the fetus, although it did point to the psychological harm of deciding to have an abortion and then later realizing the decision was not fully informed. *Ibid*. at 576. Further, it assumes that the woman does not understand what pregnancy is.
[89] *Ibid*. at 577.
[90] The court stated "this ruling will offer guidance to the district court, which is particularly important given our different view of the case." *Ibid*. at 573.
[91] *Texas Medical Providers Performing Abortion Services v Lakey*, No. A-11-CA-486-SS, 2012 WL 373132 (WD Tex 6 Feb 2012) ("[r]egardless of all the foregoing, however, this Court is required to defer to the panel's decision" at 4).

context of regulating a woman's right to choose."[92] The district court understood the appellate court's reasoning to essentially merge physicians' First Amendment rights with the Fourteenth Amendment rights of women seeking abortion, where "the doctor's right to speak, or not to speak, is wholly dependent on the contours of a woman's right to an abortion."[93] The district court saw this conflation of the two rights as problematic because it could require physicians to provide "truthful, nonmisleading, and relevant disclosures" as part of a "reasonable regulation of medical practice" so long as it did not create an undue burden on the patient, apparently relieving physicians entirely of their separate set of rights under the Constitution, including freedom of speech.[94]

The district court made a statement that is relevant to any statute or regulation that has the potential to negatively impact patient health and the patient-physician relationship. In a nod to professionalism, the court wrote that "[r]equiring doctors to take actions they believe are likely to cause harm to patients is completely at odds with the most basic tenets of medical ethics—and cannot, even under the most deferential interpretation of the phrase, be considered 'reasonable regulation of medical practice.'"[95]

The Texas federal district court found good company in the 4th Circuit Court of Appeals, which struck down North Carolina's ultrasound requirements on first amendment grounds,[96] upholding its own district court's order.[97] The North Carolina statute requires a physician or qualified technician to perform "an obstetric real-time view of the unborn child" although the woman can

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[92] *Ibid*. at 2.
[93] *Ibid*.
[94] *Ibid*. at 3. The district court also did not view the sonogram and description requirement as "relevant," even if technically truthful and nonmisleading. A sonogram is not always medically necessary to determine the location of a fetus prior to abortion, and deeming it and the required description "relevant" assumes that the woman has no idea that she is carrying a fetus. This is a bit facetious, but contradicts the assumption of capacity of adults (or minors of age of medical consent) to make medical decisions.
[95] *Ibid*. at 4.
[96] *Stuart v Camnitz*, 774 F 3d 238 (4th Cir 2014) [*Camnitz*].
[97] *Stuart v Loomis*, 992 F Supp 2d 585 (MD NC 2014) [*Stuart*].

choose to avert her eyes from the image, which the physician or technician is required to display to her.[98] The 4th Circuit's unanimous opinion demonstrates a level of discomfort with this type of legislation that is unusual in a circuit court of late and clearly interprets *Casey* differently than other circuits, returning to the spirit of *Roe* and *Thornburgh*.

The 4th Circuit determined that an intermediate scrutiny standard—rather than rational basis[99] or strict scrutiny[100]—was appropriate for its First Amendment review of the mandatory ultrasound statute, which compelled the provision of information by physicians to patients.[101] For the law to satisfy this standard, it must directly advance "a substantial government interest" and be "drawn to achieve that interest."[102] The court identified the state's interest in preserving, promoting and protecting fetal life, which had been consistently affirmed by the Supreme Court.[103] It was the means of protecting this interest, though, that troubled the court, which noted that other aspects of the statute not being challenged in the case, such as the provision of certain information, would likely satisfy this intermediate standard pursuant to *Casey* because they hewed closely to the informed consent provisions at issue in that decision.[104]

The 4th Circuit addressed physician speech in a very differently from *Lakey* and *Rounds*.[105] Even though medicine is a state-regulated profession, "professionals do not leave their speech rights at

[98] NC Gen Stat § 90-21.85 (2014).
[99] *Camnitz*, *supra* note 96 at 245. The state would treat this law as a regulation of commercial speech, and the 5th Circuit in *Lakey* had used this rational basis standard.
[100] *Ibid*. at 247 n 3.
[101] *Ibid*. at 249. This recognizes the holding in *Casey* that physicians' status as a regulated profession creates a lower standard for the regulation of speech. *Casey*, *supra* note 28 ("the physician's First Amendment rights not to speak are implicated…but only as part of the practice of medicine, subject to *reasonable* licensing and regulation by the State..." at 884 [emphasis added]).
[102] *Ibid*. at 250, citing *Sorrell v IMS Health Inc.*, 131 S Ct 2653 (2011).
[103] *Ibid*.
[104] *Ibid*. at 252.
[105] *Lakey (5th Cir.)*, *supra* note 81; *Rounds*, *supra* note 48.

the office door."[106] States have great leeway with how they regulate professions but this does not mean that physicians lose their rights by being physicians, just that the regulation might not be viewed with the same scrutiny as a law regulating the speech of an ordinary citizen.[107] Furthermore, the context of the regulation, not just the content, is important: "[w]ith all forms of compelled speech, we must look to the context of the regulation to determine when the state's regulatory authority has extended too far."[108] In the context of abortion, the state has a legitimate interest that it may promote, but that promotion must not infringe too heavily on the otherwise constitutionally protected rights of the physician and patient. For the 4th Circuit, physicians' rights are not folded into patients' rights, but deserve separate consideration.

Importantly, the court argued that the "government's regulatory interest is less potent in the context of a *self-regulating profession like medicine*."[109] The ramification of this recognition that the medical profession is deserving of more flexibility because of its tradition of self-regulation, if widely accepted, is potentially quite far-reaching. It also contrasts with the 5th Circuit's interpretation of *Casey* (in *Lakey*), that so long as information is truthful and not misleading physicians can be compelled to provide it to patients as part of the State's capacity to regulate the profession without regard to its self-regulatory capabilities and history.

The 4th Circuit also explored the potential conflict between the statute and physicians' ethical obligations to patients, especially the therapeutic privilege that would permit physicians, in normal

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[106] *Camnitz*, *supra* note 96 at 251.
[107] Content-based regulation of speech, or compulsion of speech to convey an ideological message, when applied to the average individual would fall under a strict scrutiny analysis. See e.g. *Carey v Brown*, 447 US 455 (1980); *Burson v Freeman*, 504 US 191 (1992); *RAV v City of St Paul*, 505 US 377 (1992). The Supreme Court recently addressed the free speech rights of judicial candidates and came to a similar conclusion. *Williams-Yulee v Florida Bar Assoc*, 135 S Ct 1656 (2015).
[108] *Camnitz*, *supra* note 96 at 247.
[109] *Ibid*. at 248 [emphasis added].

circumstances, to decline to provide information to patients if they believed it might be harmful to them.[110] Citing the differences between the North Carolina statute and the provisions at issue in *Casey*, the court found that the law "runs contrary to the state's interest in 'protecting the integrity and ethics of the medical profession'".[111] It explained that "[r]equiring the physician to provide the information regardless of the psychological or emotional well-being of the patent…can hardly be considered closely drawn to those state interest the provision is supposed to promote."[112] The therapeutic privilege, "albeit a limited one to be used sparingly….permits the physician to uphold his ethical obligations of benevolence."[113] Although this discussion of ethics is brief it is more than we normally see in court opinions on abortion statutes, and points to valid questions about the role of the State in regulating traditionally ethical and medical considerations.

The opinions in *Rounds*, *Lakey* and *Camnitz* create incompatible interpretations of *Casey* and *Gonzales* with no current chance of refereeing by the Supreme Court. Therefore, patients and physicians in Texas and the rest of the region covered by the 5th and 8th Circuits can be required to undergo potentially unnecessary medical procedures and hear or view information that they might

[110] *Ibid*. at 254. The district court judge was more detailed in her discussion of the impact of the statute on medical ethics, citing primarily Beauchamp and Childress' *Principles of Biomedical Ethics* and ACOG's opinion on ethical decision-making. *Stuart*, *supra* note 97 at 591.
[111] *Camnitz*, *supra* note 96 at 254, citing *Gonzales*, *supra* note 28 at 157. The AMA *Code of Medical Ethics* generally opposes the use of therapeutic privilege as creating "a conflict between the physician's obligations to promote patients' welfare and respect for their autonomy by communicating truthfully." Council on Ethical and Judicial Affairs, *Code of Medical Ethics: Current Opinions with Annotations, 2010-2011* (Chicago: American Medical Association, 2010) at 269 [CEJA, *Code of Medical Ethics*]. This raises a question about the accuracy of the 4th Circuit's recounting of medical ethics (although the AMA generally opposes therapeutic privilege, others doubtless support its utility in some circumstances), and a better characterization of the ethics at issue in *Camnitz* is that "physicians should honor patient requests not to be informed of certain medical information". *Ibid*. at 270. Under North Carolina's law, patients are not offered a meaningful opportunity to do so. Further, patients should generally be protected from receiving irrelevant information, which might only serve to overload them with information when they need the best guidance possible.
[112] *Camnitz*, *supra* note 96 at 254.
[113] *Ibid*.

not want to receive, while those residing or practicing in the region covered by the 4th Circuit are not.

5. Abortion and a Growing Distrust Between the State and Profession

Regulation of abortion is only a small part of the whole of State regulation of the medical profession. The direct effect of these laws is felt by a small number of physicians, although millions of women are within the envelope of states' regulations. However, what these laws and court decisions say about the direction of profession-State relations transcends the narrowness of the regulation. It is rare that the State so directly and completely rebukes the medical profession when there is no indication that the profession or individual physicians are otherwise acting unethically, dangerously or in contravention of patients' best interests.

What *Casey* and *Gonzales* have done is create precedent for the State to overrule the opinion of experts and professionals on matters within their expertise and replace it with the State's ideological, political and moral viewpoint. What is important about the topic of abortion and State legislative, executive and judicial decision-making is not just its impact on physicians' ability to practice ethically in this field, but also the uncertainty it creates about *any* State attempt to regulate the medical profession restrictively in spite of medical ethics and practice standards. Indeed, *Casey*'s rejection of physicians' free speech arguments eventually impacted another court's interpretation of speech restrictions in the field of gun safety and public health.

C. Gun Safety Speech Laws

Much like abortion, gun safety and gun control is a heated political topic.[114] The growth of the gun culture in the past century alongside a growing awareness of the flaws in this culture (e.g. high gun-related death rate; numerous mass murders) has given rise to a political and social awareness of the implications of widespread firearm ownership. Legislatures, combined with limited judicial decisions on the topic,[115] have incubated a permissive set of rights for individuals to own and carry firearms.

When legislatures and courts address gun ownership and possession, it is a matter of Second Amendment constitutional rights.[116] However, the medical profession has developed a different perspective on this issue. Rather than directly addressing whether and to what extent individuals should be permitted to own and carry guns in private or in public, the AMA and other medical societies look at this as a matter of public health, as they do tobacco, alcohol and drug abuse, obesity and diet, and many other medical or potentially medical problems that afflict society.

By 1987, the AMA began taking steps to address the public health aspects of firearms. Its Council on Scientific Affairs (CSA), now called the Council on Science and Public Health (CSAPH), submitted a report to the House of Delegates (HOD) entitled "Firearms as a Public Health Problem

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[114] Although not relevant to my analysis here, the *Patient Protection and Affordable Care Act* included provisions on confidentiality of firearm ownership information that have been widely publicized, leading the President to issue an executive order (touching on many concerns about the Act in general) that included a statement that physicians could ask about firearm ownership. This, in turn, led some media outlets to claim that physicians are required to ask about gun ownership. See Janet L Dolgin, "Physician Speech and State Control: Furthering Partisan Interests at the Expense of Good Health" (2014) 48 New Eng L Rev 293 at 317-319.

[115] There is not much Supreme Court precedence for Second Amendment rights, although the Court and lower courts have addressed the issue more often in recent years and generally come down on the side of broad individual rights with narrow avenues for State regulation. *District of Columbia v Heller*, 554 US 570 (2008); *McDonald v City of Chicago*, 561 US 742 (2010).

[116] US Const amend II ("[a] well regulated militia, being necessary to the security of a free state, the right of the people to keep and bear arms, shall not be infringed").

in the United States: Injuries and Deaths."[117] The Council recognized that "uncontrolled ownership and use of firearms, especially handguns, is a serious threat to the public's health inasmuch as the weapons are one of the main causes of intentional and unintentional injuries and death."[118] This conclusion stemmed from an examination of the evidence and laws of the time, where firearms-related homicides constituted over 12,000 deaths, suicides over 16,000 deaths, and accidents nearly 1700 deaths in 1983.[119] The CSA recommended that the AMA "[u]rge that government agencies, the Centers for Disease Control in particular, enlarge their efforts in the study of firearm-related injuries and in the development of ways and means of reducing such injuries and death" and "[e]ncourage the improvement or modification of firearms so as to make them as safe as humanly possible…."[120]

In the decades since this report, the AMA's position has not changed. It does not call for the abolition of handguns or other firearms,[121] but does promote regulation in the interests of public safety. Considering the shift in many states towards allowing guns (concealed or open carry) in more and more public places,[122] the AMA has advocated for the creation of hospital policies on

[117] Council on Scientific Affairs of the American Medical Association, "Report A: Firearms as a Public Health Problem in the United States: Injuries and Deaths" in American Medical Association, *Proceedings, House of Delegates, Atlanta, Georgia, December 6-9, 1987, 41st Interim Meeting* (Chicago: American Medical Association, 1987) at 233-243.
[118] *Ibid*. at 243.
[119] *Ibid*. at 234.
[120] *Ibid*. at 243.
[121] A 1993 report by the AMA Board of Trustees stemmed from a resolution submitted by the American Academy of Pediatrics that called for a ban on handguns and automatic weapons, but the Board did not go so far as to support a ban, recognizing the incredible difficulty inherent in its enforcement. Board of Trustees of the American Medical Association, "Ban on Handguns and Automatic Repeating Weapons (Resolution 209, A-93)" in American Medical Association, *House of Delegates, Proceedings, 47th Interim Meeting, December 5-9, 1993* (Chicago: American Medical Association, 1993).
[122] See e.g. US, HB 1700, *An Act Making Technical Corrections Concerning the Possession of a Handgun and Other Weapons in Certain Places; and for Other Purposes*, 89th Gen Assem, Reg Sess, Ark, 2013, (enacted) (deletes prohibition against carrying a firearm into "an establishment that sells alcoholic beverages"); Miss Code Ann § 45-9-101(13), 97-37-7 (2014) (together these sections set forth the locations in which a concealed weapon cannot be carried, and then excepts most of these prohibitions when a licensed individual completes an improved instructional course on the safe handling and use of firearms).

firearms in these facilities, within the bounds of the law.[123] AMA policy also identifies the role of individual physicians to educate, when possible, individual patients or groups on safety measures that can be used to protect patients and their families.[124]

Mainstream medical societies do not dissent from this general policy viewing guns as a public health issue,[125] and some advocate even stronger measures due to the vulnerability of their patient populations.[126] Yet the success of the profession in promoting gun violence as a public health issue and combating it through regulation and public health initiatives has been very limited. The Bureau of Justice Statistics confirms the continuing high rate of firearm violence, although it notes that incidents decreased substantially between 1993 and 2011.[127]

Recently, legislators and groups in favor of broader gun ownership and carry rights have taken steps to make physicians' attempts at public health advocacy even more difficult. In 2011 Florida enacted a statute that regulated physicians' ability to discuss firearms and firearm safety with patients.[128] As of the time of this writing, Florida was one of only three states to have successfully adopted this type of legislation.[129] The statute phrases gun ownership and safety in terms of the

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[123] American Medical Association, "H-215.977, Guns in Hospitals", online: American Medical Association <https://searchpf.ama-assn.org/SearchML/searchDetails.action?uri=%2FAMADoc%2FHOD.xml-0-1436.xml>; American Medical Association, "H-215.978, Guns in Hospitals", online: American Medical Association <https://searchpf.ama-assn.org/SearchML/searchDetails.action?uri=%2FAMADoc%2FHOD.xml-0-1437.xml>.
[124] American Medical Association, "H-145.975, Firearms Safety and Research, Reduction in Firearm Violence, and Enhancing Access to Mental Health Care", online: American Medical Association <https://searchpf.ama-assn.org/SearchML/searchDetails.action?uri=%2FAMADoc%2FHOD.xml-0-532.xml>.
[125] See e.g. American College of Emergency Physicians, *Policy Compendium* (Irving, TX: American College of Emergency Physicians, 2014) at 65; American College of Surgeons, "Statement on Firearm Injuries", online: American College of Surgeons <https://www.facs.org/about-acs/statements/12-firearm-injuries>.
[126] Council on Injury, Violence and Poison Prevention Executive Committee of the American Academy of Pediatrics, "Firearm-Related Injuries Affecting the Pediatric Population" (2012) 130 Pediatrics e1416.
[127] Bureau of Justice Statistics, US Department of Justice, "Firearm Violence, 1993-2011", online: Bureau of Justice Statistics <http://www.bjs.gov/content/pub/pdf/fv9311.pdf>. See also Brady Campaign to Prevent Gun Violence, "There are Too Many Victims of Gun Violence", online: Brady Campaign <http://www.bradycampaign.org/sites/default/files/gun-death-and-injury-stat-sheet-5-year-average.pdf>.
[128] Fla Stat Ann § 790.338 (2014).
[129] Mont Code Ann § 50-16-108 (2014). Montana's law is even more broad than Florida's, providing that "[n]o health care provider or health facility may…refuse to provide health care to a person because the person declines to

privacy interests of a patient. Thus, in general when the information "is not relevant to the patient's medical care or safety, or the safety of others", physicians are legally prohibited from entering information concerning firearm ownership into a patient's medical record[130] or from asking the patient in writing or verbally about gun or ammunition ownership by a patient or someone in the patient's home.[131]

The profession quickly responded: the Florida Medical Association adopted a policy in 2011 opposing "any attempt to restrict physician questions to patients or require questions of patients; and further legally supports, to the greatest degree possible, any FMA member subject to disciplinary action based on enforcement of the Florida gun law…if the affected physician was acting based on the medical necessity and safety of the patient or others."[132] Physicians and interest groups challenged the law in federal district court.[133]

Important in this case is that the state did not provide anything other than anecdotal evidence that physicians were discriminating against or harassing patients based on their gun ownership.[134] When the legislation was first introduced, it was intended to address a single incident (no additional evidence was provided) where "a pediatrician asked a patient's mother whether there were any

answer any questions concerning the person's ownership, possession, or use of firearms…." Mont Code Ann § 50-16-108(1)(a) (2014). Missouri's statute is aimed at prohibiting any requirement for physicians to ask about firearms or document such information in the patient's medical record, although it is not clear that any requirements existed or were going to be adopted at the federal level. Mo Rev Stat § 571.012 (2016). It does, however, contain the curious provision that "[n]o health care professional licensed in this state shall use an electronic medical record program that requires, in order to complete and save a medical record, entry of data regarding whether a patient owns, has access to, or lives in a home containing a firearm." Mo Rev Stat § 571.012(4) (2016). This is probably intended to diminish the instance of physicians asking about firearms by making this question incompatible with the growing uptake of electronic medical records.

[130] Mo Rev Stat § 571.012(1) (2016).

[131] Mo Rev Stat § 571.012(2) (2016).

[132] Florida Medical Association, "P 190.005 Physician Ability to Freely Discuss Gun Safety" in Florida Medical Association, *Public Policy Compendium* (Tallahassee: Florida Medical Association, 2012) at 33.

[133] *Wollschlaeger v Farmer*, 88 F Supp 2d 1251 (SD Fla 2012) [*Wollschlaeger, SD Fla*].

[134] *Ibid*. at 1264.

firearms in the home. When the mother refused to answer, the doctor advised her that she had 30 days to find a new pediatrician."[135] The physician decided to terminate his relationship because this refusal implicated trust in other aspects of his relationship with the parents and patient.[136] Interestingly, although the state in *Wollschlaeger* asserted that one purpose of the statute was to protect patients from discrimination or harassment, the law did not modify physicians' ability to terminate the relationship if a patient refused to answer questions about firearms still permitted under the statute.[137]

The physician-plaintiffs challenged the statutes under the First and Fourteenth Amendments,[138] focusing on the preventive medicine aspect of their practices. In order to best serve patients, they inquire (often by written questionnaire) and counsel about a wide range of behaviors and products that could impact the health of patients or their families, including "household chemicals, swimming pools, drugs, alcohol, tobacco, and firearms….diet, second-hand smoke, bicycle helmets, [and] automotive safety…" as part of a general health screening.[139] These are not necessarily based on current threats to patients' health but those that could impact them now or in the future.[140] This is no different than counseling patients about their diet to possibly prevent or delay the development of diabetes later in life.[141]

This case faced an odyssey of court decisions. The initial district court order ruled in favor of the physicians' motion for summary judgment because the law created a content-based restriction on

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[135] Florida Judiciary Committee, HR Staff Analysis, HB 155 (April 11, 2011) at 2.
[136] Fred Hiers, "Family and Pediatrician Tangle Over Gun Question", *Ocala Star Banner* (24 July 2010) online: Ocala Star Banner <http://www.ocala.com/article/20100724/ARTICLES/7241001?p=2&tc=pg>.
[137] Fla Stat Ann § 790.338(4) (2014); *Wollschlaeger, SD Fla*, *supra* note 133 at 1264-1265.
[138] *Ibid*.
[139] *Ibid*. at 1257. From my own experience, my children's physician requests that we complete a questionnaire periodically, and it includes questions relevant to public health and home safety, including whether we keep firearms in the house.
[140] *Ibid*. at 1263.
[141] *Ibid*.

physicians' speech, and the state could not provide a compelling or even legitimate interest to justify such a narrowly focused law. The restriction interfered with the free flow of "truthful, non-misleading information" which is "critical within the doctor-patient relationship."[142] The ability of the physician to provide safety information has become an important component of the patient-physician relationship.

The 11th Circuit Court of Appeals heard this case before the same 3-judge panel three times.[143] Each time, the majority ruled that the statute was a valid exercise of the state's regulation of the profession both to protect patients' privacy rights as well as their gun rights under the Second Amendment to the US Constitution. Each time the court used a different reasoning to justify its decision.

In the first opinion, the court found that "the Act is a valid regulation of professional conduct that has only an incidental effect on physician speech" and therefore "does not facially violate the First Amendment."[144] This was an interesting conclusion since the law very clearly and directly prohibits speech (and for an ideological purpose). However, the court also attempted to use medical ethics and practice to defend its pronouncement on the constitutional validity of the Florida law.

The appellate court panel paid little attention to the physicians' claim that the practice of preventive medicine required that they be permitted to inquire into activities that might impact upon the health of a patient or his or her family even in the absence of a direct connection to the current health of that patient. It determined that the state properly placed inquiries about gun ownership and the

[142] *Ibid*. at 1265.
[143] *Wollschlaeger v Florida*, 760 F 3d 1195 (11th Cir 2014) [*Wollschlaeger I*]; *Wollschlaeger v Florida*, 797 F 3d 859 (11th Cir 2015) [*Wollschlaeger II*]; *Wollschlaeger v Florida*, 814 F 3d 1159 (11th Cir 2015) [*Wollschlaeger III*].
[144] *Wollschlaeger I*, *supra* note 143 at 1217.

entering of related information into the medical records of a patient "outside the bounds of good medical care".[145] In the process, the court interpreted the Hippocratic Oath and the AMA's *Declaration of Professional Responsibility* to mean that physicians should not inquire "into private matters unless such inquiry is necessary for the practice of good medicine."[146] It phrased the issue as one of imbalance of power between patient and physician, where the patient's ability to decline to provide information (in this case about firearms) is diminished because he or she might feel obliged to answer.[147] Therefore, in order to maintain the privacy rights of patients the court deemed it proper for the state to prohibit inquiries about firearms unless relevant to the health or safety of the patient or others.[148]

The court also pointed to circumstances where the state can regulate physician speech without infringing on their constitutional free speech rights:

> [f]or example, "[a] doctor may not counsel a patient to rely on quack medicine. The First Amendment would not prohibit the doctor's loss of license for doing so." "When a drug is banned,…a doctor who treats a patient with that drug does not have a First Amendment right to speak the words necessary to provide or administer the banned drug." A doctor might face malpractice liability for communicating an inaccurate diagnosis to a patient, or for failing to timely communicate an accurate diagnosis. A doctor might face malpractice liability for giving a patient improper instructions, or for failing to provide a patient with proper instructions. In all of these scenarios, a court might hold a doctor liable for actions which involve speech and, given such state action, presumably infringe on the doctor's First Amendment rights.[149]

It is true that in each of these instances, a physician can be subject to disciplinary action by state regulators or to malpractice liability. However, none is quite like the regulation in *Wollschlaeger*

[145] *Ibid*. at 1226.
[146] *Ibid*. at 1215.
[147] *Ibid*. at 1214. This represents quite a contrast with the Supreme Court's reasoning in *Casey*, where requiring the disclosure of certain information that the challenging physicians did not believe was always necessary—or might even be harmful—did not implicate the imbalance in the patient-physician relationship.
[148] *Ibid*. at 1215.
[149] *Ibid*. at 1217.

and each also represent a circumstance where professional ethics would find a violation. They are not reconcilable with a prohibition on discussing a specific and medically relevant topic with patients.

This first *Wollschlaeger* opinion found no First Amendment violations. The second two panels to rehear the case found that the First Amendment was implicated but that under either of two standards of review—intermediate or strict scrutiny—the state satisfied its obligations to regulate only as necessary to further its interests. *Wollschlaeger II* determined that both the prohibition on writing information on firearm ownership in patients' medical records and on asking patients about firearm ownership inhibit "protected speech".[150] However, the court also viewed professional speech as subject to greater regulation than non-professional, individual speech,[151] therefore placing state regulation within intermediate scrutiny.[152] It found "a substantial state interest" in "protecting the public by regulating the medical profession so as to safeguard patient privacy",[153] which was directly advanced by the law and precisely tailored.[154] The court continued to discount professional assertions of the public health importance of firearm safety.[155]

The final 3-judge panel decision again upheld the law, but this time applied the strict scrutiny standard for its free speech analysis.[156] The majority again found that the prohibited actions fell within the meaning of "speech" protected by the Constitution,[157] but even using a strict scrutiny

[150] *Wollschlaeger II*, *supra* note 143 at 885.
[151] *Ibid*. at 887-891. See also *Casey*, *supra* note 28 ("[t]o be sure, the physician's First Amendment Rights not to speak are implicated, but only as part of the practice of medicine, subject to reasonable licensing and regulation by the State" at 884 [internal citations omitted]).
[152] *Wollschlaeger II*, *supra* note 143 at 892.
[153] *Ibid*. at 897.
[154] *Ibid*. at 899-900.
[155] *Ibid*. The dissent in this rehearing discussed the physicians' public health rationale at length. *Ibid*. at 901-934.
[156] *Wollschlaeger III*, *supra* note 143.
[157] *Ibid*. at 1184.

standard the law passed muster: "the State has asserted a compelling interest and the Act is narrowly tailored to advance that interest."[158]

Three cases with three identical resolutions but three different rationales led to a rehearing *en banc* by the full 11th Circuit, all 11 judges.[159] Unlike the previous three decisions this one—containing two majority opinions, two concurring opinions and one dissent (by the judge that authored first three majority opinions)—invalidated the portions of the Florida law prohibiting the inquiring and recording of information regarding firearm ownership. The opinions highlight the continuing difficulty of reconciling a variety of Supreme Court jurisprudence to determine the level of scrutiny to apply to professional speech restrictions, but they also decide that the law is so clearly a content- and viewpoint-based speech restriction that it fails even under an intermediate scrutiny standard.[160]

The court pointed out that legislators relied only on six anecdotes to enact the law.[161] "There was no other evidence, empirical or otherwise, presented to or cited by the Florida legislature."[162] Where the previous panels found the state's interests for enacting the law compelling,[163] the full panel discounted each in turn. Physicians don't have the authority to impact patients' Second Amendment rights to own or possess firearms;[164] privacy is not advanced by the law because

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[158] *Ibid*. at 1186. It appears that the court's decision to rehear the case was based on the recently decided US Supreme Court decision of *Reed v Town of Gilbert*, which the physicians argued placed content-based restrictions even on professional speech within the strict scrutiny test. *Ibid*.; *Reed v Town of Gilbert*, 576 US __, 135 S Ct 2218 (2015). The compelling state interests were: "(1) protection of the Second Amendment right to keep and bear arms; (2) protection of patients' privacy rights; (3) elimination of barriers to healthcare access; and (4) prevention of discrimination and harassment of firearm owners." *Wollschlaeger III*, *supra* note 143 at 1192.
[159] *Wollschlaeger v Florida*, No 12-14009, 11-cv-22026-MGC, 2017 WL 632740 (11th Cir 16 February 2017) [*Wollschlaeger IV*].
[160] *Ibid*. at 19.
[161] *Ibid*. at 28.
[162] *Ibid*.
[163] See *supra* note 158.
[164] *Wollschlaeger IV*, *supra* note 159 at 29. The court also noted that physician inquiry about firearms is consistent with other Florida policy on safe firearm storage and children. *Ibid*. at 30.

patients can decline to answer any questions and in any event state law already limits disclosure of medical records;[165] access to health care without discrimination or harassment is not advanced because physicians can still terminate the relationship and physicians and patients will always engage in discussion on topics that might be uncomfortable for the patient;[166] and the fact that the state regulates the medical profession does not mean it can regulate speech restrictively without good cause.[167]

Importantly, the court recognized and accepted physicians' reasons for inquiring about firearms in the first place: public health and safety. It argued that "[i]n 'the fields of medicine and public health…information can save lives.'"[168] Further, it cited the *profession's* standard of care that "encourages doctors to ask questions about firearms (and other potential safety hazards)" to contradict the state's claim that it can regulate the profession and therefore physician speech.[169]

Judge William Pryor, concurring in the decision, addressed his additional concern about inserting content-based speech restrictions in the patient-physician relationship that goes beyond the issue of firearms, and is important for considering the role of politics in the regulation of the medical profession. He argued that

> [i]f we upheld the Act, we could set a precedent for many other restrictions of potentially unpopular speech. Think of everything the government might seek to ban between doctor and patient as supposedly "irrelevant" to the practice of medicine….The Florida Legislature overstepped the boundaries of the First Amendment when it determined that the proper remedy for speech it considered "evil" was "enforced silence," as opposed to "more speech.[170]

[165] *Ibid*. at 32.
[166] *Ibid*. at 34-35.
[167] *Ibid*. at 36-38.
[168] *Ibid*. at 31, citing *Sorrell v IMS Health*, 564 US 552 at 566 (2011).
[169] *Ibid*. at 38.
[170] *Ibid*. at 67-69.

If this reasoning on physician speech rights had been applied in the context of abortion, as detailed in the previous Section, the conclusions of many courts might have been quite different.

The *Wollschlaeger* saga of cases demonstrates the potential for explosive political issues to infringe on professional ethical norms. It took four attempts before the 11th Circuit recognized the problem of using speech restrictions to prohibit a "good medical practice" and that Florida's authority to regulate medicine is not infinite.

III. "Protecting the Integrity and Ethics of the Medical Profession," Sometimes

A. Introduction

This section examines two related areas of medical ethics and State law: physician-assisted suicide and physician participation in capital punishment. Both topics involve the physician directly in the death of an individual, and raise issues of consent and the level of participation in the act that causes death. Although there are some occasions when medical ethics and State law converge to reach the same conclusion, there are others where the arguments advanced by each substantially diverge. Each topic will be examined in turn, with an emphasis on how medical ethics fit into state regulatory schemes.

B. Physician-Assisted Suicide

As a legal concept, suicide was mostly decriminalized in the US by the 19th century.[171] Although punishing the family of someone who committed suicide fell out of fashion by this period,[172] criminalizing assisted suicide remained the law of the states, even if an individual clearly requested

[171] See *Washington v Glucksberg*, 521 US 702 at 710-719 (1997) [*Glucksberg*].
[172] Justice Rehnquist remarked in *Glucksberg* that "this change reflected the growing consensus that it was unfair to punish the suicide's family for his wrongdoing" even though the suicide could not be punished directly. *Ibid*. at 714.

the help.[173] Physician involvement in suicide, especially pharmaceutical-based suicide, is generally treated no differently than any other assistance. Only a few states permit physicians to assist suicide, with Oregon as the first to adopt a comprehensive act detailing the minutiae of participation in 1997. Since then California, Montana,[174] Washington and Vermont, have taken the same step, but for the remainder of the country suicide is decriminalized only for an individual's actions and not those of anyone who assists. However, even as Oregon had just legalized physician-assisted suicide, the Supreme Court addressed statutes outlawing it in the companion cases of *Washington v Glucksberg* and *Vacco v Quill*.[175]

Glucksberg was a challenge to a Washington statute prohibiting the "promoting" of a suicide attempt.[176] At the same time, a separate statute permitted the "withholding or withdrawal of life-sustaining treatment,"[177] which the assisted suicide prohibition challengers viewed as a contradiction and a violation of their 14th Amendment right to choose assisted suicide, likened to the rights set forth in *Planned Parenthood of Southeast Pennsylvania v Casey*.[178] Although the district court found the law unconstitutional as a violation of protected liberty interests and the Equal Protection Clause, the 9th Circuit Court of Appeals reversed and upheld the law, noting that a constitutional right to be assisted in suicide had never been established by "a court of final

[173] See e.g. Or Rev Stat § 163.193 (2104); Tex Penal Code tit 5 § 22.08 (2015); Va Code § 8.01-622.1 (2014).
[174] Unlike other states that permit assisted suicide through legislation, the law was changed in Montana via court order, finding a constitutional right to assistance in dying. *Baxter v Montana*, 224 P 3d 1211 (Mont Sup Ct 2009).
[175] These were not the first court cases to address physician-assisted suicide bans, but they were the first in the US Supreme Court. The Michigan Supreme Court addressed the issue in perhaps the most well-known physician-assisted suicide/euthanasia case, involving Dr. Kevorkian. *People v Kevorkian*, 527 NW 2d 714 (Mich Sup Ct 1994).
[176] *Glucksberg*, *supra* note 171 at 707, citing Wash Rev Code § 9A.36.060(1).
[177] *Ibid*.
[178] *Ibid*. at 708; *Casey*, *supra* note 28. The 14th Amendment reads, in relevant part, "nor shall any state deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws." US Const amend XIV, § 1.

jurisdiction."[179] The court did not, however, deny that there was a constitutionally protected "right to die."[180]

The Supreme Court looked to legal and philosophical traditions to deny a historical right to assisted suicide,[181] but it also turned to the medical profession to further support its decision. This was not a major portion of the opinion, but it bears mention because it directly addressed the AMA's *Code* and the profession's position on physician-assisted suicide.[182]

In full, the Court's reference to the *Code* comes towards the end of the majority opinion:

> [t]he State also has an interest in protecting the integrity and ethics of the medical profession. In contrast to the Court of Appeals' conclusion that "the integrity of the medical profession would [not] be threatened in any way by [physician-assisted suicide],"…the American Medical Association, like many other medical and physicians' groups, has concluded that "[p]hysician-assisted suicide is fundamentally incompatible with the physician's role as healer."….And physician-assisted suicide could, it is argued, undermine the trust that is essential to the doctor-patient relationship by blurring the time-honored line between healing and harming.[183]

This brief recounting of professional obligations, at least as set forth by the AMA as a broadly representative body, signifies a rare instance where the Court is fully cognizant of both professional ethical standards and the potential impact if it were to rule against them.

The companion case to *Glucksberg*, *Vacco v Quill*, appears next in the Supreme Court Reporter, and with the same outcome.[184] Physicians and patients challenged New York law prohibiting assistance in suicide. Unlike in *Glucksberg*, the Court did not refer to the AMA *Code* or any other

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[179] *Glucksberg*, *supra* note 171 at 708-709.
[180] *Ibid*. at 709.
[181] *Ibid*. at 710-719.
[182] The *Code of Medical Ethics* does not take a position on the morality of suicide as an individual act, although it does advocate that physicians address the needs of patients at the end of life, and the failure to do so may be one of the roots of a desire to take one's own life. CEJA, *Code of Medical Ethics*, *supra* note 111 at 112.
[183] *Glucksberg*, *supra* note 171 at 731 [citations omitted].
[184] *Vacco v Quill*, 521 US 793 (1997) [*Vacco*].

ethical aspect of physician-assisted suicide. However, much of the reasoning used to uphold the statute parallels the profession's dichotomy between acts like withdrawing treatment and assisted suicide.[185] "First, when a patient refuses life-sustaining medical treatment, he dies from an underlying fatal disease or pathology; but if a patient ingests lethal medical prescribed by a physician, he is killed by that medication."[186] In one instance, the physician indirectly causes the death of a patient, while complying with his or her wishes, and in the other the physician is the direct cause.

These two cases determined that there was no fundamental right to physician-assisted suicide in the face of state prohibitions. However, by the time of the Supreme Court's decisions in *Glucksberg* and *Quill*, Oregon had already enacted its Death with Dignity Act.[187] This statutory framework created a legal mechanism to pursue and carry out physician-assisted suicide, limiting access to the process to the capable adult resident of Oregon who "has been determined by the attending physician and consulting physician to be suffering from a terminal disease, and who has voluntarily expressed his or her wish to die…."[188] The limitations of the statute are intended to prevent voluntary and involuntary euthanasia, restricting access to assisted suicide to those who are competent.[189] This is different from withdrawal of treatment cases, where surrogate decision-makers can apply to have care removed without the explicit consent of the patient at the time the treatment is withdrawn.[190]

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[185] CEJA, *Code of Medical Ethics*, *supra* note 111 at 88-89, 112.
[186] *Vacco*, *supra* note 184 at 801.
[187] Or Rev Stat § 127.800 et seq. (2014).
[188] Or Rev Stat § 127.805 (2014).
[189] Or Rev Stat §§ 127.805, 127.825 (2014).
[190] See CEJA, *Code of Medical Ethics*, *supra* note 111 ("[i]f the patient receiving life-sustaining treatment is incompetent, a surrogate decision maker should be identified. Without an advance directive that designates a proxy, the patient's family should become the surrogate decision maker" at 88).

Challenges to the Oregon Act, based both upon 14th Amendment and Equal Protection violations[191] and the federal government's drug regulations,[192] failed. While the Supreme Court will uphold a state's decision to outlaw physician-assisted suicide, it will not interfere with a decision to adopt legislation that legalizes and regulates it, consistent with the state's interests in the matter. In *Glucksberg*, the Court stated that the State has an interest in protecting the ethics of the profession.[193] Yet the events following this case demonstrate that this interest, at least for assisted suicide, is not very strong.

Medical societies, especially the AMA, continue to oppose physician-assisted suicide but their resistance is noticeably less vocal than with other issues in this Chapter. One reason might be that there is significant dissent within the community of physicians as to their role at the end of life. Although the AMA *Code* focuses on the physician's role as healer, which is seemingly incompatible with any action that directly causes a patient's death,[194] many physicians believe that ensuring a painless death is perfectly in line with their ethical obligations.[195] There is sincere concern with the plight of the terminally ill who might face what to healthy individuals is an

[191] *Lee v Oregon*, 107 F 3d 1382 (9th Cir 1997). The district court had enjoined enforcement of the statute due to a violation of the Equal Protection clause, but the 9th Circuit Court of Appeals vacated that decision because the plaintiffs failed to assert an injury in fact and the federal courts did not have jurisdiction. The plaintiff-patient's assertion that she might suffer a harm if her attending and consulting physician, acting pursuant to the legislation, failed to diagnose her depression and assisted in her suicide was held to be purely speculative. *Ibid*. at 1388-1390. As for plaintiff-physicians' claims that their 1st Amendment rights would be violated if forced to comply with the statute, the appellate court noted that there was no penalty for not assisting in a patient's suicide—the penalties were associated with forging a request or coercing a patient to make a request. *Ibid*. at 1391.

[192] *Gonzales v Oregon*, 546 US 243 (2006). The Supreme Court held that the US Attorney General's interpretation of the phrase "legitimate medical purpose" in the Controlled Substances Act was outside of his rulemaking power, as Congress would not "use such an obscure grant of authority to regulate areas traditionally supervised by the States' police powers." *Ibid*. at 274. An interesting aspect of this decision is that the Court recognized Congress' decision in ratifying the Convention on Psychotropic Substances that it would not "'interfere with ethical medical practice in this country as determined by [the Secretary] on the basis of a consensus of the views of the American medical and scientific community.'" *Ibid*. at 266.

[193] *Glucksberg*, *supra* note 171 at 731.

[194] CEJA, *Code of Medical Ethics*, *supra* note 111 at 112.

[195] James A Colbert, Joann Schulte & Jonathan N Adler, "Physician-Assisted Suicide—Polling Results" (2013) 369 N Eng J Med e15.

inconceivable amount of pain and suffering. Justice Souter seemed to channel this view in his concurrence in *Glucksberg*,[196] and the lower court decision also took the stance that physicians were well within their capabilities to provide aid in suicide.[197] Of course, just because physicians *can* do something does not mean that it is *ethical* to do so. The AMA has taken great pains to consider this dissent when crafting and affirming its assisted suicide policy since its initial adoption in 1994. Despite the opinion of many physicians that physician-assisted suicide is ethically compatible with their role as healers, this policy has not been modified.

As assisted suicide continues to be considered by state legislatures and courts, the profession might also be reconsidering its position. As of yet there is no indication that the AMA is planning to alter its ethics Opinion,[198] but other medical societies have a different outlook on physician-assisted suicide.[199] While the AMA continues to distinguish between withdrawing life-sustaining treatment (the underlying disease causes death), palliative care (there is a risk of death due to high dosages of palliative medications) and assisted suicide, more and more physicians express a greater tolerance for assisted suicide as an ethical and caring option for terminally ill, competent patients. The next subsection, though, addresses physician participation in lethal injection execution, where

[196] *Glucksberg*, *supra* note 171 at 779-789.
[197] The 9th Circuit cited the medical profession's "time-honored but hidden practice of physicians helping terminally ill patients to hasten their deaths" in its recounting of a historical basis to support the practice. *Compassion in Dying v State of Washington*, 79 F 3d 790 at 811 (9th Cir 1996).
[198] However, at the AMA's 2016 Annual Meeting, the HOD referred to CEJA for study a resolution that requests a study of the current state of assisted suicide and a determination on whether the AMA should take a neutral stance on the issue. American Medical Association House of Delegates, "Report of Reference Committee on Constitution and Bylaws", online: ama-assn.org < https://www.ama-assn.org/sites/default/files/media-browser/public/hod/a16-reference-committee-reports-v2.pdf> at 484 (copy on file with author) [AMA HOD, "Report of Reference Committee"].
[199] American Academy of Hospice and Palliative Medicine, "Physician-Assisted Death", online: American Academy of Hospice and Palliative Medicine <http://aahpm.org/positions/pad>; American Medical Student Association, "Principles Regarding Physician Aid in Dying" in *2015 AMSA Preamble, Purposes and Principles*, online: American Medical Student Association <http://www.amsa.org/about/constitution-bylaws/> at 79.

there is some support within the profession for a more prominent physician role but the profession has not wavered from its standards for physician behavior.

C. Physicians' Role in Capital Punishment

The death penalty remains legal in the United States, and except for a short period following *Furman v Georgia*[200] in 1972 it has been available as punishment for some crimes since the country was founded. For much of US history, capital punishment did not require any medical assistance, even though physicians devised execution methods such as the guillotine and lethal injection.[201] However, as the mechanics of execution came to resemble medical procedures with the advent of lethal injection, the profession was perceived as important for successful executions.[202]

The AMA initially adopted ethics policy on physician participation in capital punishment in 1980.[203] The Judicial Council's Opinion permitted physicians to determine or certify death as provided for by law, but otherwise "[a] physician, as a member of a profession dedicated to preserving life when there is hope of doing so, should not be a participant in a legally authorized execution."[204] This Opinion stemmed from the growing use of lethal injection as a preferred method of execution, which used medications that otherwise had non-lethal purposes (and were,

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[200] *Furman v Georgia*, 408 US 238 (1972), overruled by *Gregg v Georgia*, 428 US 153 (1976).
[201] See e.g. Judicial Council of the American Medical Association, "Report A: Capital Punishment" in American Medical Association House of Delegates, *Proceedings, House of Delegates, Chicago, Illinois, July 20-24, 1980, 129th Annual Convention* (Chicago: American Medical Association, 1980) [Judicial Council, "Capital Punishment"]; Joan M LeGraw & Michael A Grodin, "Health Professionals and Lethal Injection Execution in the United States" (2002) 24 Hum Rights Quart 382 at 398.
[202] Peter A Clark, "Physician Participation in Executions: Care Giver or Executioner?" (2006) 34 JL Med & Ethics 95; Jonathan I Groner, "Lethal Injection: A Stain on the Face of Medicine" (2002) 325 Brit Med J 1026.
[203] Judicial Council, "Capital Punishment", *supra* note 201 at 85-86.
[204] *Ibid*. at 86.

in fact, quite common in medical procedures), including an anesthetic, a paralytic, and a drug that stops the heart's beating.[205]

Despite the argument that physician administration of lethal injection would lead to its more effective use and therefore a more painless death for the executed inmate,[206] the Judicial Council maintained that the precept of "above all do no harm" remained crucial to the medical profession and did not allow for physicians to be actively involved in executions regardless of a physician's personal beliefs on the propriety of capital punishment. However, this stance—amended and expanded since its original adoption[207]—came under pressure in the middle of the last decade as complications in lethal injection procedures came to light and individual states faced criticism and lawsuits for their inability to ensure that executions could be carried out in accordance with the 8th Amendment, which prohibits cruel and unusual punishment.[208]

Many states expressly address the issue of physician participation in their statutes, regulations and lethal injection policies/procedures, with some that require physician participation and some that

[205] The drugs generally provided are sodium thiopental (the anesthetic), pancuronium bromide/Pavulon (the paralytic), and potassium chloride (for cardiac arrest). See *Morales v Hickman*, 438 F 3d 926 at 928 (9th Cir 2006).
[206] See generally Lawrence Nelson & Brandon Ashby, "Rethinking the Ethics of Physician Participation in Lethal Injection Execution" (2011) 41 Hastings Center Report 28.
[207] The current CEJA opinion on capital punishment is much more detailed than the original 1980 version, and contains prohibitions on physicians' determination of inmate competence to be executed. However, the opinion also sets forth actions that are not considered "participation," such as "testifying as to medical history and diagnoses or mental state as they relate to competence to stand trial…witnessing an execution in a totally nonprofessional capacity…and…relieving the acute suffering of a condemned person while awaiting execution…." CEJA, *Code of Medical Ethics*, *supra* note 111 at 23.
[208] US Const amend VIII ("[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishment inflicted"). See Mike Brickner, "Secrecy Won't Fix Death Penalty", *Cincinnati Enquirer* (14 November 2014), online: Cincinnati Enquirer <http://www.cincinnati.com/story/opinion/contributors/2014/11/14/opinion-secrecy-fix-death-penalty/19069161/>; Deborah W Denno, "When Legislatures Delegate Death: The Troubling Paradox Behind State Use of Electrocution and Lethal Injection and What it Says About Us" (2002) 63 Oh St LJ 63 at 100-105; Meredith Gallen, "Two Botched Executions Put Spotlight on Lethal Injection Process and State Secrecy" in *Project Press*, vol VII issue 2 (Chicago: American Bar Association, 2014), online: American Bar Association <http://www.americanbar.org/publications/project_press/2014/summer/two-botched-executions-put-spotlight-on-lethal-injection-process.html>; Emily Pokora, "Should State Codes of Medical Ethics Prohibit Physician Participation in State-Ordered Executions?" (2009) 37 W St UL Rev 1.

prohibit it. For example, North Carolina exempts "licensed health care professionals" who participate, including physicians, from disciplinary actions by their relevant licensing boards and deems "the infliction of the punishment of death by administration of the required lethal substances" not to be the practice of medicine.[209] Ohio's execution procedures document approves the use of a medical team, of which two out of three members must be qualified under law to administer and prepare drugs.[210] Physicians are not required to be on the medical team, but may be appointed as an Auxiliary Team Member to "provide consultation or advice as may be necessary."[211] This assumes that if there are problems in the execution the physician would be on hand to advise, although the policy does not anticipate or require direct participation, such as pushing the drugs, connecting the inmate to intravenous lines, or other medical procedures.

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[209] NC Gen Stat § 15-188.1 (2014). This statute was enacted in 2013, likely due to the challenge to the previous death penalty law made by the North Carolina Medical Board. See *North Carolina Department of Corrections v North Carolina Medical Board*, 675 SE 2d 641 (NC Sup Ct 2009) [*North Carolina Department of Corrections*]. Other states have taken this same route to protect physicians who participate in executions. See Al Code § 15-18-82.1(f) (2014) ("[f]or purposes of this section, prescription, preparation, compounding, dispensing, and administration of a lethal injection shall not constitute the practice of medicine, nursing, or pharmacy"); Ariz Rev Stat § 13-757(D) (2014) ("[i]f a person who participates or performs ancillary functions in an execution is licensed by a board, the licensing board shall not suspend or revoke the person's license as a result of the person's participation in an execution"); Ga Code § 17-10-42.1 (2014) ("[p]articipation in any execution of any convicted person carried out under this article shall not be the subject of any licensure challenge, suspension, or revocation for any physician or medical professional licensed in the State of Georgia"); La Rev Stat § 15:570(H) (2014) ("[i]f a person who participates or performs ancillary functions in an execution is licensed by a board, the licensing board shall not suspend or revoke the license of such person, or take any disciplinary or other adverse action against the person, as a result of participation in the execution"); Miss Code § 99-19-53 (2014) ("[a]ny infliction of the punishment of death by administration of the required lethal substance or substances in the manner required by law shall not be construed to be the practice of medicine or nursing"); Mo Rev Stat § 546.720(4) (2014) ("[n]otwithstanding any provision of law to the contrary, if a member of the execution team is licensed by a board or department, the licensing board or department shall not censure, reprimand, suspend, revoke, or take any other disciplinary action against the person's license because of his or her participation in a lawful execution"); Neb Rev Stat § 83.966(1) (2014) ("[a]ny prescription, preparation, compounding, dispensing, obtaining, or administration of the substances deemed necessary to perform a lethal injection shall not constitute the practice of medicine or any other profession relating to health care which is subject by law to regulation, licensure, or certification..."); NH Rev Stat § 630:5(XVI) (2014) ("[t]he infliction of the punishment of death by administration of the required lethal substance or substances in the manner required by this section shall not be construed to be the practice of medicine, and any pharmacist or pharmaceutical supplier is authorized to dispense drugs to the commissioner of corrections or his designee, without prescription, for carrying out the provisions of this section, notwithstanding any other provision of law").

[210] State of Ohio Department of Rehabilitation and Correction, "Execution", online: Department of Rehabilitation and Correction <http://www.drc.ohio.gov/LinkClick.aspx?fileticket=-r0rnCS3AGc%3d&portalid=0> at 2-3.

[211] *Ibid*. at 4.

At the opposite end of the spectrum are states like Illinois and Kentucky. Illinois prohibits the Department of Corrections from requesting, requiring or allowing "a health care practitioner licensed in Illinois, including but not limited to physicians and nurses, regardless of employment, to participate in an execution."[212] Likewise, Kentucky specifies that "[n]o physician shall be involved in the conduct of an execution except to certify cause of death provided that the condemned is declared dead by another person."[213]

Both Ohio and Kentucky (just a river apart) have incorporated the AMA *Code* by statute as a source of physician behavioral norms,[214] yet as shown above their approaches to physician participation in capital punishment are quite different. Although Ohio does not necessarily contemplate using physicians to carry out the execution, it prescribes a role that goes beyond that permitted by the *Code*. Conversely, Kentucky's lethal injection statute is aligned with AMA ethics policy.

Aside from the AMA's clear ethics policy against physician participation in executions, another medical society closely associated with the mechanisms of modern capital punishment responded to the increase in medicalized executions. In 2006, the American Society of Anesthesiologists openly challenged states' attempts to encourage physician participation by reiterating its opposition and asking members to refuse to participate.[215] The impetus for this policy might have been events in California,[216] where the state had asked physicians to participate in executions in

[212] 725 Ill Comp Stat 5/119-5 (2014).
[213] Ky Rev Stat § 431.220(3) (2014).
[214] Ky Rev Stat § 311.597(4) (2014); Oh Rev Code § 4731.22(B)(18) (2014).
[215] American Society of Anesthesiologists, "Statement on Physician Nonparticipation in Legally Authorized Executions", online: American Society of Anesthesiologists http://www.asahq.org/~/media/sites/asahq/files/public/resources/standards-guidelines/statement-on-physician-nonparticipation-in-legally-authorized-executions.pdf>.
[216] See Atul Gawande, "When Law and Ethics Collide—Why Physicians Participate in Executions" (2006) 354 N Eng J Med 1221 ("[t]he California Medical Association, the American Medical Association, and the American

order to comply with a court order to modify its execution protocol. In *Morales v Tilton*, two anesthesiologists declined to proceed with an execution, as the Department of Corrections had informed the court they would, because they believed that they were only present to observe the execution and not provide any active assistance.[217] To do as the Department of Corrections had indicated to the court that they would do was a violation of their ethics.[218] The protocol no longer requires the active participation of a physician—although it does not prohibit it either—and the unavailability of lethal injection drugs has led to a *de facto* moratorium on executions in California.[219]

Morales v Tilton is one of many cases where death row inmates have challenged the constitutionality of their executions based upon the procedures to be used during the execution, involving physicians only tangentially to inmates' claims.[220] Other cases represent a more direct conflict between the medical profession and the State on this issue. In 2007, the North Carolina Medical Board adopted a policy prohibiting physician involvement in executions aside from

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Society of Anesthesiologists immediately and loudly opposed such physician participation [as recently ordered by the federal district court] as a clear violation of medical ethics codes" at 1221).

[217] *Morales v Tilton*, 465 F Supp 2d 972 at 976 (ND Cal 2006) [*Tilton*]. The initial court order required the California Department of Corrections and Rehabilitation to use a "qualified individual" to ensure that the inmate is unconscious before the second and third drugs in a 3-drug protocol are injected. This person was required to have "formal training and experience in the field of general anesthesia." *Morales v Hickman*, 415 F Supp 2d 1037 at 1047 (ND Cal 2006).

[218] *Tilton*, *supra* note 217.

[219] The district court in *Morales v Cate* commented on this problem, and the diminishing supply of sodium thiopental (the barbiturate generally used in executions) in part due to the objection of European manufacturers to its use in capital punishment has further confounded states' attempts to perform executions nation-wide. See *Morales v Cate*, Nos 5-6-cv-219-JF-HRL & 5-6-cv-926-JF-HRL, 2010 WL 3835655 at 3 (ND Cal 2010). See also *Wood v Ryan*, 759 F 3d 1076 at 1085 (9th Cir 2014) [*Wood*]; European Commission, "Commission Extends Control Over Goods Which Could Be Used for Capital Punishment or Torture", online: European Commission <http://europa.eu/rapid/press-release_IP-11-1578_en.htm> ("[a]s of today, trade of certain anesthetics, such as sodium thiopental, which can be used in lethal injections, to countries that have not yet abolished the death penalty, will be tightly controlled").

[220] See also *Wood*, *supra* note 219 (inmate sought information from state on method of execution); *Roane v Leonhart*, 741 F 3d 147 (DC Cir 2014) (inmates challenged federal execution protocol); *Mann v Palmer*, 713 F 3d 1306 (11th Cir 2013) (inmate challenged method of execution as cruel and unusual).

"certifying the fact of the execution and simply being present at the time of the execution."[221] This is quite different from medical society opposition, because licensure actions by the Board can lead to suspension or revocation of a physician's medical license. This policy led to a confrontation with the Department of Corrections when physicians refused to participate in executions. Because an earlier case, *Brown v Beck*,[222] directed the Department to revise its lethal injection protocol to include the use of a licensed nurse and physician (therefore solving the 8th Amendment objection in that case),[223] the Department believed that it would be unable to proceed with executions without the participation, or at least presence, of physicians, and sued the Medical Board despite the state law on capital punishment only requiring the presence of a physician.[224]

The outcome of this case reveals the difficulty of reconciling medical ethical principles and State law when they conflict. The North Carolina Supreme Court found that the Medical Board exceeded its authority in adopting a policy that threatened disciplinary action for any physician actively participating in an execution. It viewed the Department of Correction's crafting of the lethal injection protocol as consistent with *the court's* interpretation of the Hippocratic Oath:

> [c]ertainly, the Protocol's requirement that a physician help prevent "undue pain or suffering" is consistent with the physician's oath to "do no harm." The Warden is well within his authority to require such monitoring, and defendant is without power to prevent the Warden from doing so.[225]

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[221] *North Carolina Department of Corrections*, *supra* note 209 at 643.
[222] *Brown v Beck*, 5:06-CT-3018-H (ED NC 7 April 2006). The District Court here did not require the use of physicians in the execution protocol, but required "personnel with sufficient medical training to ensure that Plaintiff is in all respects unconscious prior to and at the time of the administration of any pancuronium bromide or potassium chloride." *Ibid*. at 14.
[223] *North Carolina Department of Corrections*, *supra* note 209 at 644.
[224] *Ibid*. at 645-646. See also NC Gen Stat § 15-190 (2007) (the statute was amended after *North Carolina Department of Corrections* to refer to the current execution method and the role of physicians. Act of 5 August 2015, § 15-190, NC Sess L 2015-198 at 1); Lee Black & Robert M Sade, "Lethal Injection and Physicians: State Law vs Medical Ethics" (2007) 298 J Am Med Assoc 2779.
[225] *North Carolina Department of Corrections*, *supra* note 209 at 651.

This statement overlooks the profession's own statement on capital punishment and the fact that the AMA and the North Carolina Medical Board also considered physicians' oath to "do no harm" when adopting this policy.

What is interesting about this case is that the North Carolina Supreme Court refuted the Medical Board's authority rather than ask the Department of Corrections to modify its policy to address the concerns of the Medical Board while remaining consistent with the 8th Amendment. In the face of a statute requiring merely the presence of a physician, the court found that there must have been a greater intent that carried forward through nearly a century to the present mechanism of execution, without any legislative history to support this intent.[226] The dissenting Justice in this case pointed to the legislative grant of authority to the Medical Board to discipline licensees for departure from medical ethics, of which participation in capital punishment was a very clear instance even before the Medical Board adopted its policy.[227]

As noted above, the North Carolina legislature's resolution for any potential conflicts in the future was to modify its law to remove any actions involved in carrying out an execution from the practice of medicine and therefore from the Medical Board's jurisdiction.[228] This is a dishonest solution because physicians are very clearly being asked to use their medical training to ensure that executions proceed with minimal risk of "cruel and unusual punishment," otherwise why use them at all? Even though the concerns of the medical profession that gave rise to the North Carolina

[226] At the same time, the court dismissed the Medical Board's also-hypothetical explanations about the limitations of the statute, which it found to be without basis. *Ibid*. at 650.
[227] *Ibid*. at 652. The dissenting opinion criticized the majority for creating "a conflict between the statute and the Position Statement" and noted that it was the Department of Corrections that created the controversy by assuring a court that physicians would be used to monitor the executions, necessitating the Medical Board to develop a policy that walked the line between what the statute in question required and what professional ethics permitted. *Ibid*. at 653.
[228] NC Gen Stat § 15-188.1 (2014) ("[t]he infliction of the punishment of death by administration of the required lethal substances under this Article shall not be construed to be the practice of medicine").

Medical Board's now defunct policy[229] and the AMA's prohibition on physician participation in capital punishment remain—that physicians are being asked to use their skills to cause or monitor the death of individuals—the legislature and judiciary has created the legal fiction that their actions are not actually the practice of medicine. At this point, State law and the profession's legal order very clearly diverge.

North Carolina is not the only state where physician participation in executions has been challenged by physicians as an unethical application of medical expertise. In Georgia, individual physicians sued the Georgia Composite State Board of Medical Examiners.[230] They sought a declaratory judgment that physician participation in execution was not required under Georgia law and that AMA guidelines and Georgia law prohibit such participation.[231] This suit was filed after the Composite Board refused to open an investigation into a physician's alleged participation in executions.[232]

Although the court granted the Board's motion to dismiss because there was no justiciable controversy and no standing,[233] it went on to respond to the allegations and address the relationship between medical ethics, the AMA, the Board and capital punishment. It noted that "the AMA does provide *useful guidelines* for the conduct and standards of care to be employed by physicians generally", but declared that

> [t]he AMA…is not the governing body for physicians in this state. Instead, it is the sole province of the Board to govern the licensure, practice and discipline of physicians in the

[229] The Medical Board continues to retain a policy on capital punishment, but it recognizes that it is not permitted to take disciplinary action against any licensee who participates even though it still views such participation as unethical. North Carolina Medical Board, "Position Statements: Capital Punishment", online: North Carolina Medical Board <http://www.ncmedboard.org/position_statements/detail/capital_punishment>.
[230] *Zitrin v Georgia Composite State Board of Medical Examiners*, 2005CV103905 (Fulton County Superior Ct 31 July 2005).
[231] *Ibid*. at 1.
[232] *Ibid*.
[233] *Ibid*. at 6.

> state of Georgia. Importantly, the Board is barred from delegating such functions to any medical association, and any attempt to delegate its authority wholesale to the AMA would be unlawful.[234]

The court also recognized that state law removed any actions relating to the carrying out of an execution from the practice of medicine.[235]

In *Zitrin*, one aspect of the physician-plaintiffs' argument that the appellate court[236] did not directly address was the role of the Composite Board in regulating unethical practice. Like many states, Georgia authorizes the Composite Board to discipline a licensee who has "[e]ngaged in any unprofessional [or] unethical…conduct" including "any departure from, or failure to conform to, the minimum standards of acceptable and prevailing medical practice…."[237] The plaintiffs pointed out that the Georgia Court of Appeals had previously recognized that "[b]ecause the AMA is an organization composed of experts in the field of medicine, its code of ethics and the duties of physicians prescribed therein should be understood to reflect the standard of care of the profession."[238] Given the Composite Board's authority to discipline unethical behavior, combined with the appellate court's previous recognition of the AMA *Code* as a source for those standards, the superior court's statement that the AMA is not a governing body for physicians in Georgia is technically accurate but misleading. While the AMA does not have the authority to license and

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[234] *Ibid*. at 8-9 [emphasis added].
[235] *Ibid*. at 9.
[236] The Superior Court order was appealed and the Georgia Court of Appeals affirmed the order without addressing the physicians' substantive arguments. *Zitrin v Georgia Composite State Board of Medical Examiners*, 653 SE 2d 758 (Ga Ct App 2007). The arguments next referred to appeared in the physicians' Georgia Supreme Court brief, but certiorari was denied.
[237] Ga Code § 43-34-8(a)(7) (2016).
[238] Brief of Appellant-Physicians, *Zitrin v Georgia Composite State Board of Medical Examiners* (No. S07A0318), online: University of Michigan Law School Civil Rights Litigation Clearinghouse <http://www.clearinghouse.net/detail.php?id=9918>, citing *Ketchup v Howard*, 543 SE 2d 371 at 377 (Ga Ct App 2000). This decision was overruled after *Zitrin* in 2009 by the Georgia Supreme Court, which found that the doctrine of informed consent to which the appellate court in *Ketchup* applied the AMA's *Code* was "defined in Georgia exclusively by statutes and regulations." *Blotner v Doreika*, 678 SE 2d 80 at 82 (Ga Sup Ct 2009). The Georgia Supreme Court made no mention of the AMA *Code* in its opinion despite the court of appeal's lengthy discussion of medical ethics, and presumably the state will no longer accept professional codes as standards to the extent indicated in *Ketchup*, especially where state law has spoken on the matter.

discipline physicians pursuant to state law, its standards are influential in determining appropriate behaviors, as recognized in *Ketchup* (at least with regards to informed consent).

At issue in these cases is the tension between the organized profession's, the State's and individual physicians' interpretation of medical ethical obligations versus legal permissions. The North Carolina superior court that initially ruled against the Medical Board indicated that one reason to permit physician participation is the profession's capacity to limit the pain of the inmate being executed.[239] If the execution is going to take place regardless of physician participation, shouldn't physicians be available to ensure that it is carried out as painlessly as possible? Experience demonstrates, as in California, that the lethal injection process is not perfect, and the use of poorly trained personnel and structural and procedural deficiencies at prisons led to instances when inmates were not fully sedated and therefore likely in a great deal of pain.[240] For some physicians, the idea that the inmate could experience pain if improperly sedated endorses their role in the process. Rather than bringing about death, the participation is characterized as making the death as comfortable as possible—not inconsistent with the argument made for physicians to assist in suicide. Although major medical societies oppose physician participation in executions,[241] there is still debate amongst physicians as to their proper role.

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[239] *North Carolina Department of Corrections*, *supra* note 209 at 651.

[240] *Tilton*, *supra* note 217 at 976. See also *Taylor v Crawford*, 2006 WL 1779035 (WD Mo 2006) (noting that a physician who had performed executions in Missouri was a surgeon with no expertise in anesthesiology and also had wide discretion in the procedures used); Jeremy Kohler, "Behind the Mask of the Execution Doctor: Revelations About Dr. Alan Doerhoff Follow Judge's Halt of Lethal Injection", *St. Louis Post-Dispatch* (30 July 2006) A1 (an investigation revealed that "[t]wo Missouri hospitals won't allow [Dr. Doerhoff] to practice within their walls. He has been sued for malpractice more than 20 times, by his own estimate, and was publicly reprimanded in 2003 by the state Board of Healing Arts for failing to disclose malpractice suits to a hospital where he was treating patients").

[241] See CEJA, *Code of Medical Ethics*, *supra* note 111 at 23; American Society of Anesthesiologists, *supra* note 215. Unlike for physician-assisted suicide, I could not identify any medical society that supports active physician participation in lethal injection.

An example of this debate is a roundtable sponsored by the New England Journal of Medicine in 2008, where a few of the participants argued that it should be permissible for physicians who want to be involved with executions to do so. Dr. Truog stated that if an "inmate requests the involvement of a physician because he knows that the physician can prevent that suffering from occurring, and if there is a physician who is willing to do that, and we know from surveys that many are, I honestly can't think of any principle of medical ethics that would say that that is an unethical thing for the physician to do."[242] Likewise, Professor Denno stated that if "we're going to, however, have a method that would be cruel and constitute suffering if we did not have doctor involvement, then it suggests to me that if there are physicians in the country who are willing to be involved, or medical personnel, then I would like to think that they would not be chastised or lose their license or punished by the medical profession for volunteering to take part in an execution, to relieve suffering."[243]

In 2006, Gawande published an article containing a series of interviews with physicians and nurses involved with lethal injection executions.[244] The nurse or physician might have fallen into the role due to other work with the prison.[245] A friend or patient might have asked them to help out.[246]

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[242] Transcript, "Perspective Roundtable: Physicians and Execution", online: New England Journal of Medicine <http://www.nejm.org/doi/media/10.1056/NEJMp0800378/NEJMp0800378_transcript.pdf?area=> at 8. See *contra* Robert D Truog & Troyen A Brennan, "Participation of Physicians in Capital Punishment" (1993) 329 N Eng J Med 1346. Truog and Brennan take the position here that "the unacceptability of physicians' involvement in executions should be recognized as a mature principle of medical ethics." *Ibid*. at 1349. Further, they promoted medical societies taking the position that "involvement in capital punishment is grounds for revoking a physician's license" and communicating that position to medical boards. *Ibid*.
[243] Transcript, *supra* note 242 at 9.
[244] Gawande, *supra* note 216.
[245] *Ibid*. at 1224, 1226.
[246] *Ibid*. at 1224-1225.

None of them indicated that they participated in lethal injection executions due to fervor for capital punishment.[247]

A common theme running through Gawande's reporting is that the interviewees all seemed at least a little troubled by their role in executions and its conflict with their other obligations as health professionals, with one physician saying "'I agonize over the ethics of this every time they call me to go down there'", even though he limited his role to pronouncing death.[248] The last interview recounted by Gawande was with a physician in Georgia who, despite his opposition to the death penalty, "also felt an obligation not to abandon inmates in their dying moments…. 'The way I saw it, this is an end-of-life issue, just as with any other terminal disease. It just happens that it involves a legal process instead of a medical process.'"[249] Although Gawande reassures us that he has "always regarded involvement in executions by physicians and nurses as wrong" even though he personally favors the death penalty,[250] he provides a more humanized look at the struggles of physicians and the profession, rather than just a legalized one.

Despite the fight at the state level over physician participation in executions, the US Supreme Court does not require physicians or even nurses for lethal injection to remain a constitutional form of punishment. One of its more recent opinions on capital punishment addressed Kentucky's execution protocol.[251] As Kentucky law has long prohibited physician involvement with the execution "except to certify cause of death provided that the condemned is declared dead by another person",[252] the fact that the Supreme Court upheld a protocol that *did not* require or permit

[247] *Ibid*. ("[n]one were zealots for the death penalty, and none had a simple explanation for why they did this work. The role, most said, had crept up on them" at 1223).
[248] *Ibid*. at 1226.
[249] *Ibid*. at 1228.
[250] *Ibid*. at 1227.
[251] *Baze v Rees*, 553 US 35 (2008).
[252] Ky Rev Stat § 431.220(3) (2014).

physician involvement should signal to other states that it is okay to do the same rather than the opposite, which seems to be upping the ante (so to speak) on physicians.

So long as the death penalty remains a legal punishment in many states, governments will continue to search for methods that are constitutionally compliant. Inmates regularly challenge these methods, so we will continue to see judicial responses to state decision-making. At some point, though, given the restrictions placed on imported drugs that could potentially be used in executions—European manufacturers generally prohibit their wares' use in capital punishment, which has been abolished throughout the European Union[253]—states will be forced to either completely revise their method of choice to something other than lethal injection, or find new drugs[254] or lethal injection procedures to carry out executions. Still unknown, however, is what role physicians will be asked to play in the future, and whether courts will continue to support states' demands for a violation of clear ethics standards. Yet, as Gawande intimated,

> [m]edicine is being made an instrument of punishment. The hand of comfort that more gently places the IV, more carefully times the bolus of potassium, is also the hand of death. We cannot escape this truth. The ethics codes seem right.[255]

[253] See e.g. Steven Erlanger, "Outrage Across Ideological Spectrum in Europe Over Flawed Lethal Injection in US", *New York Times* (30 April 2014) online: New York Times <http://www.nytimes.com/2014/05/01/us/outrage-across-ideological-spectrum-in-europe-over-flawed-lethal-injection-in-us.html?_r=0>; Ross Levitt & Deborah Feyerick, "Death Penalty States Scramble for Lethal Injection Drugs", *CNN* (16 November 2013) online: CNN <http://www.cnn.com/2013/11/15/justice/states-lethal-injection-drugs/>. See also European External Action Service, Department for Human Rights and Democracy, "Background: The Death Penalty and the EU's Policy on its Abolition", online: European Union External Action <http://eeas.europa.eu/human_rights/adp/docs/death_penalty_background_en.pdf>.

[254] Some states have resorted to using compounding pharmacies, despite the inability to ensure the quality or consistency of the drugs purchased. See Levitt & Feyerick, *supra* note 253.

[255] Gawande, *supra* note 216 at 1229.

IV. Medical Ethics, Politics, Morality and Law

This Chapter raises questions of the efficacy of medical ethics as a legal order and the health of the relationship between the profession and the State. The topics of the Chapter, although not indicative of the overall relationship between the medical profession and the State, demonstrate the breakdown of the profession's legal order and its ability to work alongside the State to address important medical and ethical issues. For each—abortion, gun safety, physician assisted suicide and lethal injection—the profession has enacted ethics norms to guide physician action, all of which stem from long-standing ethical principles, and for each the State has done little to acknowledge the role of medical ethics as a normative system and conform its own legal order when necessary and proper to further the profession's overarching goals of patient health and safety. Although the US Supreme Court accepted a duty for states to protect "the integrity and ethics of the medical profession",[256] the discussion in this Chapter shows that it does so only when ethics align with how the State wants to regulate, and has otherwise interpreted ethical obligations to meet its own ends.

The results of this narrow interpretation of legal orders and normativity have been unkind to the medical profession and ethics. Legislatures have ignored the ethical implications of their enactments for each topic of this Chapter, and courts have essentially rewritten medical ethics in their decisions on abortion, gun safety discussions and lethal injection. This creates unnecessary tension between the medical organizations that promulgate ethics and physicians who are supposed to adhere to them. Further, it creates a disconnect between physicians and their patients and inserts

[256] *Glucksberg*, *supra* note 171 at 731.

the State into what was a traditionally closed relationship except when there was an actual need for intervention (see e.g. conflicts of interest in the next Chapter).

The State claims the authority to regulate these issues in the way it does because it is beholden to many different stakeholders (and semi-autonomous social fields) that all have different interests and rights and because physicians, as members of a regulated profession, are subject to different standards than if they were acting as individuals. Take, for example, abortion regulation: *Roe* recognized that due to the outcome of the procedure (the termination of a pregnancy) the State has interests *as well as* the woman. It defined the State's interest as maternal health early in the pregnancy and both maternal and fetal health and life later. Yet the way in which the State has regulated does more to damage these interests than anything the medical profession or individual physicians[257] have done since abortion was legalized.

Similarly, a federal appellate court thrice upheld a law that prohibited physician speech about firearms with no evidence that the law solved a problem that needed solving. It accepted the state's argument (again, three times) that the state sought to protect patients' privacy, second amendment rights, and access to health care without harassment or discrimination, and at the same time misconstrued physicians' ethical responsibilities and what patient privacy means. It took a rehearing by the full court (11 judges rather than 3) to point out the constitutional and practical consequences of this kind of regulation.

Physician participation in lethal injection represents another instance of a court finding a "right" that is superior to the medical profession's ethics. From the few cases that directly address medical ethics and professional attempts to enforce it, courts have placed the right (or maybe more

[257] There are instances where individual physicians provide unsafe or even horrific care, but these can be addressed by other means and restrictive abortion regulation enacted by the State does not relate to these worst cases.

appropriately the "ability") to carry out a lawful execution above the ethical prohibition against physician participation.

Finally, with physician assisted suicide, we reach a more muddled situation. There is no constitutional right to receive assistance in suicide, and it is left to each state to decide what is legal. The Supreme Court recognized that states can prohibit assisted suicide to protect the integrity and ethics of physicians,[258] but there is no requirement that they do so. As more states enact regulatory structures through which patients can receive assistance in dying, there remains a question of how to reconcile these laws with clear medical ethics dictates to the contrary.

Arguably, the existence of different groups with different rights and obligations does indeed justify the State's regulatory decisions for each issue. However, except for assisted suicide, for which there is growing support within the medical profession and now attempts to change ethics policy,[259] other means existed to address conflicts with the profession's legal order. What the legislation and judicial decisions in this Chapter show is the role that politics or a specific kind of morality has in State law when trying to solve legal problems (whether real or imaginary), and the supremacy that the State presumes when it regulates.

Politics and morality of course play a part in the design of the State's legal order,[260] and in the medical profession's as well. However, the use of politics and morality to deny or modify medical ethics (itself a form of moral rules)—especially when it can harm patients—is an affront to the

[258] *Glucksberg*, *supra* note 171 at 731.
[259] American Medical Association House of Delegates, "Report of Reference Committee on Constitution and Bylaws", *supra* note 198.
[260] According to the Supreme Court, morality should not be the foundation for State law. By this, the Court referred to the peculiar Christian morality that outlawed homosexual acts between consenting adults. *Lawrence v Texas*, 539 US 558 (2003); Rick Kozell, "Striking the Proper Balance: Articulating the Role of Morality in the Legislative and Judicial Process" (2010) 47 Am Crim L Rev 1555.

goals of the profession in adopting the ethics norms discussed in this Chapter, and even to the purposes of the State regulating physicians and health care. Often, legislators and even judges have a political agenda that underlies their decision-making. This is clear with abortion and gun gag laws, where there is vocal support for overturning *Roe* and therefore access to abortions[261] and significant fears about the protection of the rights afforded by the Second Amendment (mostly unfounded). This agenda can and has caused a rift between the adoption and enactment of a legal order based in medical ethics as well as its enforcement.

The result of what tends to be a political or moral (maybe pseudo-moral, since the moral issues of abortion are closely tied to political ideology) foundation for law has been problematic for a version of medical ethics that remains in the hands of the medical profession. What is ethical is no longer ethical, and what is considered good patient care based on current knowledge is not sufficient for legislators, regulators and judges who might contort ethics and evidence to their own ends. Physicians are then forced to adhere to State law that contradicts both their medical education and training and their sense of ethical propriety, especially in their relationships with patients. The profession must wrangle with the decision to conform ethics to State law or continue to resist State enactments by legal action or threatening action against their own members who might want to act ethically, but for whom the choice between loss of medical license or loss of medical society membership is not much of a choice at all.

What do these mean for a conceptualization of medical ethics as a legal order? If the State gives little credence to medical ethics, or it does so only when ethics are congruent with its ends, will the profession be able to continue using ethics as a source of norms and expect physicians to heed

[261] The political motivations of the Supreme Court and appellate courts becomes more clear when these courts discount medical expertise in favor of dubious and often disprovable State reasoning.

its authority? I will return to these questions in Chapter 8. In raising them here, though, I do not imply that medical ethics are always the answer to guide physician behavior, or that State law cannot provide adequate or even superior guidance in the absence of—or even in contravention to—ethics norms promulgated by the medical profession. The next Chapter examines ethics from this perspective: when the profession fails to act, or acts insufficiently to meet its own basic ethical ideals. Should our perceptions about the acceptability of the State infringing on ethical priorities be different when it is the State, rather than the profession, that is better placed to protect patients and uphold the integrity and ethics of the profession?

CHAPTER 7: THE WEAKNESS OF PROFESSIONAL ETHICS

I. CONFLICTS OF INTEREST: WHAT, ME WORRY? 266

II. REGULATION OF CONFLICTS OF INTEREST: WHO'S THE LEADER AND WHO'S THE FOLLOWER? 268

A. Conflicts of Interest: Endemic in Medicine 268

B. Fee Splitting, Fraud and Kickbacks 271

1. The Problem 271
2. The Profession's Legal Order 276
3. The State's Legal Order 277

C. Physician Self-Referral 281

1. The Problem 281
2. The Profession's Legal Order 290
3. The State's Legal Order 294

D. Physician-Industry Relationships 298

1. The Problem 298
2. The Profession's Legal Order 305
3. The State's Legal Order 310

III. CONFLICTS OF INTEREST: THE LIMITS OF SELF-REGULATION AND ETHICS? 313

> The disadvantage of relying exclusively on the profession [to regulate itself] is that physicians, not only individually but also collectively, confront a conflict between their primary interest in maintaining the integrity of the profession and their secondary interest in promoting the economic welfare of its members.[1]

I. Conflicts of Interest: What, Me Worry?

Chapter 4 laid the foundation for ethics as a form of law within the framework of legal pluralism, and the last Chapter provided instances when this law is severely challenged by the State. This interference does not stem from a legitimate need to protect patients or regulate dangerous practices, but more often it is based in political expediency or a moral interpretation of health care and individual and collective rights at odds with professional morals. In those examples, the State substituted its own interpretation of what was "ethical" or minimized the importance of ethics in the action at issue. These were cases of the profession's legal order failing to be transferred to the State when their legal orders targeted the same activity.

This Chapter explores the nearly opposite situation, where the State finds a legitimate need to intervene in medical practices that present risk for patients and for which the medical profession's own legal order has proven insufficient. The question I ask in this Chapter is not whether State interference with or discarding of medical ethics as a legal order is inappropriate, but whether it is critical to ensure that the profession's legal order of medical ethics remains legitimate.

The Chapter focuses on the economics of health care. The medical profession exists in a market environment: physicians are paid for their services, and offer services somewhat competitively to the public. Relying on their training and skills for their livelihood, physicians might be tempted to prescribe, operate, refer or take some other professional action that is more for their benefit than that of their patients. This is true of virtually all occupations in a market-based economy, but

[1] Dennis F Thompson, "Understanding Financial Conflicts of Interest" (1993) 329 New Eng J Med 573 at 575.

physicians have special obligations that are intended to curtail these temptations. The profession has established a narrow set of rules on how financial issues should be dealt with, among them rules regarding conflicts of interest. These rules require that physicians place the well-being of patients ahead of their own financial interests, so for example a physician should not perform a procedure or prescribe a medication that is medically unnecessary but financially lucrative for the physician.

"Conflicts of interest" is a broad term, defined as "a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest."[2] For physicians, the primary interest is the patient's welfare,[3] although there can be legitimate competing primary interests that require a different kind of analysis than secondary interests would.[4] Secondary interests range from the relatively innocuous academic sources, such as the competition to publish, obtain grant funding and gain tenure, to the more insidious direct payment for prescribing medication or patient referrals. I focus here on financial conflicts "not because it is more pernicious than other secondary interests but because it is more objective and fungible."[5]

A preliminary problem that I should address, which underlies the premise of this Chapter, relates to the interpretation of ethics norms and principles. I am critical of the profession throughout this

[2] Institute of Medicine of the National Academies, *Conflict of Interest in Medical Research, Education and Practice*, Bernard Lo & Marilyn J Field, eds (Washington, DC: National Academies Press, 2009) at 46. See also Thompson, *supra* note 1 ("[a] conflict of interest is a set of conditions in which professional judgment concerning a primary interest…tends to be unduly influenced by a secondary interest…" at 573).
[3] *Ibid*.
[4] In some instances, the safety of third parties is sufficient for abrogating the basic ethical (and legal) requirement of confidentiality. Limited resources might also give reason to consider other factors than the welfare of a specific patient, such as when an emergency requires the allocation of resources to less severe injuries or illnesses.
[5] Thompson, *supra* note 1 at 573. See also Lisa Rosenbaum, "Understanding Bias – The Case for Careful Study" (2015) 372 N Eng J Med 1959 ("[w]hether our judgments are motivated by fatigue, hunger, institutional norms, the diagnosis of the last patient we saw, or a memory of a patient who died, we are all biased in countless subtle ways" at 1961).

Chapter because of how I interpret its basic ethics principles to apply to the issues examined here. I do not believe that this interpretation is improper, but clearly there is the chance that a substantial portion of the profession interpret their obligations differently—they are trained physicians and I, of course, am not, so it is possible that something in their training and education leads these physicians and their organizations to a different conclusion. However, given the current direction of ethics both in the academic world and in formal ethics documents like the AMA's *Code of Medical Ethics*, the gravity that I give to many of the basic ethics principles of the profession is likely not far afield from how they were intended to be received.

This Chapter highlights the difficulties inherent in self-regulation and the development of a profession's legal order (a problem experienced by the State as well). It takes the interchange between the profession and State in a different direction from the previous Chapter, now forcing or encouraging the profession to accept the State's law on conflicts because its own is weak and non-representative of the ethical values that underlie physicians' moral obligations and legal orders. Primarily, it raises a question of the efficacy of a portion of a legal order, if it is internally inconsistent with other parts of that legal order.

II. Regulation of Conflicts of Interest: Who's the Leader and Who's the Follower?

A. Conflicts of Interest: Endemic in Medicine

One inescapable fact of the US health care system is that it has been firmly implanted in capitalism: "[physicians] are at one and the same time scientists engaged in a vital humanitarian endeavor and free enterprise merchants operating in a capitalistic marketplace where their skills and knowledge

can be of enormous financial value."[6] From the earliest days of the State, physicians were left to barter or charge for services as a part of the market economy. As much of the industrialized west transformed health care into a State-supported and regulated industry, creating various models of social medicine and insurance where the State provided substantial financial and logistical support, the US maintained its capitalistic bent and resisted attempts to move towards a more public system.[7] Physicians are an integral part of US health care, and must balance the American entrepreneurialism inherent in this history with the ethical obligations that are the core of professional self-regulation and autonomy and any conception of a professional legal order.

As part of a market-based health care system, physicians expect to be fairly compensated for their work.[8] This in itself is not problematic: even in more socialized health care systems physicians are paid, although maybe not at the rates to which American physicians have become accustomed.[9] The problems discussed in this Chapter arise not because physicians generate personal income,

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[6] Paul D Jesilow, Henry N Pontell & Gilbert Geis, "Medical Criminals: Physicians and White-Collar Offenses" (1985) 2 Justice Quart 149.

[7] See Paul Starr, *The Social Transformation of American Medicine* (New York: Basic Books, 1982) at 235-289 for a detailed discussion of the many failed efforts in the first half of the 20th century to establish some form of public health insurance.

[8] Percival made a historical argument as to the propriety of accepting remuneration for services, arguing that there should be both a moral and legal right to some sort of payment. Thomas Percival, *Medical Ethics; or, a Code of Institutes and Precepts, Adapted to the Professional Conduct of Physicians and Surgeons*, 3d ed (Oxford: John Henry Parker, 1849) at 147.

[9] See e.g. Rie Fujisawa & Gaetan Lafortune, *OECD Health Working Papers No. 41- The Remuneration of General Practitioners and Specialists in 14 OECD Countries: What are the Factors Influencing Variations Across Countries?* (Paris: Organisation for Economic Co-operation and Development, 2008), online: Organisation for Economic Co-operation and Development <http://www.oecd.org/health/health-systems/41925333.pdf>. This paper notes that physicians in the US are generally responsible for the costs of attending medical school, while most other countries examined pay for the education or provide it at a far lower cost (such as Canada). This is not a major factor in the higher physician income, but is a minor consideration. For example, tuition at Harvard—a preeminent US medical school—is over $55,000 per year not including living expenses, insurance or fees and other expenses. Harvard Medical School, "Harvard Medical School 2015-2016 M.D. Student Cost of Attendance Budgets", online: Harvard University <http://hms.harvard.edu/sites/default/files/assets/Sites/Financial_Aid/files/2016%20Budget%20-FINAL.pdf>. In contrast, medical education at McGill University *including* fees is just over $7,000 for the first year and declines thereafter, although tuition and fees for international students (such as those wanting to avoid the higher tuition of the likes of Harvard) is still $40,000, and by the 4th year is under $25,000. McGill University, "Fee Calculator – Undergraduate Tuition and Fees", online: McGill University <http://www.mcgill.ca/student-accounts/tuition-charges/fallwinter-term-tuition-and-fees/undergraduate-fees>.

but because of new market incentives that have come to characterize the profession and the health system generally.

Given the wide variety of circumstances that can create conflicts of interest in the practice of medicine, it is not surprising that the profession has spoken on only a small number of them. The complex contractual arrangements that now typify physician, hospital, insurer (including the State) and industry relationships create innumerable opportunities for financial exploitation either openly or hidden as part of an otherwise legitimate arrangement. For some arrangements, the organized profession has long opposed activities that could endanger patients or cause them to lose trust in physicians. For others, the profession has not been as proactive.

The concept of financial conflicts of interest has been a part of the ethical consciousness of the organized profession since the inception of the AMA in 1847.[10] The first *Code of Medical Ethics* required that "physicians must be ever ready and prompt to administer professional aid to all applicants, *without prior stipulation of personal advantages to themselves*" (emphasis added).[11] This *Code* further cautioned physicians against unnecessary visits to patients, as they might "render him liable to be suspected of interested motives."[12]

At base, the medical profession's historical response to financial conflicts of interest has been reliance on the idea that physicians' primary obligations are to patients, with other interests being secondary or even further down the line. The AMA's Principle VIII states "[a] physician shall,

[10] Percival's *Medical Ethics* also contained provisions implying some duty to avoid conflicts, although these were not so straightforward. See Percival, *supra* note 8 at 55 (unnecessary visits to patients), 61 (dispensation of nostrums), 75 (recommendation of physician by apothecary).
[11] American Medical Association, *Report of the Committee on a Code of Medical Ethics for the Government of the Medical Profession of the United States: Code of Medical Ethics* (Chicago: American Medical Association, 1847) at 85 [AMA, *Code of Medical Ethics (1847)*].
[12] *Ibid*. at 94.

while caring for a patient, regard responsibility to the patient as paramount."[13] A second Principle also addresses conflicts of interest, directing physicians to

> uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities.[14]

The more specific ethics policies for conflicts, in the form of the Opinions that make up the bulk of the *Code of Medical Ethics*, stem primarily from these two Principles.

This Section explores the variety of the medical profession's and State's responses to financial conflicts of interest. For three issues—fee splitting (fraud and kickbacks), self-referral, and physician-industry relationships—I will explore how the profession and the State regulate conflicts of interest that raise the prospect of physicians prioritizing self-interest.

B. Fee Splitting, Fraud and Kickbacks

1. The Problem

Fee splitting, fraud and kickbacks are universally viewed with repugnance by both the profession and the State. Compared to the other forms of conflicts of interest discussed in this Chapter, these represent generally clear instances of unethical, and illegal, behavior, and have a much longer history of being regulated first by the profession and then the State than many other conflicts of interest. The organized medical profession and the State continue to prohibit most forms of these conflicts, and physicians generally accept their legitimacy in doing so, at least as evidenced by the long-standing ethical prohibitions and the lack of visible resistance to parallel State regulation.

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[13] Council on Ethical and Judicial Affairs, *Code of Medical Ethics: Current Opinions with Annotations, 2010-2011* (Chicago: American Medical Association, 2010) at xvii [CEJA, *Code of Medical Ethics*].
[14] *Ibid*.

The terms "fee splitting", "fraud" and "kickback" cover a wide variety of activities. "Fee splitting" is typically associated with physicians literally splitting a patient's fee, with one physician receiving a portion of the fee for referring the patient to the physician performing the service.[15] There might be some nominal service to justify the fee in the face of ethical prohibitions, but the fee is intended to reward a referral. This can extend beyond fee splitting between physicians to include any kind of payment received by a physician solely in return for referrals, so payment by a pharmaceutical manufacturer for prescribing a drug or by a health facility for admitting a certain number of patients can fall within the prohibition of the ethics policy.[16] The purported ethical justification for prohibiting this form of payment is that it influences physicians to refer patients for other than patients' benefit, and represents receiving remuneration without providing any services. As the AMA Judicial Council put it in 1913, "it is the patient's business to know for what he is paying, whether it is that he is paying for the best work obtainable from the best man to perform that work or whether he is paying an inferior man to consummate a dishonest bargain with his physician, and the patient has a legal and moral right to know which he obtains."[17]

The State does not use the same terminology, preferring the term "kickback" to signify essentially the same behavior. If a physician receives a payment solely for referring a patient to another physician, for a service or for a drug or device, he or she could run afoul of anti-kickback statutes. As will be discussed later in this Section, there are many exceptions to the general prohibition because the rule covers activity that *could* be a legitimate business relationship or a function made necessary by the modern health care system.

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[15] See e.g. American Medical Association, *Proceedings of the Minneapolis Session, Minutes of the Sixty-Fourth Annual Session of the American Medical Association, Held at Minneapolis, June 16-20, 1913* (Chicago: American Medical Association, 1913) at 13-14.
[16] See e.g. CEJA, *Code of Medical Ethics*, *supra* note 13 at 193.
[17] *Ibid*. at 14.

While "fee splitting" and "kickback" refer to a specific class of activity, "fraud" is a very broad term covering a very broad set of activities, and could encompass fee splitting and kickbacks if they were not already handled as distinct issues by both the profession and the State.[18] It can include most activities that are less than an honest dealing between physicians and anyone or any entity that they serve professionally, such as the submission by physicians (or health facilities) of claims for services never rendered; the provision of unnecessary services; and upcoding[19] of services performed to obtain a higher rate of payment. There are many federal and state statutes that address what are basically matters of fraud, and the profession as well has adopted policies that cover a variety of activities that fall under the broad umbrella of "fraud."

As laws, policies and norms change, so too do physician practices. Modern medicine has shifted substantially from the more obvious instances of fee splitting where there was no service of substance provided by the referring physician. As noted by Jacobs and Goodman, the growth and then decline of the prohibition against the corporate practice of medicine and the creation of the "professional corporation" gave rise to arrangements that might have fit within the traditional definition of fee splitting but probably not within its spirit.[20] The fact that more and more physicians have become employees of various types of organization—receiving salaries and/or incentive-based income—makes the determination of fee splitting all the more difficult. For example, modern group practice or employment agreements are sustained by the sharing of income

[18] For example, *Black's Law Dictionary* defines fraud as "A knowing misrepresentation of the truth or concealment of material fact to induce another to act to his or her detriment….Unconscionable dealing…." Bryan A Garner, ed, *Black's Law Dictionary*, 7th ed (St. Paul: West Group, 1999) at 670.

[19] Upcoding is informally defined as "billing for services at a level of complexity that is higher than the service actually provided or documented in the file" and would typically lead to a higher reimbursement. Centers for Medicare and Medicaid Services, "Common Types of Health Care Fraud", online: Centers for Medicare and Medicaid Services <http://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/fwa-factsheet.pdf>.

[20] Richard O Jacobs & Elizabeth Goodman, "Splitting Fees or Splitting Hairs? Fee Splitting and Health Care – The Florida Experience" (1999) 8 Ann Health L 239.

that might have formerly been prohibited under fee spitting rules.[21] Yet these arrangements are so common today that calling them fee splitting (or kickbacks) and thus prohibiting them would create a major disruption in health services and void many of the efficiencies that group practice creates.

Prior to the State financing health care in the 1960s, the State took little initiative to involve itself in health care economics. Kickbacks or fee splitting, while unethical, were not likely to be considered illegal.[22] However, once health care dollars began to flow (quite rapidly) from public coffers, the State took a greater interest in its return on investment. What once reflected "an established and widespread practice in that industry and in those localities"[23] was now a threat to State finances.

The State has an ever-increasing financial interest in the US health care system. By cost, the Medicare and Medicaid programs represent a large part of the federal budget,[24] although state Children's Health Insurance Programs and the federal Veterans Affairs are also important targets of State investment.[25] In these programs, where the State makes payment directly to physicians,

[21] Even in the 1940s, though, it was ethical for physicians to work in a group practice that divided income so long as the division was based on "the value of the services contributed by each individual participant." American Medical Association, *Digest of Official Actions, 1846-1958* (Chicago: American Medical Association, 1959) at 268 [AMA, *Digest of Official Actions, 1846-1958*].
[22] See e.g. *Lilly v Commissioner of Internal Revenue*, 343 US 90 (1952) (one-third of retail price of eyeglasses paid to prescribing physicians by optical business was deductible as business expense by that business). The Court took this view despite the long-standing ethical prohibition against fee-splitting.
[23] *Ibid*. at 91.
[24] Medicaid spending in 2013 was over $438 billion and Medicare spending was $583 billion. Kaiser Family Foundation, "Total Medicaid Spending", online: Kaiser Family Foundation <http://kff.org/medicaid/state-indicator/total-medicaid-spending/>; Kaiser Family Foundation, "The Facts on Medicare Spending and Financing", online: Kaiser Family Foundation <http://kff.org/medicare/fact-sheet/medicare-spending-and-financing-fact-sheet/>.
[25] The Children's Health Insurance Programs cost over $10.5 billion in 2009, while health care provided by the VA cost the federal government nearly $56 billion in 2013. Kaiser Family Foundation, "Total CHIP Expenditures", online: Kaiser Family Foundation <http://kff.org/other/state-indicator/total-chip-spending/>; United States Department of Veterans Affairs, "National Center for Veterans Analysis and Statistics: Expenditures", online: United States Department of Veterans Affairs <http://www.va.gov/vetdata/Expenditures.asp> (see Expenditures Table 2015).

health facilities and other health professionals, kickbacks and fraud in the issuance of payments and self-referral are of major concern to state and federal regulators.[26]

The US Government Accountability Office estimated that in 2012 Medicare made $44 billion in "improper payments",[27] a small amount of the $555 billion total cost of the program but still very substantial considering what that money could have otherwise been used for in a time of tightening state and federal budgets.[28] Although "[t]here are no reliable estimates of the extent of fraud in the Medicare program or the health care system as a whole [because] fraud is difficult to detect, as those involved engaged in intentional deception",[29] the State has made efforts to combat it. According to the Health and Human Services Office of the Inspector General (OIG), the government "won or negotiated over $1.9 billion in judgments and settlements, and attained additional administrative impositions in health care fraud cases and proceedings" in 2015.[30]

The problems of fee splitting/kickbacks and fraud are well-recognized weaknesses in the ethical comportment of physicians. The medical profession and the State have carved out rules and

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[26] The more recent introduction of state and federal health insurance exchanges and the accompanying subsidies created by the Patient Protection and Affordable Care Act has added to this financial entanglement. *Patient Protection and Affordable Care Act*, Pub L No 111-148, 124 Stat 119 (2010) [*PPACA*].

[27] This includes payment based on fraudulent submissions as well as mistakes by the Medicare program and physicians and facilities. See Centers for Medicare and Medicaid Services, *Medicare Fee-for-Service 2013 Improper Payments Report* (Washington DC: Centers for Medicare and Medicaid Services, 2014), online: Centers for Medicare and Medicaid Services <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/CERT-Reports-Items/Downloads/MedicareFee-for-Service2013ImproperPaymentsReport.pdf> at 9-10 (improper payments include payments in error or in incorrect amount; to an ineligible recipient; that duplicates a payment; or that does not account for credit or applicable discounts).

[28] See United States Government Accountability Office, *Testimony: GAO's 2013 High-Risk Update - Medicare and Medicaid*, Report No GAO-13-433T (Washington, DC: US GAO, 2013), online: United States Government Accountability Office <http://www.gao.gov/products/GAO-13-433T> at 1.

[29] United States Government Accountability Office, *Testimony Before the Subcommittee on Health, Committee on Ways and Means, House of Representatives: Medicare Fraud – Progress Made, But More Action Needed to Address Medicare Fraud, Waste, and Abuse*, Report No GAO-14-560T (Washington, DC: US GAO, 2014) at 1 [US GAO, *Medicare Fraud – Progress Made, But More Action Needed*].

[30] Department of Health and Human Services and Department of Justice, "Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2015", online: Office of the Inspector General <http://oig.hhs.gov/publications/docs/hcfac/FY2015-hcfac.pdf> at 8.

standards in their respective regulation of physicians in an attempt to limit the harm caused by these practices, which will be examined in the next two subsections.

2. The Profession's Legal Order

The profession continues to hold fee splitting unethical as it has for over a century, except that today determining what a fee-split is has become more difficult as the health care delivery system has become more complex.[31] Many of the ethics Opinions in the modern *Code* attempt to balance obligations to patients with physicians' ability to earn a living and the business environment in which many physicians now find themselves.

The *Code* continues to prohibit fee splitting and contains a number of Opinions on the issue. Opinion 6.02 is basic and direct:

> [p]ayment by or to a physician solely for the referral of a patient is fee splitting and is unethical.
>
> A physician may not accept payment in kind, in any form, from any source, such as a pharmaceutical company or pharmacist, an optical company, or the manufacturer of medical appliances and devices, for prescribing or referring a patient to said source.[32]

This covers a wide range of activity, so long as it is intended to garner referrals or prescriptions, and is justified on the grounds that "the payment violates the requirement to deal honestly with patients and colleagues."[33]

A second opinion on fee splitting (6.03) applies specifically to health facilities.[34] This Opinion states that "[c]linics, laboratories, hospitals, or other health care facilities that compensate

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[31] See e.g. Jacobs & Goodman, *supra* note 20; John H Budd, "What is Wrong with Fee Splitting?" (1966) 195 J Am Med Assoc 161.
[32] CEJA, *Code of Medical Ethics*, *supra* note 13 at 193.
[33] *Ibid*.
[34] *Ibid*. at 195.

physicians for referral of patients are engaged in fee splitting which is unethical."[35] Again, this is a very clear statement of unethical activity: if a physician is paid solely for referral of a patient and not for any of his or her own services such payment is unethical.

As an ethical issue, fee splitting has become less central to official guidance. CEJA has not released a report on fee splitting in decades, and the most recent update to the Opinion was 1994.[36] Other societies have similar policies on fee splitting, but these are not central to their ethical guidance on conflicts.[37] However, the dearth of recent statements on the issue might be due to State regulatory actions that overshadow anything the profession can do on its own, as well as the basic ethical underpinnings of the policy remaining the same over a century after the first fee splitting policy was adopted.

3. The State's Legal Order

By the late 1970s and early 1980s, both federal and state governments began to enact anti-kickback laws to address essentially the same acts that the profession had been seeking to prohibit for a long time. The force of these laws in a way makes the ethics provisions superfluous. And, as will be discussed in Section III, the profession never had much success with enforcing fee splitting prohibitions, making State regulation an alternative basis for disciplinary action.

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[35] *Ibid*.
[36] *Ibid*. at 193.
[37] See e.g. Colorado Medical Society, "Ethics Policy 170.997, Corporate Practice of Medicine", online: Colorado Medical Society <http://www.cms.org/about/policies/170-ethics>; Medical and Chirurgical Faculty of Maryland, "Ethical Opinions § 501, Division of Fees", online: MedChi: The Maryland State Medical Society <http://www.medchi.org/Portals/18/files/Law%20&%20Advocacy/Ethics%20Opinions/SEC_500.pdf?ver=2009-09-02-040000-000>; Minnesota Medical Association, "Policy 250.04, Defining 'Illegal Fee-Splitting'", online: Minnesota Medical Association <http://www.mnmed.org/MMA/media/siteimages/Policycomp2015.pdf>; Washington State Medical Association, *Policy Compendium* (Seattle: Washington State Medical Association, 2016), online: Washington State Medical Association <https://wsma.org/doc_library/AboutWSMA/Policies/policy%20compendium%202016_20160706.pdf> at 31-32.

States have enacted a variety of statutes aimed at fraudulent behavior,[38] and they have adopted systems for identifying and prosecuting fraud associated with Medicaid and other state health care programs.[39] These Medicaid fraud control agencies might differ in size and the extent of arrest and prosecution authority, but all are tasked with maintaining the integrity of their state's health care programs.[40] Given the complexity of Medicaid financing and expenditures, the variations between state programs,[41] and the amount that Medicaid spending represents in states' budgets,[42] it is no surprise that states have taken these measures to limit their exposure and financial liabilities.

Federal efforts targeting health care fraud and abuse are expansive, and there are a variety of laws that define civil and criminal activities and penalties.[43] These extend beyond just Medicare, although this program tends to be the primary focus of federal enforcement due to its size and scope as well as the federal government's primacy in administering it. The statute excluding certain individuals and entities from participation in Medicare applies not only to those convicted of crimes related to Medicare, but to crimes against any state health care program or involving patient abuse or controlled substances (presumably including the physician's personal use or

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[38] See e.g. 305 Ill Comp Stat 5/8A-2.5, 8A-3, 8A-3.5, 8A-13, 8A-14, 8A-15 (2014).
[39] See National Association of Medicaid Fraud Control Units, *Statistical Survey of State Medicaid Fraud Control Units* (Washington, DC: National Association of Medicaid Fraud Control Units, 2014).
[40] *Ibid*. Most have prosecutorial authority, while fewer—although still a majority—have arrest authority.
[41] Federal law sets a floor for state Medicaid programs but otherwise states are free to design a program that they believe best fits their needs. See 42 USC § 1396 (2014) (Medicaid and CHIP Payment and Access Commission); 42 USC § 1396a (2014) (state plans for medical assistance); 42 USC § 1396c (2014) (operation of state plans). This has led to substantial differences amongst the states in who and what is covered. See generally Vernon K Smith et al, *Medicaid in an Era of Health and Delivery Reform: Results From a 50-State Medicaid Budget Survey for State Fiscal Years 2014 and 2015* (Menlo Park, Cal: The Henry J Kaiser Family Foundation, 2014), online: Kaiser Family Foundation <https://kaiserfamilyfoundation.files.wordpress.com/2014/10/8639-medicaid-in-an-era-of-health-delivery-system-reform3.pdf>.
[42] According to the National Association of Medicaid Fraud Control Units, Medicaid budgets range from $585 million (Wyoming) to $65.6 billion (California). National Association of Medicaid Fraud Control Units, *supra* note 39 at 12-13.
[43] 42 USC § 1320a-7 (2014) (exclusion of certain individuals and entities from participation in Medicare and state health care programs); 42 USC § 1320a-7a (2014) (civil monetary penalties); 42 USC § 1320a-7b (2014) (criminal penalties for acts involving federal health programs); 42 USC § 1320a-7c (2014) (Fraud and Abuse Control Program).

improper prescribing) without regard to payor.[44] Civil penalties are applicable to fraudulent behavior by physicians and health facilities against both state and federal health programs.[45] Likewise, criminal penalties for fraud and abuse are applicable to violations involving federal and state programs, although the boundaries of enforcement are narrowed to "federal health care programs" for much of this provision.[46]

Despite stringent rules against fraud and abuse, some activities that might otherwise constitute fraud under relevant statutes are excepted from the general rules and prohibitions.[47] Kickbacks (including fee-splitting) provide a particularly telling example of how some activities that would normally be prohibited under a broad regulation are tolerated because they create lower risk of fraudulent behavior than others, or lead to activities that the State prefers to promote rather than prohibit.

Physicians can be criminally prosecuted under federal (and state) law for soliciting or paying a kickback for the referral of patients.[48] Despite the statute clearly applying to anyone who willfully and knowingly solicits, receives, offers or pays any remuneration (including kickbacks) for referrals,[49] there are a wide variety of exceptions to the general prohibition against payments without legitimate purpose, and many have very specific criteria that must be satisfied before the physician qualifies.[50] For example, and despite being a primary target for both anti-kickback and

[44] 42 USC § 1320a-7(a) (2014). The statute also sets forth permissive exclusions.
[45] 42 USC § 1320a-7a (2014). In addition to prohibiting the submission of fraudulent or misleading claims, the statute prohibits "payments to induce reduction or limitation of services". This prohibition applies to payments made by hospitals or critical access hospitals, so insurer payment mechanisms that have the purpose and effect of reducing the amount of care are not included in this. 42 USC § 1320a-7a(b) (2014).
[46] 42 USC § 1320a-7b (2014).
[47] There are generally no carve-outs in the AMA *Code*, although the AMA is unlikely to pursue a practice that has become accepted in the profession so long as it has only limited risks of creating a conflict of interest.
[48] 42 USC § 1320a-7b(b) (2014).
[49] 42 USC § 1320a-7b(b)(1) & (b)(2).
[50] 42 CFR § 1001.952 (2014). There are 25 total safe harbors in the regulation.

self-referral, certain investment interests are excluded from the general prohibitions. The criteria for the exception relate primarily to the terms and returns of the investment—that they must essentially be the same for all investors without special privileges for investors in a position to refer patients—and limitations on the amount of referral revenue generated by investors.[51] Other safe harbors include leases on space[52] and equipment,[53] personal services and management contracts,[54] and referral services.[55] For each of these much of the criteria to qualify for an exception relate to fair practices and not including any terms that tie the arrangement to referrals.

The threat of civil and criminal sanction for violation is an important deterrent. However, given the complexity of many health care contracts it might be difficult for physicians and others (perhaps even the State) to know for certain whether their investment, lease or other arrangement violates the fraud and anti-kickback statutes. The Department of Health and Human Services (HHS) Office of the Inspector General (OIG) therefore allows individuals and entities to submit information to it for consideration and application of the relevant statutes and regulations, and provides an interpretation of whether the arrangement might constitute a violation.[56] These advisory opinions are an important source of guidance where statutes and regulations fail to provide sufficient clarity, and can point to specific relationships that might raise flags with OIG and those that might not even though the relationships could *potentially* violate federal law. No regulation can incorporate all circumstances and agreements that might violate the law—and

[51] 42 CFR § 1001.952(a).
[52] 42 CFR § 1001.952(b).
[53] 42 CFR § 1001.952(c).
[54] 42 CFR § 1001.952(d).
[55] 42 CFR § 1001.952(f).
[56] The statutory authority for issuing advisory opinions is 42 USC § 1320a-7d(b) (2014). An advisory opinion is binding on the Secretary of Health and Human Services and the party (or parties) requesting the opinion. *Ibid.*

neither can medical ethics—therefore the public access to advisory opinions provides additional context.

Addressing fraud and abuse in health care is a difficult proposition. The variety of actors—physicians, insurers, health facilities, device and drug manufacturers, and laboratories, to name a few—and the amount of money flowing in and out of the system make fraud difficult to identify. And, as the GAO recognized, because fraud stems from intentional deception, it is impossible to entirely prevent.[57] Despite difficulties in enforcing fraud and abuse laws, the efforts of the HHS OIG and other federal law enforcement entities under the umbrella of the Health Care Fraud and Abuse Program[58] led to over a thousand actions being initiated against health care providers (including facilities) for Medicare fraud in 2013, recovering $4.3 billion.[59]

C. Physician Self-Referral

1. The Problem

Self-referral in medicine is generally described as when a physician has a financial interest in the services or facility to which he or she refers a patient even if not providing services directly.[60] Once it became profitable to own health facilities or complex medical equipment, or hold stock in medically related companies, it also became profitable to prescribe those goods or services to

[57] US GAO, *Medicare Fraud – Progress Made, But More Action Needed*, *supra* note 29 at 1.
[58] *Health Insurance Portability and Accountability Act of 1996*, Pub L 104-191, 42 USC § 1320a-7c.
[59] Department of Health and Human Services and Department of Justice, "Health Care Fraud and Abuse Control Program: Annual Report for Fiscal Year 2013", online: Office of the Inspector General <https://oig.hhs.gov/publications/docs/hcfac/FY2013-hcfac.pdf> at 1. The monetary recovery includes actions began in earlier years but finalized in 2013.
[60] See e.g. Council on Ethical and Judicial Affairs, "Report 1: Physicians' Self-Referral (resolution 17, A-07)" in American Medical Association, *House of Delegates Proceeding, Interim Meeting, November 8-10, 2008* (Chicago: American Medical Association, 2008) at 154, 155 [CEJA, "Physicians' Self-Referral"]. For example, it would not be self-referral to order tests for a patient and then interpret and provide the results, but it would be if the physician had an ownership interest in the lab running the test.

patients. Thus, if the investment generates income for a physician based on referral to the service or facility, then the physician is incentivized to maximize the use regardless of the medical needs of the patient.

The types of self-referral that have become a major topic in health care stem from changes in the structure of the health care industry and its payment mechanisms. For some specialties, the reimbursement for time spent with patients in the course of treatment is overshadowed by the reimbursement for a variety of tests or imaging, or for procedures performed in hospitals (which might receive a higher rate).[61] Many of these used to take place in independent hospitals or other facilities due to the high costs of equipment, but as technology became less expensive physicians also began to invest in imaging and testing facilities, or to purchase or lease imaging machines for their own or a group practice to which they could refer patients.[62] Some have argued that the convenience of offering these to patients within the same facility is beneficial to patients, as it may be less costly than the same test performed in a hospital setting,[63] but the dangers of overutilization

[61] For example, the Missouri Department of Social Services publishes a fee schedule for radiological services. Payment for many imaging services, such as MRIs and CTs, are substantially higher than payments for reviewing the image (the "professional component") and for use of x-rays. Missouri Department of Social Services, "Medicaid Fee Schedule for the Technical Component of Hospital Outpatient Radiology Procedures", online: Missouri Department of Social Services <https://dss.mo.gov/mhd/providers/files/outpatient-hospital-radiology-fee-schedule.xlsx>. See also American College of Radiology, "Updated 2014 Medicare Physician Fee Schedule Payment Impact Tables for Radiology and Radiation Oncology Services", online: American College of Radiology <http://www.acr.org/News-Publications/News/News-Articles/2013/Economics/20131213-2014-Medicare-Physician-Fee-Schedule-Payment-Cuts> [American College of Radiology, "Fee Schedule"]. Both documents show efforts to reduce the rates for some services, especially more expensive scans, and increase the rates for others. See also Margot Sanger-Katz, "When Hospitals Buy Doctors' Offices, and Patient Fees Soar", *New York Times* (6 February 2015), online: New York Times <http://www.nytimes.com/2015/02/07/upshot/medicare-proposal-would-even-out-doctors-pay.html?_r=0&abt=0002&abg=1>.

[62] See generally Leonard Berlin & Jonathan W Berlin, "Leasing Imaging Facilities to Referring Physicians: Fee Shifting or Fee Splitting?" (2005) 234 Radiology 44; David C Levin et al, "Ownership or Leasing of CT Scanners by Nonradiologist Physicians: A Rapidly Growing Trend That Raises Concern About Self-Referral" (2008) 5 J Am Coll Radiol 1206.

[63] See e.g. *Fresenius Medical Care Holdings v Tucker*, 704 F 3d 935 at 938 (11th Cir 2013) (plaintiffs argued that their vertical integration business model for providing end-stage renal disease services, which violated Florida law but not federal, was more efficient and better for patients than non-integrated services). Stephen Brill published an article in *Time* magazine detailing the incredibly high prices that hospitals have been documented to charge patients (and their insurers). Stephen Brill, "Bitter Pill: Why Medical Bills are Killing Us", *Time* (20 February 2013), online:

and needless tests—and hence higher costs—were quickly recognized by the profession and State and self-referral came to be viewed with misgiving.[64]

Just prior to the passage of the federal Stark Law, which prohibited many self-referral arrangements,[65] the Hastings Center Report published an article that questioned many of the rationalizations for physician joint ventures while exploring the ethical arguments against these investments.[66] It addressed the argument that joint ventures are only an extension of commonly accepted practices that create some level of conflict of interest and the assertion (still common today) that there is a social value in joint ventures that outweighs the risks.[67] Green believed both of these failed to overcome the ethical objections to practices that created an incentive to place the physician's interest ahead of the patient's. He wrote "such practices patently violate the most elemental ethical standards governing not only medicine but ordinary business conduct, especially the requirement that an agent standing in a fiduciary relationship to another person avoid 'self-dealing' and give undivided attention to the interests of that person."[68] In this context, Green saw "no compelling reasons to bend the standards…."[69]

This is an important recognition, often unaddressed by supporters of physician economic arrangements that classify as self-referral. In limited circumstances, investments might provide

Time <http://time.com/198/bitter-pill-why-medical-bills-are-killing-us/>. He did not examine the prices of physician-owned facilities or equipment so the two cannot be compared, but he argued that costs at hospitals are inexplicably high.

[64] See e.g. 225 ILCS 47/5 (2014) ("[g]enerally, referral practices are positive occurrences. However, self-referrals may result in over utilization of health services, increased overall costs of the health care systems, and may affect the quality of health care").

[65] 42 USC § 1395nn (2016).

[66] Ronald M Green, "Medical Joint Venturing: An Ethical Perspective" (1990) 20 Hastings Center Report 22.

[67] *Ibid*. at 24-25.

[68] *Ibid*. at 23.

[69] *Ibid*.

better care or services in an underserved area,[70] but do these justify the abrogation of traditional ethical and fiduciary responsibilities?[71] Self-referral arrangements are not quite the same as fee splitting, which has long been prohibited by the profession, but are similar enough that the profession's decision to largely accept many self-referral practices while prohibiting fee-splitting leads to serious questions about the profession's ability to fully advance its legal order.[72]

Following decades of reports, policies and laws, the ethical jumble has yet to be resolved. More recent examinations of self-referral raised the same concerns as Green did and provided additional confirmation of the dangers inherent in these arrangements. In 2012, a few years after the AMA adopted its current Opinion on self-referral, Robertson, Rose and Kesselheim reviewed available evidence of the impact of self-referral on physician behavior.[73] A number of studies showed that physicians were more likely to refer patients to services for which they received some form of payment, at times ordering unnecessary services.[74] Other studies showed inappropriate scans, the greater use of physical therapy services that more than offset the lower cost at the physician-owned facilities, and "an increased frequency in the use of surgery, diagnostic, and ancillary services at the specialty hospital" in which the physician has a financial interest.[75] The authors concluded that, despite the limitations of the studies they examined, the evidence was clear "that conflicts of interest contribute to bias" and "[c]onflicting interests create substantial distortions in the decisions

[70] Green recognized the strength of these arguments, especially when a joint venture could bring better and more efficient care to remote areas, going so far as to argue that a complete prohibition of self-referral could retain an exception for "sole rural providers." *Ibid*. at 25.
[71] Physicians are generally considered to be in a fiduciary relationship with patients, as they are "entrusted with power…to be used for the benefit of another and legally held to the highest standard of conduct." Marc A Rodwin, "Strains in the Fiduciary Metaphor: Divided Physician Loyalties and Obligations in a Changing Health Care System" (1995) 21 Am JL & Med 241 at 243.
[72] Green, *supra* note 66 ("[c]learly, however, apart from the absence of an immediate *quid pro quo*, nothing ethically distinguishes the newer practices of self-referral from older forms of fee-splitting" at 24).
[73] Christopher Robertson, Susannah Rose & Aaron S Kesselheim, "Effect of Financial Relationships on the Behavior of Health Care Professionals: A Review of the Evidence" (2012) 40 JL Med & Ethics 452.
[74] *Ibid*. at 453-456.
[75] *Ibid*. at 455-456.

made by health care professionals"[76] (they discussed conflicts raised by industry relationships and salary incentives as well as self-referral).

Falit reasoned in 2006 that "the proper question is not whether permitting professionals to refer patients and clients to their own centers will increase competition and decrease prices, but whether the reduction in price outweighs any potential diminution in quality."[77] He argued that physicians' investment in ancillary service centers should be permissible, although referring their own patients to centers in which they have an interest should not.[78] First, market drivers that can help increase quality might diminish when physicians refer to their own facilities because of their "ability to generate demand".[79] Second, the profession's claimed ability to identify market need and invest appropriately does not necessitate self-referral: "[a]dditional investment…is undesirable if it is prompted by the ability to overutilize ancillary centers and artificially create demand."[80] However, Falit would allow for limited exceptions in the instance where there was a need due to lack of services in the area, although this would be narrower than the AMA's (and the Stark law's) exception.[81] Finally, even diluted interests retain the potential to influence utilization making some exceptions, such as the whole hospital exception in Stark, unlikely to completely cure any conflict of interest.[82]

Abuse of legal and ethical exceptions to the general rule proscribing self-referral are also cited as reason to abolish many practices. The AMA Opinion and the Stark law (which is more detailed)

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[76] *Ibid*. at 463.
[77] Benjamin P Falit, "Ancillary Services and Self-Referral Arrangements in the Medical and Legal Professions: Do Current Ethical, Legislative, and Regulatory Policies Adequately Serve the Interests of Patients and Clients?" (2006) 58 S Car L Rev 371 at 401.
[78] See generally *ibid*.
[79] *Ibid*. at 402.
[80] *Ibid*.
[81] *Ibid*. at 404.
[82] *Ibid*. at 404-408.

contain exceptions for in-office ancillary services. Yet current use of this exception threatens the integrity of the general prohibitions.[83] The exception was established to ensure that physicians were not penalized for services they would typically perform in their offices and to encourage the formation of multi-specialty group practices.[84] The exception, though, has ballooned to the purchase and use of equipment that might typically have been under the purview of another specialty or offered only at larger facilities:

> [w]hen initially proposed in the early 1990s, exemptions to federal self-referral and antikickback laws seemed reasonable compromises that respected the sanctity of physicians' autonomy in their practices….By the turn of the millennium, however, these self-referral and "safe harbor" exemptions were not effective in restraining physicians' financial interests from influencing care. Advances in medical technology and practice transformed the self-referral exemptions into potentially lucrative opportunities for physicians.[85]

Further, the exception has been used to develop arrangements that would clearly be in violation of the spirit of ethical and legal prohibitions.

> The in-office exception in current law was justified under the assumption that when physicians provide imaging to patients within their offices, they do so for patients' convenience and to monitor quality of care. However, the majority of self-referral providers for MRIs and CT scans (61 percent and 64 percent, respectively) did not have the imaging equipment in their offices in 2004. Rather, physicians have figured out how to take advantage of the exemptions in existing law by establishing referral arrangements with other imaging facilities that involve minimal financial risk for the referring physician.[86]

These arrangements might include "sham leases" or agreements that permit the use of off-site imaging facilities while remaining within the letter of the law. "The Office of the Inspector

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[83] David C Levin, Vijay M Rao & Alan D Kaye, "Why the In-Office Ancillary Services Exception to the Stark Laws Needs to be Changed—And Why Most Physicians (Not Just Radiologists) Should Support that Change" (2009) 6 J Am Coll Radiol 390 ("[o]ne might logically wonder why this huge loophole was ever allowed in the first place, considering that it essentially guts an important purpose of the Stark laws" at 390).

[84] *Ibid*.; CEJA, "Physicians' Self-Referral", *supra* note 60 at 158.

[85] Hoangmai H Pham et al, "Financial Pressures Spur Physician Entrepreneurialism" (2004) 23 Health Aff 70 at 78-79. See also Levin, Rao & Kaye, *supra* note 83.

[86] Jean M Mitchell, "The Prevalence of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging" (2007) 26 Health Aff w415 at w423 [Mitchell, "Prevalence of Physician Self-Referral Arrangements"].

General…views these types of arrangements as an opportunity for referring physicians to bill and retain remuneration that is illicit under the anti-kickback statute, even though they appear to meet the 'safe harbor' guidelines."[87] As many have pointed out, convenience represented by in-office services for the patient is not sufficient grounds to permit practices that can have the potential of increasing prices and decreasing quality.[88]

However, just as some commentators view self-referral as irreconcilable with ethics no matter what the safeguards, others believe that physician investment continues to be the answer to more efficient, quality care. Physicians who invest in facilities and services are seeking to "escape hierarchical control; to participate in management decisions in terms of facilities, equipment, and scheduling of procedures; and to define policies to make patient care more efficient, effective and friendly."[89] To proponents, these activities have been unfairly maligned by established facilities that fear competition, and that are willing partners when circumstances permit.[90] Really, competition represented by specialty hospitals can improve "access to high-quality and cost effective medical care."[91]

In 2004, Herzlinger linked physician ownership to productivity, comparing this to other industries where owners were intimately involved with the work (such as Microsoft, Wal-Mart, and GE).[92] Rather than argue that self-referral is a necessary evil to obtain higher quality and cheaper care, she blames the problems inherent in these practices on insurers and government setting prices that

[87] *Ibid*.
[88] See e.g. Robertson, Rose & Kesselheim, *supra* note 73; J Mitchell, "Urologists' Self-Referral for Pathology of Biopsy Specimens Linked to Increased Use and Lower Prostate Cancer Detection" (2012) 31 Health Aff 741.
[89] Sylvan Lee Weinberg, "Physician Ownership in Specialty Heart Hospitals: Successful and Under Siege" (2005) 3 Am Heart Hosp J 71 at 72.
[90] See generally *ibid*.
[91] *Ibid*. at 74.
[92] Regina E Herzlinger, "Specialization and Its Discontents: The Pernicious Impact of Regulations Against Specialization and Physician Ownership on the US Healthcare System" (2004) 109 Circulation 2376.

are not supported by the market. That is, if you allow prices to be set by normal market mechanisms, the incentives for self-referral would be less since it is the artificially high prices set by third parties that drives physician investment.[93] Essentially, the services most likely to encourage self-referral are not necessarily deserving of high levels of reimbursement that they currently receive.

As these commentators note, it is true that competition is one source of animosity towards physician ownership of facilities or equipment,[94] and in many industries entrepreneurism is a factor in raising quality and lowering costs. However, such arguments obscure the ethical issues inherent in self-referral. Yes, some studies have found that the quality or costs of care at physician-owned facilities is better than average.[95] The increased quality or lower costs per patient or procedure, though, might also be accompanied by increases in volume as physicians make more referrals to these entities than they might have prior to obtaining a financial interest.[96] This quality might also be indicative of accepting less complex cases or healthier patients than those left to general hospitals.[97] Further, the benefits of physician ownership—more focused services, knowledge of what patients need, potentially less bureaucracy—are not weighed very convincingly against

[93] *Ibid*. at 2377.
[94] John Bian & Michael J Morrisey, "Free-Standing Ambulatory Surgery Centers and Hospital Surgery Volume" (2007) 44 Inquiry 200 at 202. Bian and Morrisey reviewed allegations that hospitals used a variety of methods to limit competition, including closing medical staff and obtaining exclusive contracts with insurers.
[95] See e.g. Askar Chukmaitov et al, "Strategy, Structure, and Patient Quality Outcomes in Ambulatory Surgical Centers (1997-2004)" (2011) 68 Med Care Res Rev 202; Peter Cram et al, "Acute Myocardial Infarction and Coronary Artery Bypass Grafting Outcomes in Specialty and General Hospitals: Analysis of State Inpatient Data" (2010) 45 Health Serv Res 62; Peter Cram et al, "A Comparison of Total Hip and Knee Replacement in Specialty and General Hospitals" (2007) 89 J Bone & Joint Surg 1975. Limitations for these studies include the patient populations, which might comprise primarily Medicare patients or less complex cases.
[96] Jean M Mitchell, "Effects of Physician-Owned Limited-Service Hospitals: Evidence from Arizona" (2005) 24 Health Aff w5-481.
[97] See e.g. Liam O'Neill & Arthur J Hartz, "Lower Mortality Rates at Cardiac Specialty Hospitals Traceable to Healthier Patients and to Doctors' Performing More Procedures" (2012) 31 Health Aff 806.

drawbacks. While those who oppose self-referral might acknowledge some of the benefits of these arrangements,[98] those convinced of the benefits give little stock to the dangers.[99]

What experience has taught, albeit in a limited way without large numbers of studies to conclusively demonstrate, is that physician ownership of health facilities has the potential to lead to more efficient use of health care resources, but all too often devolves into a piggy bank for investors at the risk of patient welfare and needs. A 2010 House Report on the amendments to Stark limiting the growth of physician-owned hospitals succinctly stated the reality of the exception:

> Since enactment of the self-referral laws, entities have been created that identify and license themselves as "hospitals" under state law. However, many of these facilities no longer provide the full range of services a layperson would expect from a hospital. Instead, they limit their services to a narrow band of services. These bands have also tended to be profit centers for hospitals—most commonly cardiac procedures and orthopedic procedures. In effect, they've taken a "subdivision of a hospital" and made it a free-standing hospital in order to circumvent the prohibition in the physician self-referral laws which prohibit self-referral when the ownership is "merely in a subdivision of a hospital."[100]

The more recent evidence concerning physician-owned hospital costs, the impact on other hospitals in their service areas, and the risks to patients who encounter serious life-threatening complications was sufficient for Congress to curtail the use of the whole-hospital exception in the future.[101]

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[98] See e.g. Robertson, Rose & Kesselheim, *supra* note 73 ("for some of the studies [they examined] it is possible that, even if financial relationships are changing physician behaviors, they are changing them for the better in certain situations" at 463).

[99] See e.g. Weinberg, *supra* note 89. Weinberg recounts the resistance to physician-owned specialty hospitals, focusing primarily on the economic and legal efforts rather than ethical considerations (the article was written before CEJA's new and more restrictive Opinion on self-referral was adopted in 2008). See also Herzlinger, *supra* note 92.

[100] US, House of Representatives Committee on the Budget, 111th Cong, *The Reconciliation Act of 2010: Report of the Committee on the Budget, House of Representatives, to Accompany HR 4872, vol 1 div 1* (HR Rep No 111-443) (Washington, DC: US Government Printing Office, 2010) at 355-356.

[101] Medicare Payment Advisory Commission, *Report to the Congress: Physician-Owned Specialty Hospitals* (Washington, DC: Medicare Payment Advisory Commission, March 2005) [Medicare Payment Advisory

Self-referral regulation is a constantly changing field for both the profession and the State. The recent amendment of the AMA *Code* to better reflect current thinking on the issue and the regular amending of State law to address new concerns and new technology demonstrate that legal orders in this area are hardly settled matters.

2. The Profession's Legal Order

Like fee splitting, this issue received attention from the profession well before it was memorialized in federal law. The early view of the Judicial Council was that the ownership of stock in laboratories or clinics deserved the same treatment as fee splitting.[102] By the 1980s, though, the AMA had a number of provisions in place allowing some forms of self-referral, essentially reversing its earlier position. Rather than an outright prohibition, the AMA permitted such arrangements so long as it was disclosed to the patient prior to utilization and any serious conflict was resolved in the patient's favor.[103] It continuously affirmed this and similar conflicts of interest policies by recognizing that the conflict existed but envisioning an offset through disclosure[104] and

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Commission, *Report to the Congress, 2005*]. See also Joshua E Perry, "Physician-Owned Specialty Hospitals and the Patient Protection and Affordable Care Act: Health Care Reform at the Intersection of Law and Ethics" (2012) 49 Am Bus LJ 369.

[102] AMA, *Digest of Official Actions, 1846-1958*, *supra* note 21 at 266. This decision stemmed from a 1926 report.

[103] Council on Ethical and Judicial Affairs, "Report A: Conflicts of Interest" in American Medical Association, *Proceedings of the House of Delegates, 40th Interim Meeting, December 7-10, 1986* (Chicago: American Medical Association, 1986) at 216 (quoting the Council's opinion on "Health Facility Ownership by Physicians", since replaced). The 1986 report did not specifically address the contractual requirements of self-referral in the same way that later reports and opinions did.

[104] Disclosure as a cure for conflicts of interest or to ensure informed consent is a closely followed topic in the bioethics literature. Depending on the type of conflict, there are questions of the necessity of the relationship that leads to disclosure (self-referral versus medical research, for example) and the real impact of the disclosure. See e.g. Robertson, Rose & Kesselheim, *supra* note 73; Atul Gawande, "The Cost Conundrum", *New Yorker* (1 June 2009) at 36; Roy Spece et al, "An Empirical Method for Materiality: Would Conflict of Interest Disclosures Change Patient Decisions?" (2014) 40 Am JL & Med 253. An undeniable fact, though, is that the conflict will continue to exist regardless of whether it is disclosed: like a cold medication, disclosure is an attempt to address the symptoms of a conflict but leaves the underlying cause intact. Institute of Medicine, *supra* note 2 at 77. Indeed, it is possible that a physician will see little need to take additional action, believing that disclosure alone satisfies his or her ethical obligations. George Leowenstein, Sunita Sah & Daylian M Cain, "The Unintended Consequences of Conflict of Interest Disclosure" (2012) 307 J Am Med Assoc 669 at 670.

the oft-endorsed ethical nature of physicians—the ideal of the noble physician who puts the needs of the patient ahead of his own.[105]

The modern provision in the *Code* related to self-referral arrangements, Opinion 8.0321 "Physicians' Self-Referral", is more prohibitive than earlier self-referral Opinions but still permits ownership interests if certain criteria are met. Unlike the State law to be discussed below, the *Code* uses "should not", greatly limiting the applicability and utility of this provision: "[i]n general, physicians *should not* refer patients to a health care facility that is outside their office practice and at which they do not directly provide care or services when they have a financial interest in that facility."[106] Demonstrating the limits of ethics in the current State regulatory environment, the Opinion goes on to state that "[p]hysicians who enter into *legally permissible* contractual relationships…are expected to uphold their responsibilities to patients first."[107] Like previous self-referral provisions, disclosure to patients is one mechanism to dilute the impact of the conflict.[108]

The American College of Physicians (ACP), another very large physician organization that encompasses different specialties and practices, is also direct but permissive on the ethical

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[105] We know, and the AMA should have known, that this is not always the case. See *ibid*.; American Medical Association Board of Trustees, "Report J: Physician Conflict of Interest (Resolution 11, I-83)" in American Medical Association, *Proceedings: House of Delegates, Chicago, Illinois, June 17-21, 1984, 133rd Annual Meeting* (Chicago: American Medical Association, 1984) at 87; Judicial Council, "Report D: Ethical Implications of Certain Physician-Hospital Profit-Sharing Arrangements" in American Medical Association, *Proceedings: House of Delegates, Chicago, Illinois, June 17-21, 1984, 133rd Annual Meeting* (Chicago: American Medical Association, 1984) at 242; Judicial Council, "Report C: Conflict of Interest – Guidelines" in American Medical Association, *Proceedings: House of Delegates, Honolulu, Hawaii, December 2-5, 1984, 38th Interim Meeting* (Chicago: American Medical Association, 1984) at 175; Council on Ethical and Judicial Affairs, "Report C: Conflicts of Interest: Update" in American Medical Association, *Proceedings: House of Delegates, Chicago, Illinois, June 18-22, 1989, 138th Annual Meeting* (Chicago: American Medical Association, 1989) at 188.

[106] CEJA, *Code of Medical Ethics*, *supra* note 13 at 220 [emphasis added]. It is possible that the "should" here is in recognition of the limits of CEJA's disciplinary power, as well as the AMA's overall hesitancy to legislate in absolutes on these matters given anti-trust concerns.

[107] *Ibid*. [emphasis added]. This implies that the "legal" can trump the "ethical".

[108] *Ibid*. ("[d]isclose their financial interest in the facility, product, or equipment to patients; inform them of available alternatives for referral; and assure them that their ongoing care is not conditioned on accepting the recommended referral" at 221).

propriety of self-referral. It recognizes the dangers inherent in physician ownership of health facilities to which they might refer patients. The ACP, like the AMA, states "[p]hysicians should not refer patients to an outside facility in which they have invested and at which they do not directly provide care."[109] In both the ACP and AMA policies, provision of care at the facility is a criterion for permissible ownership interests. This requirement does not truly address the potential conflicts that arise from incentives to refer: it only limits the types of facilities in which physicians might invest.

Other medical societies share the AMA's and ACP's latitude on matters of physician ownership and investment interests. The American Academy of Dermatology states "the dermatologist must disclose this interest to the patient" and "[t]he dermatologist has an obligation to know the applicable laws regarding physician ownership, compensation and control of these services and facilities."[110] Like the AMA, disclosure is the primary means of diffusing the conflict and the Academy places great weight on what is *legally* permissible. The American Academy of Orthopaedic Surgeons has nearly word-for-word the same provision in its *Code of Ethics and Professionalism*.[111] Similarly, the American Association for Thoracic Surgery[112] and Society for Thoracic Surgeons[113] rely on disclosure and the physician resolving the conflict in the best interests

[109] American College of Physicians Ethics, Professionalism and Human Rights Committee, "American College of Physicians Ethics Manual, Sixth Edition" (2012) 156 Ann Intern Med 73 at 88.
[110] American Academy of Dermatology and AAD Association, "Code of Medical Ethics for Dermatologists", online: American Academy of Dermatology <https://www.aad.org/Forms/Policies/ar.aspx> at § III.B.
[111] American Academy of Orthopaedic Surgeons, "Code of Medical Ethics and Professionalism for Orthopaedic Surgeons", online: American Academy of Orthopaedic Surgeons <http://www.aaos.org/uploadedFiles/PreProduction/About/Opinion_Statements/ethics/Code%20of%20Ethics%202013%20color%20logo.pdf> at § III.B.
[112] American Association for Thoracic Surgery, "Code of Ethics", online: American Association for Thoracic Surgery <http://www.aats.org/AATSIMIS/AATS/Association/By-Laws_and_Policies/Code_of_Ethics/CODE_OF_ETHICS.aspx> at § 8.3.
[113] Society of Thoracic Surgeons, "Code of Ethics", online: Society of Thoracic Surgeons <http://www.sts.org/about-sts/policies/code-ethics> at § 8.3.

of the patient. Finally, the American Academy of Pain Medicine extensively quotes AMA policies on self-referral and fees and charges in support of its own policies, which mirror the AMA's.[114]

Some medical societies are less ambivalent towards self-referral than the AMA and other societies, reflecting the view that certain investment interests will *always* have the potential to influence physician decisions even when measures are taken to reduce that risk. The American College of Radiology (ACR) asserts that

> [t]he practice of physicians referring patients to health care facilities in which they have a financial interest is not in the best interests of patients. Self-referral may improperly influence the judgments of those physicians referring patients to such facilities. Members with ownership interests participating in such arrangements may be in violation of these Rules of Ethics.[115]

Despite the declaration that self-referral is not in the best interests of patients the ACR did not clearly call these arrangements a violation of ethics, but rather stated that they *may* be a violation.[116] Given that many investment interests remain legal the ACR might be hesitant to completely prohibit all self-referral practices, although its statement on their impact is more prohibitive than the AMA's and is justified merely on the risk that these practices "*may* improperly influence the judgments" of physicians.[117]

The profession has by-and-large settled the matter of self-referral on the side of a cautious permissibility. For other types of conflicts, the profession has erred on the other side of caution

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[114] American Academy of Pain Medicine, *Ethics Charter* (Chicago: American Academy of Pain Medicine, 2003) at 8.
[115] American College of Radiology, *2016-2017 Bylaws* (Reston, VA: American College of Radiology, 2016), online: American College of Radiology <http://www.acr.org/~/media/ACR/Documents/PDF/Membership/Governance/2016_2017%20Code%20of%20Ethics.pdf> at 30 [American College of Radiology, *Bylaws*].
[116] Radiology was an early focus of medical joint ventures that allowed physicians to purchase expensive equipment to which they and others could refer patients for tests. Perhaps because of this experience the ACR has taken a slightly different position of self-referral than other societies. See generally Green, *supra* note 66.
[117] American College of Radiology, *Bylaws*, *supra* note 115 [emphasis added].

and prohibited questionable practices. This was the case with fee splitting, which represents the same ethical dangers as self-referral: financial incentives influencing decision-making. Under the present ethics guidance, the profession accepts the risks inherent in self-referral without convincingly addressing the consequences.

3. The State's Legal Order

Both federal and state legislatures have enacted laws to circumscribe the ability of physicians to refer patients for services or facilities in which they or family members have an economic interest. The federal self-referral statute, popularly known as the Stark Law for the legislator who introduced it, prohibits referral for "designated health services" by physicians to entities in which the physician or immediate family members have certain financial relationships, including ownership, investment or compensation arrangements.[118] Individual state laws are similar;[119] for example, California provides that

> it is unlawful for a licensee to refer a person for laboratory, diagnostic nuclear medicine, radiation oncology, physical therapy, physical rehabilitation, psychometric testing, home infusion therapy, or diagnostic imaging goods or services if the licensee or his or her immediate family has a financial interest with the person or in the entity that receives the referral.[120]

Likewise, Illinois and Florida prohibit the referral of patients for services in which the physician holds an ownership or investment interest, with certain exceptions.[121]

However, states and the federal government recognized the economic stresses of physicians and the need to encourage the provision of health services in rural and underserved areas by carving

[118] 42 USC § 1395nn(a) (2015).
[119] These laws help fill the gap left by Stark when the physician/facility does not receive federal money and is not referring for "designated services".
[120] Cal Bus & Prof Code § 650.01(a) (2015).
[121] 225 Ill Comp Stat 47/20 (2015); Fla Stat § 456.053(5) (2015).

out exceptions to the general rule, hoping to limit the negative impact of self-referral while continuing to permit some referrals and the accompanying economic benefit to physicians and availability of care to patients. The federal Stark Law contains a broad exception known as the in-office ancillary services exception.[122] Referral for services (with some exclusions) is not prohibited when they are furnished

> personally by the referring physician, personally by a physician who is a member of the same group practice as the referring physician, or personally by individuals who are directly supervised by the physician or by another physician in the group practice, and…in a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of designated health services, or…in the case of a referring physician who is a member of a group practice, in another building which is used by the group practice…for the provision of some or all of the group's clinical laboratory services, or for the centralized provision of the group's designated health services (other than clinical laboratory services)….[123]

In keeping with the hesitancy to prohibit physicians from ordering procedures that they personally provide, state self-referral laws also permit the otherwise prohibited referral of patients for services performed by the referring physician.[124]

Yet given the creativity of physicians and entities in structuring ownership and responsibilities, the in-office ancillary services exception creates wide latitude for the continuance of practices that encourage unnecessary referrals while still being within the letter of the law, greatly reducing the effectiveness of the self-referral prohibition.[125] One concern of regulators is the referral of patients for diagnostic imaging, which depending on the type can be quite expensive.[126] If a physician

[122] 42 USC § 1395nn(b)(2) (2014).
[123] 42 USC § 1395nn(b)(2)(A) (2014).
[124] See e.g. 225 Ill Comp Stat 47/20 ("…unless the health care worker directly provides health services within the entity and will be personally involved with the provision of care to the referred patient").
[125] See e.g. Berlin & Berlin, *supra* note 62; Levin, Rao & Kaye, *supra* note 83; Patrick A Sutton, "The Stark Law in Retrospect" (2011) 20 Ann Health L 15; Eli Y Adashi & Robert P Kocher, "Physician Self-Referral: Regulation by Exceptions" (2015) 313 J Am Med Assoc 457.
[126] See e.g. Missouri Department of Social Services, *supra* note 61; American College of Radiology, "Fee Schedule", *supra* note 61.

group practice, or even an individual physician, purchases or leases the equipment for use in their office, the exception permits the referral of patients for that service despite the overarching goal of Stark (and similar state legislation) to prevent this type of referral incentive.[127]

Another broad exclusion from the prohibitions of Stark is the hospital exception.[128] If the facility to which a patient is referred is considered a hospital (rather than an ambulatory surgical center or a medical specialty facility) meeting certain criteria, the physician's ownership interest is believed to be less problematic since the investment is diluted by all of the services provided by the hospital.[129] When the self-referral prohibition was first contemplated, this exemption was intended to serve the health needs of rural areas by encouraging the development of health facilities where there might otherwise be none or very few.[130] The actual use of this exception, though, has not been so valorous.

Physician-owned hospitals are no longer relegated to rural regions and have proliferated in population centers, competing with general hospitals or large hospital systems. They have been accused of cherry-picking for less complicated patients, leaving general hospitals with sicker, more complex cases, and avoiding Medicaid patients because of the lower reimbursement.[131] Some studies have also shown that costs at these facilities are not significantly less than at community and general hospitals.[132] This is important because one justification for physician-owned hospitals

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[127] See e.g. Pham et al, *supra* note 85. Pham et al found that the decline in reimbursements from traditional sources for physicians' directly-provided services led many physicians to invest in ancillary services to make up for this loss therefore causing a large growth in these services, which was not the intent of Stark but has become a side-effect of health care financing changes.
[128] 42 USC § 1395nn(d)(3) (2014).
[129] See House of Representatives Committee on the Budget, *supra* note 100 at 355. The report noted the reason for the original exception: "[o]wnership in a whole hospital was not then viewed as a significant incentive for self-referral because these hospitals were usually the only hospitals in the area and they provided a breadth of services."
[130] *Ibid*.
[131] *Ibid*. at 355-356. See also Medicare Payment Advisory Commission, *Report to the Congress, 2005*, *supra* note 101 (detailing many of the concerns about physician-owned hospitals).
[132] *Ibid*.

is the reduced costs due to reduced bureaucracy compared to other hospitals, while quality and efficiency would be improved due to greater physician control.[133] Studies of some hospitals and services have indicated that referrals—and therefore costs—actually increased, possibly due to the incentive to refer more patients.[134]

In the decades since the Stark Law was enacted, Congress has continued to seek ways to alleviate concerns over the financial and quality implications of self-referral.[135] Amendments to Stark have limited the breadth of the in-office ancillary services and hospital exceptions, with the Patient Protection and Affordable Care Act severely limiting the expansion of existing physician-owned hospitals and the establishment of new ones.[136]

These efforts continue to be resisted by physicians, especially those who have a financial stake in the viability of the various exceptions to Stark. Critics of self-referral regulation include Physician Hospitals of America (PHA), an association formed to advocate for the interests of physician-owned hospitals, including lobbying against legislation that negatively impacts the viability of these facilities.[137] PHA recently expressed support for H.R. 2513 in the federal Congress, entitled "Patient Access to Higher Quality Health Care Act of 2015" and introduced to restore the federal

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[133] See generally CEJA, *Code of Medical Ethics*, *supra* note 13 at 220; Theodore N McDowell, "Physician Self-Referral Arrangements: Legitimate Business or Unethical 'Entrepreneurialism'" (1989) 15 Am JL & Med 61;
[134] Mitchell, "Prevalence of Physician Self-Referral Arrangements", *supra* note 86; G Scott Gazelle et al, "Utilization of Diagnostic Medical Imaging: Comparison of Radiologist Referral Versus Same-Specialty Referral" (2007) 245 Radiology 517; Jean M Mitchell, "Effect of Physician Ownership of Specialty Hospitals and Ambulatory Surgical Centers on Frequency of Use of Outpatient Orthopedic Surgery" (2010) 145 Arch Surg 732. See also Gawande, "The Cost Conundrum", *supra* note 104. Gawande investigated a town in Texas with much higher than the national average costs for Medicare, finding that many physicians in the town viewed their practices as revenue streams, prescribing more and more expensive treatments than physicians in other locales.
[135] See House of Representatives Committee on the Budget, *supra* note 100 at 357. Congress attempted numerous times to amend the Stark Law to address the growth of physician-owned hospitals, including passing a moratorium on new hospitals as part of the Medicare Modernization Act of 2003. *Medicare Modernization Act of 2003*, Pub. L. 108-173, § 507, 117 Stat. 2066 (2003).
[136] *Ibid*.; *PPACA*, *supra* note 26 at § 6001.
[137] Physician Hospitals of America, online: Physician Hospitals of American <http://www.physicianhospitals.org/>.

self-referral statute to what it was before the PPACA greatly restricted the growth of physician-owned hospitals.[138] Much like Herzlinger, PHA prefers a market solution for health care, asserting that physician-owned hospitals represent one way to offer patients quality care.[139]

The State response to self-referral, like the medical profession's, focused primarily on the relationships most likely to disserve patients and increase health care costs. While state and federal law and regulation has been substantially more successful than self-regulation at limiting the impact or proliferation of unethical practices, much like fraud and anti-kickback enforcement there is only so much that can be done to stamp out prohibited practices. In the end, State law has driven changes to the profession's legal order but has not fully contributed to the ethical betterment of medicine, as the permissibility of State law has been a crutch for the continuing laxity of the profession's legal order.

D. Physician-Industry Relationships

1. The Problem

There are some conflicts of interest that the profession has had a difficult time coming to terms with despite some medical societies and the ethics literature taking—or, in the case of CEJA, attempting to take—a strong stance on the matter. Chief among these is the relationship between physicians and the pharmaceutical and device industry. This topic is very complex and

[138] Physician Hospitals of America, "Support HR 2513", online: Physician Hospitals of America <http://www.physicianhospitals.org/?page=Talking_Points> [Physician Hospitals of America, "Support HR 2513"]; R Blake Curd, "Letter to Member of Congress: Support H.R. 2513", online: Physician Hospitals of America <http://www.physicianhospitals.org/resource/resmgr/Advocacy_976/PHA_Letter_to_House_2015_Fly.doc>.
[139] Physician Hospitals of America, "About PHA: PHA Values", online: Physician Hospitals of America <http://www.physicianhospitals.org/?page=About>.

encompasses medical education, residency, practice, research, the State[140] and the public,[141] so I will not delve into it in detail, but it is useful here to provide a brief discussion since it represents an area where medical ethics and physician practice diverge.

Pharmaceuticals and medical devices are very important components of modern health care. Drugs can be as commonplace as anesthetics used in everyday surgery (or in lethal injection executions) or as specialized as a treatment targeted at a tumor with a specific genetic marker. Likewise, medical devices include a set of surgical tools, but also a metal or ceramic knee. The "market" generally sets prices for these,[142] but there are business practices that have the effect of greatly distorting this market, increasing both costs and use.

Amongst the practices most plainly leading to a conflict is paying physicians or giving them substantial gifts to prescribe a medication or use a device. This has been well documented, although mostly stamped out by the profession, industry and State.[143] These practices included vacations for physicians,[144] awarding airline tickets when meeting prescription thresholds,[145] payment for conducting sham "clinical trials" of a drug, and cash payments to read a company's

[140] The federal Food and Drug Administration regulates pharmaceuticals and devices, and the Federal Communications Commission regulates advertising. Medicare and Medicaid also directly pay for drugs and devices for beneficiaries, so there is a substantial financial entanglement between the State and industry as well.
[141] The public is the target of direct to consumer advertising, and also the beneficiary of new and effective medication and devices.
[142] I use the term "market" here very loosely since, much like physicians' services, the market is not as competitive as in other industries.
[143] Such practices originated as "commissions" in the early 20th century, when a physician would ask a manufacturer for commissions on goods sold due to his referral. See e.g. Judicial Council, "Report of the Judicial Council" in American Medical Association, *Sixty-Sixth Annual Session, Held at San Francisco, Calif., June 21-25, 1915—Minutes of the House of Delegates* (Chicago: American Medical Association, 1915) at 12.
[144] John C Nelson, "A Snorkel, a 5-Iron, and a Pen" (1990) 264 J Am Med Assoc 742.
[145] John Graves, "Frequent-Flyer Programs for Drug Prescribing" (1987) 317 N Eng J Med 252. See contra Joseph M Mahady, "Reply to Frequent-Flyer Programs for Drug Prescribing" (1987) 317 N Eng J Med 252 (as representative of a company referred to by Dr. Graves, Mahady argued that the gifts Graves wrote of, including plane tickets, textbooks and equipment, were essentially honoraria for physicians who participated in surveys and processing paperwork in return for their substantial time).

literature.[146] These garnered attention in the late 1980s and into the early 1990s when federal hearings highlighted the problem[147] and the profession began to more publicly discuss the implications of payments and gifts on the future of professionalism.[148]

David Orentlicher noted that those within the profession "were troubled both by the magnitude and kinds of industry gift giving."[149] He studied reports of money and gifts provided to physicians—intended to influence their prescribing—that led eventually to the development of an AMA ethics policy.[150] Despite recognizing gifts as a problem, this new policy continued to allow many practices. For example, meals and textbooks were permissible if they served a "genuine educational function."[151] The "modest meal" envisioned as acceptable in the policy might be accompanied by an informational presentation about a drug or device. In the next sentence, the Opinion stated "cash gifts *should not* be accepted."[152] Excluding honoraria for presenting at conferences and the reimbursement of travel expenses for such activities, the report accompanying the Opinion noted that cash payments "serve only the physician's personal interests and therefore

[146] "Kennedy Hearings Say No More Free Lunch – or Much Else – From Drug Firms" (1991) 265 J Am Med Assoc 440 (the "clinical trials" were funded by pharmaceutical company marketing divisions and consisted primarily of providing demographic data).
[147] *Ibid*.
[148] Prior to the development of large pharmaceutical manufacturers, the AMA expressed concern over the relationship between pharmaceuticals and physician profits via arrangements with pharmacies. See e.g. AMA, *Digest of Official Actions, 1846-1958*, *supra* note 21 at 273. Having a direct or indirect investment interest in a pharmacy is not the same as receiving a payment or gift from a manufacturer for prescribing their drug, but the underlying ethical issues are analogous.
[149] David Orentlicher, "The Influence of a Professional Organization on Physician Behavior" (1994) 57 Albany L Rev 583 at 592.
[150] *Ibid*. at 593; Council on Ethical and Judicial Affairs, "Opinion of the Council on Ethical and Judicial Affairs: Gifts to Physicians from Industry" in American Medical Association, *Proceedings: House of Delegates, Orlando, Florida, December 2-5, 1990, 44th Interim Meeting* (Chicago: American Medical Association, 1990) [CEJA, "Opinion, Gifts to Physicians from Industry, 1990"] at 191. The American College of Physicians beat the AMA to the punch, adopting a position paper of gifts from industry months before the AMA adopted its policy. American College of Physicians "Physicians and the Pharmaceutical Industry" (1990) 112 Ann Intern Med 624. Many of its positions are similar to what the AMA eventually adopted.
[151] CEJA, "Opinion, Gifts to Physicians from Industry, 1990", *supra* note 150.
[152] *Ibid*. [emphasis added].

should not be accepted from industry."[153] The Opinion and Report also prohibited the express linking of a gift or payment to prescribing practices ("strings attached").[154] It would be easy to avoid this prohibition by a nod and a wink, such as by calling a physician a "consultant," leaving a particularly large loophole.[155]

The pharmaceutical industry encouraged adherence to the AMA policy, and eventually adopted its own guidelines limiting the type and value of items that could be given to physicians.[156] Given the voluntary nature of the pharmaceutical manufacturer umbrella organization and the lack of any mechanisms to enforce the policy its utility is questionable, but it was an important statement on the public perception of "big pharma" that such a policy was adopted at all. Orentlicher pointed out that the joint statements on gifts to physicians from industry were perhaps of greater benefit to pharmaceutical manufacturers than physicians: by the AMA making most gifts and payments ethically unacceptable and the Pharmaceutical Research and Manufacturers of America (PhRMA) likewise prohibiting many gifts and payments by its members, the industry was able to save substantial sums of money that otherwise would have gone to physicians or health care entities (essentially as bribes or kickbacks).[157]

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[153] Council on Ethical and Judicial Affairs, "Report G: Gifts to Physicians from Industry" in American Medical Association, *Proceedings: House of Delegates, Orlando, Florida, December 2-5, 1990, 44th Interim Meeting* (Chicago: American Medical Association, 1990) 192 at 195 [CEJA, "Report, Gifts to Physicians from Industry, 1990"].

[154] CEJA, "Opinion, Gifts to Physicians from Industry, 1990", *supra* note 150; American College of Physicians, *supra* note 150.

[155] See e.g. US, *Examining the Relationship Between the Medical Device Industry and Physicians, Testimony of Gregory E Demske, Assistant Inspector General for Legal Affairs: Hearing Before the Senate Special Committee on Aging*, 110th Cong (2008); Jerome Schofferman & John Banja, "Conflicts of Interest in Pain Medicine: Practice Patterns and Relationships with Industry" (2008) 139 Pain 494 ("[i]n some instances, paying physicians or researchers as consultants is no more than a form of gifting" at 495); Niten Singh et al, "New Paradigms for Physician-Industry Relations: Overview and Application for SVS Members" (2011) 54 J Vasc Surg 26S at 27S.

[156] Orentlicher, *supra* note 149 at 594; Teri Randall, "AMA, Pharmaceutical Association Form 'Solid Front' on Gift-Giving Guidelines" (1991) 265 J Am Med Assoc 2304; Pharmaceutical Research and Manufacturers of America, *Code on Interactions with Healthcare Professionals* (Washington DC: Pharmaceutical Research and Manufacturers of America, 2008).

[157] Orentlicher, *supra* note 149 at 594-595.

Physician-industry relationships are not just a concern in clinical practice contexts but also in medical education. Knowing the types of drugs and devices available for patients is a critical part of medical education at all levels. As with clinical relationships, the industry attempts to build ties with medical students, residents and practicing physicians through both marketing and educational efforts.[158] These might consist of meals for medical students or residents, presentations at educational conferences and the provision of promotional materials. These activities might not rise to the level of influence that large gifts and cash represent, but have caused concern within and outside of the profession all the same.

Conflicts of interest involving the pharmaceutical and device industry extend to biomedical research as well. Research, a source of what could be considered *beneficial* conflicts, often requires the partnership and cooperation of physicians, researchers, medical institutions and industry to research and bring to market new drugs and devices. Physicians' relationships with industry in research can take the form of performing research on behalf of industry, publishing articles disseminating the results of that research, presenting at educational events, and preparing clinical guidelines. Each of these raise questions about the propriety of the relationship, but given the need for research and the ensuing medical advances the goal is often to minimize the impact of conflicts rather than outright prohibit them.

Like some self-referral arrangements, a primary means to limit the risk of a conflict in research is to disclose it to patients, colleagues and institutions. Policies requiring disclosure of financial ties between researchers/authors and industry recognize the importance of the relationships that give rise to the discovery and implementation of new medical information and technology, and ensure

[158] See e.g. Schofferman & Banja, *supra* note 155; Singh et al, *supra* note 155.

"that users of research can take these conflicts into account when weighing upon the evidence."[159] While there is a clear discomfort with the implications of disclosure,[160] it is an important outlet since conflict avoidance is not likely in this particular area.

Voluntary disclosure, though, is not guaranteed. A 2005 article in *Nature* explored clinical guidelines panels and the relationships that some members have with pharmaceutical companies whose products they are ultimately responsible for recommending or not.[161] Two problems were identified: first, less than half of the total number of practice guidelines examined in the study (more than 200) identified author conflicts of interest and second, only about a third of these disclosed no industry influence.[162] The amount of influence actually exercised by industry over the development of guidelines is unknown, but the study identified relationships between physicians and pharmaceuticals that included payments for lectures or consulting.[163]

A 2002 article in JAMA indicated a similar problem in the development of guidelines.[164] The authors identified a lack of public conflict disclosure for most of the clinical guidelines examined (42 of 44)[165] but also found that 19% of respondents believed that industry relationships influenced colleagues' recommendations.[166] Conversely, "[o]nly 7% believed their own relationships influenced the treatment recommendations."[167]

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[159] Thomas Ploug & Søren Holm, "Conflict of Interest Disclosure and the Polarisation of Scientific Communities" (2015) 41 J Med Ethics 356.
[160] *Ibid*.
[161] "Cash Interests Taint Drug Advice" (2005) 437 Nature 1070.
[162] *Ibid*.
[163] *Ibid*. Even these relationships can lead to improper influence over medical practice. The Institute of Medicine refers to the example of speakers' bureaus, wherein the content and media reflects the sponsor's position rather than an independently researched presentation. Institute of Medicine, *supra* note 2 at 153.
[164] Niteesh K Choudhry, Henry Thomas Stelfox & Allan S Detsky, "Relationships Between Authors of Clinical Practice Guidelines and the Pharmaceutical Industry" (2002) 287 J Am Med Assoc 612.
[165] However, 45% of respondents indicated that there was a discussion amongst guideline authors about industry relationships prior to the drafting of the guideline. *Ibid*. at 614.
[166] *Ibid*.
[167] *Ibid*.

Although disclosure has become an important component of researcher-industry relationships, disclosure of a financial relationships has not been a common suggestion in the physician-patient relationship in the clinical context despite the wide variety of relationships that clinicians continue to have with pharmaceutical and device manufacturers or their representatives. This might be in part because of how researcher (or institution) and industry relationships are structured, but also because funding of research, participation in manufacturer panels or employment by industry are deemed relevant to the quality and source of information.[168] To also demonstrate the difference between the research and clinical contexts, industry funding of research is generally required to be disclosed to research participants but there is no requirement that it be disclosed to patients who might be prescribed the drug or device that their physician might also be researching or had previously studied.

Much of the hesitance to disclose or limit relationships or interactions between physicians and industry stems from a belief by physicians that their relationships or gifts and meals received will have no influence on their practice, and that disclosure could harm relationships with patients and sow distrust.[169] Compared to past instances of cash or lavish gifts, these things appear to be much more minor; however, research indicates that even small gifts or benefits for physicians can

[168] Authors are generally required to disclose any financial support received or conflicts of interest relevant to a manuscript. See International Committee of Medical Journal Editors, *Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals* (International Committee of Medical Journal Editors, 2016), online: International Committee of Medical Journal Editors <http://www.icmje.org/icmje-recommendations.pdf>. The more recently debated phenomenon of "ghost writing," where a physician or research expert is named as author even though the manuscript is written by another party (often industry employees), is also of concern. See e.g. PLoS Medicine Editors, "Ghostwriting: The Dirty Little Secret of Medical Publishing that Just Got Bigger" (2009) 6 PLoS Med 1; Tobenna D Anekwe, "Profits and Plagarism: The Case of Medical Ghostwriting" (2010) 24 Bioethics 267; Xavier Bosch, Bijan Esfandiari & Leemon McHenry, "Challenging Medical Ghostwriting in US Courts" (2012) 9 PLoS Med e1001163; Ben Almassi, "Medical Ghostwriting and Informed Consent" (2014) 28 Bioethics 491. See contra Serina Stretton, "Systematic Review on the Primary and Secondary Reporting of the Prevalence of Ghostwriting in the Medical Literature" (2014) 4 Brit Med J Open e004777.

[169] See e.g. Nelson, *supra* note 144.

influence them.[170] There is little justification for these things, and although the risk of direct influence is probably lower than for previous practices the risk is still present.

As will be addressed in the next subsection, the profession has in the past decade taken a different approach to physician-industry relationships that includes consideration of even the small things that might give rise to a conflict. For some relationships, disclosure is still viewed—reasonably—as the best way to minimize the risk of conflicts and to allow patients to make fully informed decisions. For others, there is still tension within medical societies as to the extent of appropriate self-regulation.

2. The Profession's Legal Order

The modern *Code of Medical Ethics* flatly prohibits many interactions, gifts and payments from the pharmaceutical and device industry. The current Opinion on gifts to physicians from industry was adopted in 2014, and recognizes the importance of the relationship between the profession and the pharmaceutical and biotechnology industry, which has the potential to greatly improve public health. It also cautions against relationships that "damage public trust and tarnish the reputation of both parties."[171] Unlike the initial CEJA Opinion on gifts, this one cites the risk represented by gifts "of subtly biasing—*or being perceived to bias*—professional judgment in the

[170] See e.g. Dana Katz, Arthur L Caplan & Jon F Merz, "All Gifts Large and Small: Toward an Understanding of the Ethics of Pharmaceutical Industry Gift Giving" (2003) 3 Am J Bioethics 39; Paul R Lichter, "Debunking Myths in Physician-Industry Conflicts of Interest (2008) 146 Am J Ophthal 159 at 163; Adriane Fugh-Berman & Shahram Ahari, "Following the Script: How Drug Reps Make Friends and Influence Doctors" (2007) 4 PLoS Med e150; David W McFadden, Elizabeth Calvario & Cynthia Graves, "The Devil is in the Details: The Pharmaceutical Industry's Use of Gifts to Physicians as Marketing Strategy" (2007) 140 J Surg Research 1 ("[s]ocial science research continues to show that the impulse to reciprocate from even a token gift can be powerful influence on behavior…" at 2).

[171] Council on Ethical and Judicial Affairs, "Opinion 9.6.2 – Gifts to Physicians from Industry", online: American Medical Association <https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-9.pdf> at 16 [CEJA, "Gifts to Physicians from Industry"]. Although "public trust" is an intangible good, it plays an important role in many ethics Opinions and in professionalism in general.

care of patients."[172] Accordingly, CEJA and the AMA prohibit all cash gifts as well as "gifts for which reciprocity is expected or implied."[173] However, and in line with the assertion that some relationships are beneficial, the Opinion permits some gifts of minimal value that directly benefit patients and some funding of medical trainees if certain criteria are met.[174]

Not long before this general Opinion on gifts to physicians from industry, CEJA focused its efforts on medical education. First introduced in 2008, CEJA proposed an ethics Opinion on financial relationships with medical industries in medical education, but substantial resistance within the AMA to this addition delayed its adoption by a few years. The initial proposed Opinion was very strict and applied to all types of medical education, recognizing that "industry support of professional education has raised concerns that threaten the integrity of medicine's educational function."[175] It went on to demand that "[i]ndividual physicians and institutions of medicine, such as medical schools, teaching hospitals, and professional organizations (including state and medical specialty societies) *must not accept industry funding* to support professional education activities."[176] The HOD declined to adopt this Opinion, despite an extensive report explaining the basis for such a restrictive policy. Many AMA members likely felt personally offended by the presumption that industry funding created a conflict of interest that was not otherwise avoidable.[177] In addition, industry funding of educational events was considered by many to be crucial to the

[172] *Ibid*. [emphasis added].
[173] *Ibid*. at 17.
[174] *Ibid*.
[175] Council on Ethical and Judicial Affairs, "Reports of the Council on Ethical and Judicial Affairs: 1 Industry Support of Professional Education in Medicine" in American Medical Association, *Proceedings of the American Medical Association House of Delegates, 157th Annual meeting, June 14-17, 2008* (Chicago: American Medical Association, 2008) 237 at 242 [CEJA, "Industry Support of Professional Education, 2008"].
[176] *Ibid*. [emphasis added].
[177] Stossel, a long-time critic of the profession's efforts to address many conflicts arising from industry-physician relationships, directly confronted the report, arguing that it "based [its] conclusions on an arbitrary, obsolete, and frankly untenable definition of professionalism." Thomas P Stossel, "Response to AMA's Council on Ethical and Judicial Affairs Draft Report on 'Ethical Guidance for Physicians and the Profession with Respect to Industry Support for Professional Education in Medicine'" (2008) 10 Medscape J Med 137.

provision of high-quality educational programs.[178] However, CEJA pointed out that some medical societies were able to provide educational programs without industry support, and while divesting the profession of industry funding might be difficult in the short term, there were no long-term barriers to proceeding without it.[179] It was not until the 2011 Annual Meeting of the HOD that the Opinion was adopted, three years and four reports after the first report was debated, and applicable *only* to continuing medical education (CME).[180] It specified that "[w]hen possible, CME should be provided without [pharmaceutical, biomedical or medical device company] support or the participation of individuals who have financial interests in the educational subject matter."[181] Still unknown is whether and to what extent the profession will adhere to this less restrictive guidance.

CEJA's 2008 industry funding of education report, while not adopted, made an important statement about the best solution to the risks of overt and subtle pharmaceutical and device manufacturer influence over medical education:

> [w]e are not convinced that attempting to manage industry influence in professional education is a prudent use of resources. Rather, avoiding the influence altogether is essential to ensuring the integrity of professional education. Avoiding influence-creating situations altogether is effective, simple, and does not place the burden of sustaining objectivity entirely on individual physicians.[182]

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[178] See Lichter, *supra* note 170 ("(b)ut members themselves are used to paying bargain rates or even nothing for much of their CME and other medical programs because of their own accustomed receipt of industry largesse. Thus it is natural for organizational leadership to approach industry for funding" at 164).
[179] CEJA, "Industry Support of Professional Education, 2008", *supra* note 175 at 240-241.
[180] See Council on Ethical and Judicial Affairs, "Reports of the Council on Ethical and Judicial Affairs: 1 Financial Relationships with Industry in Continuing Medical Education" in *Proceedings of the American Medical Association House of Delegates, 160th Annual Meeting, June 18-21, 2011* (Chicago: American Medical Association, 2011) at 197.
[181] *Ibid*. at 203.
[182] CEJA, "Industry Support of Professional Education, 2008", *supra* note 175 at 240.

This is applicable not just to medical education but to all industry-related conflicts of interest, including the provision of meals, small gifts, and other things that are intended to promote the manufacturer's message.

Industry-related conflicts of interest are possible in clinical care and medical education, but biomedical research also presents opportunity for practices and relationships that have the potential to displace physician priorities. Although biomedical research is not a major focus for the AMA, the *Code* contains a number of Opinions addressed directly to the ethical tensions inherent in research. One Opinion requires researchers to disclose financial ties to journals and medical centers where the research is taking place.[183] However, given the AMA's separation from the editorial processes of medical journals, even its own Journal of the American Medical Association, enforcement of ethical responsibilities of researchers and authors is generally left to the journals themselves.[184]

For clinical trials, the *Code* goes further and requires disclosure of financial conflicts of interests to participants. The same provision is not present in the general Opinion on biomedical research (Opinion 8.031), although this is the same Opinion that directs physicians to disclose to their institutions, funders and journals.[185] Another chapter in the *Code* addresses research more generally, and contains provisions requiring disclosure to participants of "whether investigators or subjects stand to gain financially from the research findings"[186] of research involving DNA databanks (Opinion 2.079) and potential financial gain for the researcher and potentially the

[183] CEJA, *Code of Medical Ethics*, *supra* note 13 at 216.
[184] The International Committee of Medical Journal Editors has developed forms for reporting conflicts of interest as part of the manuscript review process. International Committee of Medical Journal Editors, "Conflicts of Interest", online: International Committee of Medical Journal Editors <http://www.icmje.org/conflicts-of-interest/>.
[185] CEJA, *Code of Medical Ethics*, *supra* note 13 at 218.
[186] *Ibid*. at 45.

research subject in the research using human tissue (Opinion 2.08).[187] Finally, when it comes to referring patients to research studies, physicians' acceptance of payment for a referral ("finder's fee") has also been deemed unethical.[188]

The AMA and other medical societies[189] have addressed conflicts of interest involving the pharmaceutical and device industry in a variety of ways, depending on the type of conflict. The AMA has prohibited cash payments without legitimate purpose (e.g. speaker and consulting fees) and lavish travel and gifts, but gifts of "minimal value" and presumably inexpensive meals are still permitted.[190] In research especially, disclosure is generally viewed as the primary means to limit the potential risk represented by a conflict since many physician/researcher-industry relationships are unavoidable if research is to happen at all. However, the *Code* Opinions pertaining to research are inconsistent on when disclosure is ethically required, specifically calling for it for some types of research (clinical trials, commercial tissue use and DNA databanks) but not for all (the general Opinion on biomedical research).[191] Ethics norms tend to recognize that some conflicts are unavoidable within the current structure of our health care and research systems. They have more

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[187] *Ibid*. at 46.
[188] *Ibid*. at 195.
[189] See e.g. Singh et al, *supra* note 155; American Academy of Dermatology, "Position Statement on Physician/Industry Interaction", online: American Academy of Dermatology <https://www.aad.org/Forms/Policies/Uploads/PS/PS-Physician-Industry%20Interactions.pdf>; American Psychiatric Association, *Opinions of the Ethics Committee on the Principles of Medical Ethics, 2009 Edition* (Arlington: American Psychiatric Association, 2009); American Society of Clinical Oncology, "American Society of Clinical Oncology: Revised Conflict of Interest Policy" (2006) 24 J Clin Oncol 1; Society of Thoracic Surgeons, "Ethical Standards for Cardiothoracic Surgeons Relating to Industry", online: Society of Thoracic Surgeons <http://www.sts.org/about-sts/policies/ethical-standards-cardiothoracic-surgeons-relating-industry>. Societies might also have policies pertaining to society relations with industry. See e.g. American Academy of Dermatology, "Code for Interactions with Companies", online: American Academy of Dermatology <https://www.aad.org/forms/policies/uploads/ar/ar%20code%20for%20interactions%20with%20companies.pdf>; American Society of Clinical Oncology, "American Society of Clinical Oncology: Policy for Relationships with Companies" (2013) 31 J Clin Oncol 2043.
[190] CEJA, "Gifts to Physicians from Industry", *supra* note 171.
[191] CEJA, *Code of Medical Ethics*, *supra* note 13 at 45, 46, 216, 218.

recently expanded to more minor conflicts of interest, and it is likely that ethics restrictions will become more severe as support from within the profession—and external pressure—increases.

3. The State's Legal Order

The medical profession and the State view pharmaceutical and device industry conflicts of interest very differently in terms of how and who is regulated. There is very little State regulation aimed specifically at physician-industry relationships, and many interactions are subsumed by fraud and abuse statutes.[192] Some relationships are addressed in a comparatively minor way, and others fall within the boundaries of drug regulation to address what is primarily viewed as an industry problem rather than a physician problem.[193] Primarily, though, State interest in physician-industry relationships is their cost impact on State health care programs.

Much like what has happened within the medical profession, payments or the provision of gifts or food have received increased scrutiny by the State in recent years. As noted above in Subsection 1, Congress became interested in industry gift-giving practices when public disclosures made clear that physicians could be swayed by gifts and this in turn could increase costs for the federal government.[194] For those practices that fall outside the bounds of fraud and kickbacks and are therefore still *legal*, the State has taken additional steps to target conflicts resulting from industry

[192] Payments and gifts intended to influence prescription habits could be construed as bribes or kickbacks, and therefore fall within relevant federal and state laws for these classes of activity.
[193] See e.g. 21 CFR § 202.1 (2016). This regulation pertains to prescription drug advertisement.
[194] Never mind that federal legislators and presidential candidates regularly receive contributions from pharmaceutical and device manufacturers, amongst many other interests that fund our electoral excesses. The Center for Responsive Politics notes the increase in lobbying and political contribution efforts in the years prior to the passage of Medicare Part D, which does not permit the federal government to negotiate lower prices for pharmaceuticals. Center for Responsive Politics, "Influence and Lobbying: Pharmaceutical and Health Products", online: Center for Responsive Politics <https://www.opensecrets.org/industries/indus.php?ind=H04>; Juliette Cubanski & Tricia Neuman, "Searching for Savings in Medicare Drug Price Negotiations", online: Kaiser Family Foundation <http://kff.org/medicare/issue-brief/searching-for-savings-in-medicare-drug-price-negotiations/>; 42 USC § 1395w-111(i) (2016).

relationships with physicians that might not extinguish them, but potentially reduces the risk of improper influence.

A recent means to discourage conflicted relationships between physicians and industry was the creation of a database that contains information on things of value given to physicians by drug or device manufacturers. Designed to meet requirements set forth in the Patient Protection and Affordable Care Act,[195] the database sheds at least a little light on what had previously been a very opaque practice. This law, known as the Physician Payment Sunshine Act, requires manufacturers to report to the Department of Health and Human Services "any payment or other transfer of value" made to a "covered recipient", which is defined as either a physician or teaching hospital.[196] The information that must be provided is quite detailed, and includes the name and business address of the recipient, the amount of the payment or transfer of value, and descriptions of the form and nature of the payment or transfer of value.[197] Note that nothing in the statute *prohibits* payments or transfers of value, so long as they are not prohibited by other laws. This statute is just about *reporting* them.

The information is accessible through a website operated by the Centers for Medicare and Medicaid Services.[198] Searches can be performed for individual physicians, teaching hospitals or companies making the payment. For patients, it can be helpful to search for their physician to see if he or she has received anything of value from a pharmaceutical or device manufacturer. This can be something as small as the provision of food and beverages (possibly in return for listening to a presentation or receiving other information from a company) or as large as stock ownership

[195] *PPACA*, *supra* note 26 at § 6002.
[196] 42 USC §§ 1320a-7h(a)(1)(A) & (e)(6) (2015).
[197] 42 USC § 1320a-7h(a)(1)(A) (2015).
[198] Centers for Medicare and Medicaid Services, "Open Payments", online: Centers for Medicare and Medicaid Services <http://www.cms.gov/openpayments/>.

in a company. Disclosed payments also include speaker or presenter fees and payments for research performed by the physician, although many of the research payments are received by the hospitals supporting the research. Unfortunately, though, the search engine does not allow the public to search for specific types of payments.

This database is a good step towards ending at least some of the mystery surrounding physician-industry relationships. However, it is limited in that it only requires disclosure rather than prohibiting some practices that might influence physicians. As discussed previously, disclosure alone might not cure all actual or potential conflicts. In addition, a failure to disclose is subject to a monetary penalty,[199] but it is unclear how aggressive regulators will be in enforcing the statute. As well, "[i]t is also unclear how [reported data] will be understood by persons unfamiliar with the practice of medicine."[200] Some patients might view their physicians suspiciously even if there is no need, and other patients might not take seriously the consequence of a conflict if the physician is deeply involved with a manufacturer.

With the exercise of regulatory powers over drug and device manufacturers, the State has eliminated or at least curtailed to some extent many potentially harmful practices. Drugs must be tested and approved before being offered to the public, they must continue to be monitored following approval to ensure safety as a larger number of individuals are exposed to potential risks, and advertising and marketing must meet certain minimum requirements.[201] However, when it

[199] 42 USC § 1320a-7h(b) (2015).
[200] L Citrome, "Are You a Sunshine Superman? The US Sunshine Act and Reporting Requirements" (2014) 68 Intl J Clin Prac 1175 at 1176. Ratain raised a similar issue about "creating the illusion of a relationship between specific physicians and companies with whom they may not wish to be associated." Mark J Ratain, "Forecasting Unanticipated Consequences of 'The Sunshine Act': Mostly Cloudy" (2014) 32 J Clin Oncol 2293.
[201] See e.g. 21 CFR § 314.80 (2016) (post-marketing reporting of adverse drug experiences); US National Library of Medicine, "FAQ, Clinical Trial Phases: What are Clinical Trial Phases?", online: National Library of Medicine <http://www.nlm.nih.gov/services/ctphases.html> ("Phase IV: Studies are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-

comes to conflicts of interest arising from physician-industry relationships, the State has been much less involved. This might be due to its traditional role in regulating other aspects of the pharmaceutical and device industry (primarily drug and device safety) rather than its relations with physicians, since the profession and its various bodies like societies and medical schools typically dealt with—or attempted to deal with—conflicts. Yet the creation of a reporting database under the auspices of the Physician Payment Sunshine Act shows that the federal government is beginning to pay more attention certain conflicts than it had in the past, possibly an acknowledgement that these can harm State finances in the same way as other activities more closely related to fraud and kickback.[202]

III. Conflicts of Interest: The Limits of Self-Regulation and Ethics?

Financial conflicts of interest are a difficult area to regulate in medicine. Although resource limitations of the medical profession (and the State) play some role in the imperfect enforcement of the profession's legal order, the nature of conflicts set them apart from other aspects of medical ethics. They are less about the patient and his or her interest than the physician's interest, creating a tension in the patient-physician relationship distinct from the issues discussed in the previous Chapter and generally unlike other ethics topics in the AMA *Code* and other normative ethics documents.

Given the role that money plays in the basic functioning of our health care system, at one extreme it could be argued that all physicians who are paid for their work face an incentive to do more to

term use"); Patricia I Carter, "Federal Regulation of Pharmaceuticals in the United States and Canada" (1999) 21 Loyola LA Int'l & Comp LJ 215.

[202] One study found that more than $1.1 billion in payments were made to physicians in 2014 and reported to the database. Kavita Parikh, William Fleischman & Shantanu Agrawal, "Industry Relationships with Physicians: Findings from the Open Payments Sunshine Act" (2016) 137 Pediatrics e20154440.

earn more, even if it is not in the best interests of their patients. Despite the inherent risk that any form of payment could lead to biased decision making, reasonable people do not challenge the right to receive payment for service. If we cannot (and should not) deny outright the right for physicians to be paid for their services, the question then becomes what kind of payment or relationship is sufficiently problematic to prohibit or strictly control. To return to a very basic statement of ethical principle: secondary interests should not take precedent over primary interests.[203]

If we use this as the foundation of a general normative policy for conflicts of interest, it is likely that many relationships currently considered ethical would become unethical. Yet if we consider patient best interests in an expansive manner, some of these relationships can be justified on the grounds that they are required to do things that promote patients' well-being even if they risk an overbearing physician self-interest. Researcher-industry relationships such as funding clinical trials can be viewed from this perspective, as can the establishment of a physician-owned health facility if it serves an otherwise underserved population whose lack of access to health services creates a health risk. Thus, it is not just the relationship but its context and purpose that can help us determine how it should be regulated. We cannot deem all financial relationships that increases the risk of improper influence as unethical, although we can view them skeptically.

Some have questioned whether conflicts of interest should be regulated at all in absence of *demonstrable* harm to patients. Although the medical profession has determined that even the risk of a conflict influencing physicians' decisions is sufficient to at least create mechanisms to mitigate

[203] See e.g. CEJA, *Code of Medical Ethics*, *supra* note 13 ("VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount" at xvii).

some conflicts[204] and maintain the integrity of and confidence in professional judgment[205] it can be difficult to prove *actual harm* from a conflict. Proponents of some practices have targeted this as justification for a relaxation of conflicts regulation.[206]

This raises the question in ethics—and in State law as well—of what evidence is necessary prior to regulating a practice. The answer appears somewhat dependent on the practice at issue. For fee splitting and kickbacks, both now prohibited (for the most part), little empirical evidence has ever been presented but anecdotes and the clear connection between payment and referral was sufficient to presume the invalidity of these transactions. Conversely, some evidence has been adduced that self-referral practices tend to increase referrals for services that lead to greater financial benefit for the physician-investor.[207] However, these primarily show a correlation between the financial interest and increased referrals rather than a direct acknowledgement by physicians that they do indeed increase their referral volume to increase their investment returns.[208] The same can be said for many studies that purport to demonstrate the influence of pharmaceutical

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[204] Many of the AMA *Code*'s conflict provisions are not completely prohibitive, and set forth criteria for minimizing risks. See e.g. *ibid*. at 220 (physician self-referral); Council on Ethical and Judicial Affairs, "Opinion E-9.2.7, Financial Relationship With Industry in Continuing Medical Education", online: American Medical Association <https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-9.pdf> at 7; CEJA, "Gifts to Physicians from Industry", *supra* note 171.

[205] Thompson, *supra* note 1 at 573-574. Thompson notes that these are the basic purposes of conflicts rules.

[206] D Barton, T Stossel & L Stell, "After 20 Years, Industry Critics Bury Skeptics, Despite Empirical Vacuum" (2014) 68 Int J Clin Prac 666; Thomas P Stossel & Lance K Stell, "Time to 'Walk the Walk' About Industry Ties to Advance Health" (2011) 17 Nature Med 437 ("[i]nsinuations of corruption by those who call for increased oversight and regulation of the interaction between academia and industry require quantitative evidence—for a start, providing a denominator as well as a numerator" at 437).

[207] See e.g. United States Government Accounting Office, *Specialty Hospitals: Information on National Market Share, Physician Ownership, and Patients Served*, Report No GAO-03-683R (Washington, DC: US Government Accounting Office, 2003); Medicare Payment Advisory Commission, *Report to the Congress, 2005*, *supra* note 101; Medicare Payment Advisory Commission, *Report to the Congress: Physician-Owned Specialty Hospitals Revisited* (Washington, DC: Medicare Payment Advisory Commission, 2006); Institute of Medicine, *supra* note 2 at 169-170.

[208] See e.g. Robertson, Rose & Kesselheim, *supra* note 73. See also Steven D Wales, "The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals" (2003) 27 L & Psych Rev 1 ("[s]ome [commentators] said, for example, that the numbers 'do not necessarily lead to the conclusion that physicians with ownership interests in facilities overutilize those facilities'" at 6).

ties on physicians' prescribing decisions.[209] For both self-referral and pharmaceutical industry relationships, though, the lack of clear evidence of causation has led to tentativeness in taking stronger regulatory positions.[210]

Yet the basic definition of conflict of interest—a relationship that risks the physician placing secondary interests before primary interests—*does not require that the individual physician actually act on the conflict.* "In simple terms, a COI exists if a reasonable observer finds it plausible that the average person *could be* (not necessarily would be) swayed by secondary interests."[211] This interpretation of conflicts of interest points to an inconsistency with professional norms that reflect a belief that there must be evidence that harm will occur prior to regulating an activity or relationship.

Important considerations, then, are the need for the relationship and the likelihood of the relationship creating a risk of influence. Fee splitting was deemed unethical and eventually illegal in part because there was no legitimate purpose served by the practice other than to enrich the physician making the referral. Examining some of the conflicts of interest surveyed in this Chapter, they do create a risk of influence over physicians' decisions, and do not always have a legitimate purpose. Most obvious are the small gifts from pharmaceutical and device manufacturers, including meals. Other than reminding physicians about the existence of a drug, notepads and pens do not advance medical care or the patient-physician relationship, however convenient they might be. This might seem nit-picky, but there are indications that these types of

[209] See e.g. Rosenbaum, *supra* note 5.
[210] I should note here that requiring clear evidence before regulating a practice is a higher standard than required for much of State law regulation of health care, as the previous Chapter's discussion of "partial-birth" abortion indicates.
[211] Schofferman & Banja, *supra* note 155 at 494.

gifts (trinkets) promote a subconscious bias in favor of prescribing the medication.[212] They also might cause patients to ask about the medication, especially if the patient has seen direct-to-consumer advertising on the same product. Some medical societies, such as the American Medical Student Association, are uncomfortable enough with these types of gifts to prohibit them in their own policies.[213]

Another example is physician self-referral. There are some investment interests that advance both the availability and quality of health care, and this was the purpose of excepting certain self-referral investments from the general prohibitions in federal and state law. The growth of physician-owned health facilities and equipment, though, has far exceeded the purpose of this exception. Their existence alongside non-physician-owned entities gives doubt to their purpose and value, and amplifies the corrupting effect of the conflict on referral decisions and volume of care.[214] Advocates of physician ownership continue to espouse their benefits and resist restrictive State regulation, but have not defended very well the *need* for these relationships when the services are duplicative and there might be other ways to improve quality within existing frameworks without creating conflicted relationships.[215]

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[212] See e.g Katz, Caplan & Merz, *supra* note 170; Lichter, *supra* note 170 ("(i)f a company makes what seems to a charitable contribution, it is done with business intent" at 163); Fugh-Berman & Ahari, *supra* note 170 ("[g]ifts create both expectation and obligation" at e150); McFadden, Calvario & Graves, *supra* note 170 ("[s]ocial science research continues to show that the impulse to reciprocate from even a token gift can be powerful influence on behavior…" at 2). See *contra* Nelson, *supra* note 144 ("…I must admit a certain love of gimmicks. I am grateful for the countless free pens, pads, keyrings, and other gadgets I've acquired from pharmaceutical companies over the years. Perhaps they believe regular reminders of a certain product may facilitate my using it, but I honestly do not believe even one of these pens influenced my prescribing habits" at 144).

[213] American Medical Student Association, *2015 AMSA Preamble, Purposes and Principles*, online: American Medical Students Association <www.amsa.org/about/constitution-bylaws/> (the Association "opposes the use of promotional gimmicks and inappropriate gifts serving no educational or informational purpose to influence medical students and physicians…" at 40).

[214] See e.g. Green, *supra* note 66; Gawande, *supra* note 104; Pham et al, *supra* note 85.

[215] Weinberg, *supra* note 89; Herzlinger, *supra* note 92.

In reality, aside from enforcement problems the primary shortcoming of professional self-regulation of conflicts of interest is that the profession is often very liberal with what it tolerates when there is no legitimate need. It is understandable that many in the profession feel that the direction of health care (and health care reimbursement) requires relationships that are undoubtedly conflicts of interest. However, this does not justify policy positions that continue to tolerate relationships that are recognized to be conflicted when placed within an ethics framework that requires physicians to make self-interest secondary.

The State, while not a perfect regulator of the medical profession, has led regulatory efforts against conflicts of interest in many relationships. It has used bribery and kickback laws to prosecute fee splitting and some physician-industry relationships that fit those criteria. It enacted the federal Stark Law (and many state-level laws) to prohibit most self-referral arrangements well before the medical profession established official guidance. However, it is also susceptible to influence from the medical profession, or at least segments of it. For example, Physician Hospitals of America has lobbied against stricter Stark limitations.[216] Yet the State's efforts in many areas led to a strengthening of the AMA's ethics, especially with regards to self-referral.

What this Chapter shows is that medical ethics does not always equate with a well-functioning legal order, internally consistent in its norms and applications. The medical profession has expertise in medical knowledge, research and the provision of health care, but conflicts of interest do not fit squarely within these categories even though they might exist as part of the practice of medicine. The profession *should* be able to identify conflicts, but has confirmed the need for

[216] Physician Hospitals of America, "Support HR 2513", *supra* note 138; R Blake Curd, *supra* note 138.

support from outside of the social field to ensure that conflicts are minimized and when necessary continue to be secondary to patients' interests.

The profession's expertise in clinical matters and the State's experience in financial and criminal matters creates the potential for cooperation. Neither semi-autonomous social field has the capability to fully regulate conflicts of interest without the input and support of the other. Yet there has not been a conscious recognition that conflicts regulation requires that they work together, and indeed they often work in opposition especially when the profession believes the State has overregulated or the State believes that physicians are engaging in fraudulent behavior that is not sufficient addressed by the profession.

Conflicts of interest represent a different kind of ethical issue than other matters. They demonstrate why semi-autonomy in regulation can be beneficial, providing the opportunity to transfer norms between the medical profession and State when needed to better reflect the ethical obligations of physicians to place patients' interests before their own. The direction of conflicts regulation by the profession indicates that this will continue to be the case, but a substantial barrier remains the profession's ability to recognize conflicted relationships and when they are unnecessary.

CHAPTER 8: LEGAL PLURALISM – A FRAMEWORK FOR THE PAST AND FUTURE OF NORMATIVE ETHICS AND THE PROFESSION-STATE RELATIONSHIP

I. LEGAL PLURALISM AND MEDICAL ETHICS..... 321

II. THE NATURE OF HEALTH CARE AND MEDICAL ETHICS: NECESSITATING COLLABORATION..... 325

A. Introduction 325

B. External Impacts of Medical Ethics..... 326

C. The Economic and Social Uniqueness of Health Care..... 328

III. LEGAL PLURALISM: IMPERFECT, BUT A BETTER WAY..... 330

A. Imperfect 330

B. A Better Way 332

IV. ETHICS AS CRUCIAL LAW FOR THE MEDICAL PROFESSION..... 338

> There is a general utility in looking at legal rules in terms of the semi-autonomous social fields on which they impinge. It tempers any tendency to exaggerate the potential effectiveness of legislation as an instrument of social engineering, while demonstrating when and how and through what processes it actually is effective. It provides a framework within which to examine the way rules that are potentially enforceable by the state fit with the rules and patterns that are propelled by other processes and forces.[1]

I. Legal Pluralism and Medical Ethics

In this Thesis I look for a different way to view the relationship between the medical profession and the State and the normative place and potential of medical ethics, using legal pluralism as the lens.[2] I use this theory rather than traditional explanations of the medical profession and ethics, such as professionalism, because it does not restrict the sourcing of authority and law to the State, and it better reflects the historical development of the profession and the role that ethics has and continues to play as the primary means of self-regulation from the mid-19th century onward.

Medical ethics is congruent with legal pluralism's legal orders: a set of laws, rules or norms, and means of coercion and enforcement. The medical profession is congruent with pluralism's semi-autonomous social fields, exhibiting substantial autonomy but remaining bound to the State for much of its regulation, and even to other semi-autonomous social fields with which the profession and physicians must interact as part of their work. With these interpretations of medical ethics and the medical profession, legal pluralism can be a foundation for describing the reality of the internal and external relationships of the semi-autonomous social field.

A more typical conception of the relationship between physicians and the State is the theory of professionalism. In this notion of the profession and what it means to be a professional there is something like semi-autonomy, similar to legal pluralism, but it is dependent on State acquiescence

[1] Sally Falk Moore, "Law and Social Change: The Semi-Autonomous Social Field as an Appropriate Subject of Study" (1973) 7 L & Soc'y Rev 719 at 742.
[2] See *ibid*.; John Griffiths, "What is Legal Pluralism?" (1986) 24 J Legal Pluralism 1.

and subject to State intervention. While the profession and pretty much everyone else (including the State) seem to accept this accounting of professional authority, it is incredibly restrictive in the expansiveness of its gifts to the State and the totality of its subjugation of the medical profession.

Conversely, with legal pluralism the limitations on the autonomy of social fields (their "semi-autonomy") stems from their interactions with other social fields but is not dependent on these social fields, leaving internal independence mostly intact and not expressly subjugating any one group to any other. Social fields might adopt or amend their own norms based on the world around them, but this does not deny their own inherent authority to create those norms in the first place, giving them more space to develop law.

The use of legal pluralism in this Thesis does not lead to a perfect, all-encompassing explanation for how the medical profession and the State relate to each other. Neither the profession nor the State explicitly view medical ethics as a legal order, or as anything akin to State law. However, the difficulty here is not with finding elements of law in medical ethics, but determining how "normative" ethics is and can be in an environment that places so much emphasis on external regulation by the State. Legal pluralism provides a way to characterize and analyze actions and relationships outside of the traditional and restrictive conceptions of how the profession and State are "supposed" to interact.

For medical ethics, it can *look* like a legal order, but how it *performs* is determined by context and the reality of medical practice. As Chapter 4 emphasized, the content of ethics codes and institutional structures created for their design and implementation shows a conscious decision to place ethics in the realm of rules for behavior. That many medical societies have mechanisms to enforce ethics against member violations further strengthens the notion of ethics as a legal order

for physicians and separate from any regulation that the State implements. The profession has established a remarkably complex network of policy-making and discipline, with quasi-legislative, -executive and -judicial bodies operating like parallel State institutions.

Ethics is *intended* to be a normative system, as its content, structure and accompanying institutions all attest to. However, this recital of objective factors representative of a semi-autonomous social field and legal order does not necessarily indicate or predict how medical ethics performs as a set of rules, nor does it address the challenges to ethics' existence as a legal order stemming from the medical profession's relationship with the State. Assigning the labels "semi-autonomous" and "legal order" must be accompanied by discourse of the realities of the social field. Beyond the four corners of ethics and governance documents, medical ethics is challenged by external forces, primarily the State, as well as internal forces that raise questions of its efficacy as a legal order and its independence from State diktat.

The State often regulates in parallel to or in conflict with semi-autonomous social fields, something unavoidable even within a framework of legal pluralism.[3] Conflicting regulation, though, can create dissonance for members of a semi-autonomous social field, who must determine which norm or law they are obliged to follow. Chapter 6 points to instances when State and professional regulation are in such serious conflict that the profession's self-regulatory effectiveness is curtailed or even negated. For each of the issues discussed in the Chapter, the State had the opportunity to weigh the concepts of medical ethics against whatever the purpose of the State regulation and with limited exception came down on the side of State interests, even if inimical to medical ethics and

[3] The theory in legal pluralism is not that the State does not regulate a semi-autonomous social field at all, but that the social field regulates in spite of State regulation, which might or might not agree or conflict with the legal order of the social field. See e.g. *ibid*.; Moore, *supra* note 1; Shaun Larcom, "Problematic Legal Pluralism: Causes and Some Potential 'Cures'" (2014) 46 J Legal Pluralism 193.

the State's own obligations towards patients and the public health. Although the US Supreme Court at one time recognized an important purpose of State regulation of medicine—that it can protect "the integrity and ethics of the medical profession"[4]—subsequent State action demonstrated the limits of this interest, or maybe the consequences of political self-interest.

The strain on the medical profession's legal order of ethics, far from being caused solely by the State, has roots in professional action and inaction as well. Chapter 7 addresses an important problem for medical ethics: conflicts of interest that raise the prospect of care being based on factors other than patient needs. Some of these conflicts are squarely within the control of the profession, physician groups or individual physicians, and these are the conflicts that dilute the efficacy of ethics as a legal order. As McCullough put it, "physicians should commit themselves to the protection and promotion of the health-related interests of the sick as their primary concern and motivation, and keep self-interest systematically secondary."[5] In the vacuum of effective professional regulation of conflicts the State interceded and enacted its own, creating a template that the profession has since been forced to emulate and, only very recently, to strengthen.

As Tamanaha argued "[l]aw is whatever people identify and treat through their social practices as 'law'."[6] If the carrots and sticks of the State cause physicians to conform their behavior to State law rather than the profession's, or if the profession's law is not perceived to have legitimacy for some types of regulation (e.g. conflicts of interest), more and more of the profession's legal order could chip away.

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[4] *Washington v Glucksberg*, 521 US 702 at 731 (1997).
[5] Laurence B McCullough, "The Ethical Concept of Medicine as a Profession: Its Origins in Modern Medical Ethics and Implications for Physicians" in Nuala Kenny & Wayne Shelton, eds, *Lost Virtue: Advances in Bioethics*, vol 10 (Bingley, UK: Emerald Group Publishing, 2006) at 23.
[6] Brian Z Tamanaha, "A Non-Essentialist Version of Legal Pluralism" (2000) 27 JL & Soc'y 296 at 313.

The difference between medical ethics as a legal order on paper and its existence in the everyday practice of medicine lays in how it is treated by both the medical profession and the State. If physicians adhere to ethics, participate in its continuing development, and promote it as a legal order (even if they do not use this specific terminology), ethics can retain its normative power. This does not mean that ethics alone serves to guide physician behavior. There is good reason for skepticism about complete autonomy, at the least because of the profession's questionable ability to regulate all areas of medical practice—particularly conflicts of interest—but also because of the broad reach of medical ethics as a legal order and the nature of health care as a massive system made up of many different interested parties and semi-autonomous social fields. Medical ethics can be a "law" for physicians, but it is not the only law.

Section II places medical ethics and the medical profession in context: health care is a unique enterprise, requiring a different and more complex regulation than many other fields of regulation. Section III suggests conceptual flaws with medical ethics as a legal order, but also ways in which the authority of ethics and the medical profession can be improved and why it should be, and at the same time enhancing relations between the profession and State.

II. The Nature of Health Care and Medical Ethics: Necessitating Collaboration

A. Introduction

The previous Section highlighted the difficulty of reconciling the medical profession's legal order as established in documents and by enforcement mechanisms with the reality of medical practice, the extensive regulation of physicians and health care by the State, and the shortcomings of self-regulation. Medical ethics as a normative system, though, is not a matter of black and white, where either the profession retains the authority to determine behavioral standards or it does not. Rather,

the characteristics of medical practice, medical ethics, and the health care system place the profession and medical ethics in an unusual position for a social field and legal order. There are two facets to the reality of the legal order of medical ethics that I will explore in this subsection: (1) the nature of medical ethics that denies it an isolation from other social fields; and (2) the nature of health care that increases the complexities faced by the profession and its relationships with the State and other semi-autonomous social fields.

B. External Impacts of Medical Ethics

Medical ethics and the medical profession present an unusual and challenging case of legal pluralism for illuminating the relationship between the profession and the State. Many legal pluralism analyses focus on groups who formulate a legal order directed at members, which might tangentially impact outsiders.[7] Medical ethics applies to physicians as members of the semi-autonomous social field, but many ethics rules directly target their relationships with patients and others external to the social field. While patients, insurers, health facilities and the State are all drawn into the legal order, they have little or no direct input into its content.

The social fields explored by Moore in her seminal work on legal pluralism demonstrate the distinction between largely self-contained legal orders and those that are not.[8] She examined the garment industry in New York City, and the Chagga people in Africa. Although the legal orders of each of these semi-autonomous social fields co-existed and at times conflicted with the rules of the State, the legal orders found their own authority and controlled behavior in limited

[7] The current emphasis in legal pluralism on *global* legal pluralism raises similar questions about aspects of legal orders that are directed at influencing other social fields and legal orders. See e.g. Paul Schiff Berman, "Global Legal Pluralism" (2007) 80 S Cal L Rev 1155.
[8] Moore, *supra* note 1.

circumstances to the exclusion of State law. These legal orders might nominally impact outsiders,[9] but the rules were directed to and consequential primarily for members of the social field.[10] Sanctions imposed by the social field were sufficiently severe to cause individuals and organizations to choose the legal order of their social field rather than recourse to the State's.

The way in which medical ethics works primarily to promote certain behavior towards those outside of the semi-autonomous social field (patients especially) sets the medical profession and ethics apart from Moore's examples. A determination that an action is "ethical" can affect the care a patient receives, as can the alternative that it is "unethical." To revive the example of conflicts of interest, the long-time loose regulation of self-referral by the profession means that patients may have been subject to physician decisions and recommendations based on less than their best interests. For end-of-life issues, the profession deems it ethical to remove or terminate life-sustaining treatment,[11] while it finds unethical (for the most part) active assistance in the ending of a patient's life, even if medical judgment is that the patient's death is inevitable. Thus, a distinction in *how* a patient's life ends is the line between ethical and unethical.

That medical ethics directly affects insiders *and* outsiders to the semi-autonomous social field confirms the need for (some) State regulation of this legal order. If ethics norms permit or require something that is detrimental to patient health and safety, the limitation on the profession's autonomy can be justified as corrective action: State regulation of conflicts of interest, for example, can be understood as a reaction to ethical shortcomings. Normative proclamations that impact

[9] For the garment industry, purchasers of the goods might be the most likely impacted by the legal order, and for the Chagga people anyone from outside the community seeking to purchase real property would be faced with the social field's legal order.
[10] Moore, *supra* note 1 at 724-729, 740.
[11] Council on Ethical and Judicial Affairs, *Code of Medical Ethics: Current Opinions with Annotations, 2010-2011* (Chicago: American Medical Association, 2010) at 88.

health resources or finances are likewise subject to State response because they can drive costs and health care use outside of the semi-autonomous social field. However, the State's regulation of physicians and health care should still rely on medical science, unless evidence dictates otherwise, for it to be a legitimate expression of the State's responsibility to promote patient safety and public health and its own financial well-being. A State determination that something is *not* ethical or that a specific practice should be prohibited or required when a valid interpretation of medical ethics says otherwise (e.g. "partial-birth abortion," mandatory pre-abortion ultrasounds) can negatively impact patients' health just as professional decisions can. This conjoining of professional and State actions is indicative of the complexities of medical ethics as a legal order.

Medical ethics attempts to control physician-physician, patient-physician, industry-physician, and State-physician relationships, to name a few. In the modern health care system, these external relationships are critical to the patient-physician relationship that is at the core of a legal order rooted in medical ethics. The extension of ethics outside of the semi-autonomous social field complicates whatever "semi-autonomy" the medical profession wishes to exercise, raising questions about the amount of control that the profession really exerts over the comportment of members in light of its relative lack of control over the actions of those outside the social field. It also asks whether State interaction and regulation of the profession and health care can serve to direct relationships between the profession and outsiders in a way that furthers ethical obligations.

C. The Economic and Social Uniqueness of Health Care

In the US, we try very hard to define health care as a marketable good, subject to the same economics of supply and demand as other marketable goods and services. However, this fails to account for the many unique characteristics of health care that sets it apart from other goods and services, both making its value difficult to measure and subjecting it to manipulation. If health

care is indeed a collection of marketable goods and services, it is provided within an opaque structure, even to those who work within the system. Information asymmetry is common, and the regular presence of life or death, or at least sick or healthy, circumstances make the purchasers of health services less able to negotiate or seek cheaper but still effective providers and services. Health care providers—health care professionals as well as health care facilities—retain leverage over patients and potential patients that is uncommon in other markets.

Information asymmetry stems from the highly technical nature of medicine. Its providers undergo years of training, with physicians exceeding 8 years for medical school, residency and fellowships. There are few accessible and objective ways to differentiate between the quality of care provided by different providers and institutions. Insurance limitations or limited availability of care in the patient's geographic area reduce patients' ability to seek other sources of care. Medical ethics serves to dampen the effects of information asymmetry and patient vulnerability by placing constraints on physician behaviors that could be used to take advantage of their superior knowledge.

State regulation of physicians, beginning with licensing laws, seeks to satisfy the same ends. Licensing ensures a minimum level of medical knowledge and technical training. Laws designed to limit the effects of conflicts of interest reduce physical risks to patients and financial risks to the State. Regulation of health care facilities (including statutes such as the Emergency Medical Treatment and Active Labor Act,[12] discussed in Chapter 5) and the incorporation of medical malpractice into tort law provide a basic guarantee that those who intentionally or unintentionally cause harm to patients are subject to civil and criminal penalty.

[12] 42 USC § 1395dd (2017).

The fluidity of medical technology, health and disease create economic circumstances uncommon in other types of markets. Few other products or services relate so closely to life and death, and the social perceptions of health care and medicine are important drivers of usage and therefore costs. These characteristics call for close regulation by the medical profession through its ethics, but also by the State to limit the negative effects of inadequate professional self-regulation and to address those market flaws outside of the profession's control. As will be discussed in the next Section, though, there are intransigencies in the profession-State relationship that have created barriers to sufficient and efficient cooperation between the profession and State.

III. Legal Pluralism: Imperfect, But a Better Way

A. Imperfect

As I have argued throughout this Thesis, legal pluralism provides a novel way of conceiving the relationship between the medical profession and its legal order of medical ethics, and the State and its law. It teaches that our normally constrained view of law should be much broader, and that we should accordingly consider the role of semi-autonomous social fields and the ways in which they might develop their own legal orders—in isolation but also through interaction with other social fields. This interpretation of what law is and how it is created and organized fits well with the medical profession's past. However, the profession's present has fallen out of this framework in part due to the State's growing regulation of physicians and health care and the atrophy of ethics in some instances as an authoritative body of norms.

The normativity of medical ethics, generally accepted by the profession, has been constrained by conflicting State action. Conflicting legal orders are not unusual in legal pluralism, but the way in which the profession and physicians have responded to differences between professional and State

law has contributed to the limitations now faced by the profession when adopting and enforcing ethics standards. I have stressed that it takes an appreciation by the social field that its legal order is authoritative for it to be so (a primary difference from professionalism), and it is clear from medical society pronouncements and actions that they view the normative value of ethics in some cases as secondary to the command authority of the State. The imperfection of using legal pluralism to explore the modern relationship between the medical profession and the State and the source and implementation of professional semi-autonomy is that the medical profession has, when distinguishing between professional and State law, refused to cooperate with this conception.

A challenge for the medical profession and for individual physicians as well is how to resolve conflicts between deeply held ethical beliefs and norms, and what are often politically-driven State policies. This is especially problematic when the State shows little sign of being willing to compromise, accepting ethics as anything other than sporadically useful, or even meeting its own obligations to protect patients and promote public health in a legitimate manner. I say *legitimate* here because although the State proclaims a legitimate purpose for legislating such areas as abortion, gun safety discussions and lethal injection, the legislation that it enacts can have little connection with accepted medical practices or ethics.

Although the medical profession does not need acquiescence to its legal order by the State—the "weak" legal pluralism contested by Griffiths[13]—the role undertaken by the State to regulate physicians and health care requires some kind of approval by or regulatory space from the State in order for ethics to remain a vibrant exposition of physician obligations apart from State law. The State's seemingly endless search for regulatory dominance ignores the critical limits of (1) its

[13] Griffiths, *supra* note 2 at 5.

expertise and (2) the reach of the universally applicable legal order that is State law. For the profession's part, its desire for a more complete independence, harkening back to the golden age of medicine,[14] is not realistic in the modern health care system: there are valid reasons for a more limited self-regulation than what the profession appears to endorse in many circumstances. What is needed is a balance between an enhanced self-regulation of those things that the profession is particularly qualified to understand and regulate, and a ceding or sharing of regulatory authority for those things that physicians and the profession are not especially qualified or capable of effectively regulating.

The self-regulation envisioned by legal pluralism incorporates the notion that norms will be shared across legal orders, and that some regulation sourced in other social fields represents a limitation on the self-regulation of any social field. In sum, no social field is an island,[15] and it is crucial for the effective expression of its legal order that the profession recognize the limits of its autonomy, and the State the limits of its authority.

B. A Better Way

If the current relationship between the medical profession and the State is an imperfect reflection of the concepts of legal pluralism, how might this relationship be altered to better express the legal order of medical ethics, which both parties have reason to support? There are now occurrences of close collaboration, extreme hostility, and regulation by the profession in isolation, but as a general matter the State has come to view ethics as convenient in some circumstances and as an obstacle to its own goals in others. This is not a sustainable relationship, as each time the State openly

[14] See e.g. John C Burnham, "American Medicine's Golden Age: What Happened to It?" (1982) 215 Science 1474.
[15] The first two lines of John Donne's poem are appropriate here: "No man is an island entire to itself; every man is a piece of the continent, part of the main…." John Donne, "Meditation XVII: Devotions upon Emergent Occasions, 'No Man is an Island'", online: Dalhousie University <https://web.cs.dal.ca/~johnston/poetry/island.html>.

maligns medical ethics the less authority ethics has within the profession and the easier it becomes for the State to extend its opposing norms to other areas of medicine and ethics. After all, legislation and court decisions create precedent for future action, and in health care and ethics we have already seen reasoning for a physician-assisted suicide ban (protecting the integrity and ethics of the medical profession) extended to abortion and gun safety discussions, two completely different contexts with different ethical imperatives.

To start with an obvious point: the State is not *required* to incorporate ethics norms into its own legal order. There are times when medical ethics are at odds with other legitimate State interests and the State must balance them, sometimes at the expense of medical ethical values. However, a more consistent contemplation of the *ethical* implications of State actions—rather than primarily the political—can also serve to satisfy State interests and obligations in a consistent and meaningful way, especially for patient and public health. Regulating in opposition to medical ethics when those ethics serve the same interests that the State is *supposed* to serve benefits neither the medical profession nor the State in the long term.

Moving to a less obvious point in the current state of affairs: the medical profession is not *required* to incorporate State norms into its legal order. At times, it seems like both the profession and the State expect that State law, with few exceptions, will be reflected in professional law, but it is not imperative. Ethics norms remain in place that directly challenge the law of many states, for example the continuing prohibition on physician participation in lethal injection execution, which is contravened by states that permit physician involvement or require it for executions to proceed. In these instances, the question is whether the profession will enforce its norms. There is evidence too that for some issues, conflicts of interest for example, the State has taken the regulatory lead,

with the profession slowly following suit. While State law is not *required* to be accepted by the profession, sometimes it is advisable.

In a weak nod to weak legal pluralism, what is most needed in the current environment is a very basic recognition by State institutions that medical ethics has value, not only within the profession but also for patients and the State: ethics can serve to check the worst instincts of physicians *and* State regulators. The State is not required to adopt or even acknowledge medical ethics norms, but the unique nature of the relationship between the profession and the State calls for positive action by the State not typically envisioned by a legal pluralist.

An especially large barrier to the State's acceptance of normativity in medical ethics is the substantial divergence in perception of the inherent authority of State law compared to medical ethics. The placement of medical ethics as the province of physicians and not necessarily the State—as well as the belief that the State is the primary regulator of physicians—has an obvious resolution: a more widespread incorporation of ethics into the State legal order.

Some states do this by naming the AMA *Code* or a national or other ethics guidance document in their licensing statutes. This method does not guarantee that regulators (legislators especially, but the judiciary as well) will apply or consider ethics norms when developing or adjudicating contrary policy, but it provides a concrete basis for a legal argument in *State* courts or legislatures or before administrative bodies that medical ethics is a part of the State's legal order, even though the content of ethics is developed by professional bodies.[16]

[16] This would directly address the court's argument in *Zitrin* that the AMA does not set ethics policy for the state, as well as provide more clarification of what constitutes "unprofessional" or "unethical" conduct, the vague phrases often used in medical licensing statutes. *Zitrin v Georgia Composite State Board of Medical Examiners*, 2005CV103905 (Fulton County Superior Ct 31 July 2005).

An alternative to wholesale adoption of the *Code* or other professional ethics normative documents into State law (incorporation by reference) is the transfer of specific norms or policies from ethics documents as need arises. Many provisions in licensing statutes already reflect the ethical obligations of physicians even if unintentionally. For example, states prohibit sexual relationships between patients and physicians, prescribing medication or treatment without medical need, and breaching confidentiality.[17] However, for the most part the provisions of ethics documents like the *Code* are much more detailed maps for physician behavior than what states provide. There is good reason for states not issuing guidance with similar detail as the profession, but there are also instances when this detail could reinforce established professional norms. If a physician violates an ethics norm that is part of the profession's legal order but not clearly the State's, there is less chance of penalty from the State—and therefore less incentive for compliance and a strong legal order based in medical ethics. In addition, acceptance of medical expertise when shaping these laws and regulations can keep the State's legal order up-to-date.

If legislatures do not want to enact specific ethics norms into State law, they can still promote the ability of state medical licensing boards to do so and also support the decisions of these boards: while legislatures contain a smattering of elected experts on medicine or medical ethics, medical boards have this knowledge built in. A basic acceptance of the authority and utility of medical ethics in general statutes combined with this extension of power to medical boards could provide grounds to defend medical board actions.[18] The punitive powers of medical boards far exceed

[17] See e.g. Ark Stat § 17-95-409(a)(2)(N) (2017); Fla Stat § 458.329, 458.331(1)(j), (q) (2017).

[18] However, there is still the possibility that the State will overrule a decision of a medical board even if a policy or rule is adopted within its authority. See *North Carolina Department of Corrections v North Carolina Medical Board*, 675 SE 2d 641 (NC Sup Ct 2009). North Carolina law permits the Medical Board to consider unprofessional conduct, including the "departure from, or the failure to conform to, the standards of acceptable and prevailing medical practice, or the ethics of the medical profession…." NC Gen Stat § 90-14(a)(6) (2017). Interestingly, this statute was not modified even though the state has removed participation in lethal injection from the definition of medical practice and the ethical prohibition against physician participation remains. NC Gen Stat § 15-188.1 (2014).

those of medical societies and favors this authority as well, giving additional incentive for physicians to comply with their ethical obligations. The ability of medical boards to generate policy using their expertise, if generally permitted under state laws, can both better reflect the ethical ideals of medicine and provide a flexibility not offered by legislative enactments alone, as regulations can be easier to change than state or federal statutes.

Even without the specific adoption of ethics norms by the State or medical boards, the profession can continue to promote ethics through lobbying efforts and by resistance to State law that it believes contravenes ethics, and which does so without good cause. Since medical ethics are the *profession's* legal order and not directly the State's, the profession must take some responsibility to further the legal order in the face of State intransigence. This might consist of more strongly advocating for State legislation that allows for the ethical considerations of the profession; state and medical specialty societies becoming more active in promulgating and disseminating ethics standards;[19] and more unified resistance to State law that asks physicians to violate ethics norms.[20]

Further, the profession can do more to ensure that medical ethics becomes an integral part of medical education. While the vast majority of medical education is rightly focused on the technical and scientific aspects of medical practice and the knowledge requisite for treating patients, it is important to include a professionalism component to medical training to promote the humanistic nature of medicine and to reinforce the foundations of self-regulation. Medical students generally receive basic ethics training; however, once this is taught, what happens during residency and

[19] As discussed in Chapter 4, many specialty societies, even large ones, have scant mention of ethics in their own policies. At times, referring to or adopting the AMA's *Code* is sufficient, but developing ethics norms specifically for the society's members or specialty can address issues that the *Code* does not.

[20] Typically, the AMA and one or a few affected specialty societies or state medical societies might act as litigants or *amicus* in court cases, while other societies look on. A more widespread resistance to ethically dubious State policies could have higher impact.

medical practice, where continuing medical education (CME) becomes the primary source of new or reaffirming information? Most CME is geared towards changes in medical knowledge, new techniques, developments in pharmaceuticals and similar topics, and ethics are not a large part of the curricula, if included at all.[21] If ethics are to remain an authoritative set of norms, its importance must be reiterated even for physicians who have been practicing for years. Although the basic ethical foundations of medicine change only slowly, new technologies or medical practices arise often enough that there is a need to regularly update physicians' understanding of how ethics impacts their work.

The medical profession must accept responsibility not only for the advancement of its legal order and the transfer of appropriate norms to the State, but also for the appropriation of State norms into its own legal order where reflective of basic ethical principles. As discussed in Chapter 7 and earlier in this Chapter, not all ethical assertions made by the profession comply with basic ethical principles and, especially where money is involved, physicians and the profession have often been forced to play catch-up with State-initiated regulation. The Stark Law[22] and other conflicts of interest regulation has tended to pave the way for eventual professional norms where either there were none or what norms there were represented a weaker regulation than the State's offering. The translation of State norms into professional norms has served an important purpose: to fill in gaps or strengthen medical ethics.

[21] The Accreditation Council for Continuing Medical Education (ACCME) is the primary accreditation body for CME, but there is no explicit requirement that CME programs contain an ethics component. Accreditation Council for Continuing Medical Education, *The Accreditation Requirements and Descriptions of the Accreditation Council for Continuing Medical Education* (Chicago: Accreditation Council for Continuing Medical Education, 2016), online: Accreditation Council for Continuing Medical Education <http://www.accme.org/sites/default/files/626_20160929_Accreditation_Requirements_Document_1.pdf>.
[22] 42 USC § 1395nn (2017).

The tensions in the current relationship between the medical profession and the State are not sourced to one or the other party, as both have contributed to deficiencies that have led to at least some degradation of the normative authority of medical ethics and the organized profession. Yet I believe there is hope to reform the relationship to regain legitimacy in regulation by both social fields. The concepts of legal pluralism provide a framework within which to design a better relationship, allowing for the development of a legal order by the profession and anticipating the interactions between the profession and the State that guide this development and the transfer of norms between social fields.

IV. Ethics as Crucial Law for the Medical Profession

Medical ethics serves a critical purpose for physicians, patients, the State and others who are involved in health care and the provision or receipt of medical services. It provides a set of behavioral norms for physicians and, in many instances, creates a *higher* standard for behavior than demanded by State law.[23] The need for standards like those imposed by ethics stems from the physical, emotional, economic and social roles play by health care and illness: Flexner recognized that "[t]he overwhelming importance of preventive medicine, sanitation, and public health indicates that in modern life the medical profession is an organ differentiated by society for its own highest purposes, not a business to be exploited by individuals according to their own

[23] See e.g. Council on Ethical and Judicial Affairs, *Code of Medical Ethics*, *supra* note 11 at 1-2; American Academy of Dermatology, "Code of Medical Ethics for Dermatologists", online: American Academy of Dermatology <https://www.aad.org/forms/policies/uploads/ar/ar%20code%20of%20medical%20ethics%20for%20dermatologists.pdf>.

fancy."[24] Medical ethics provides a means for the profession to promote "its own highest purposes."

Medical ethics serves other purposes as well. In a society dominated by State regulation, ethics can act as a bulwark against intrusive State law that promotes interest inapposite to patient and public health and safety. It reminds physicians that their primary obligation is to patients, not themselves or others outside of the patient-physician relationship, or even the State.

The complication of conventional interpretations of the relationship between the medical profession and State, and therefore of the normative authority of medical ethics, provides a caveat to these roles of ethics in the profession and the US health care system. The conception of professional self-regulation as hierarchically inferior to State law—promoted by theories like professionalism—provides an inherent and perceptual limitation to the authority of medical ethics. Professional pronouncements or norms are subject to State law, and conflicts will likely be settled in favor of State law. The individual states' active regulation of medicine through professional licensing further incentivizes physicians to react primarily to State law, rather than to the professional law of ethics.

An alternative understanding of the role of medical ethics in the regulation of physician behavior and professional relationships is exemplified by the relational structures proposed by legal pluralism. This theory provides a useful tool for explaining the potential for medical ethics beyond the constraints of orthodox analyses. The utility of legal pluralism lies in its paradoxical separation

[24] Abraham Flexner, *Medical Education in the United States and Canada: A Report to the Carnegie Foundation for the Advancement of Teaching* (New York: The Carnegie Foundation for the Advancement of Teaching, 1910) at 19.

and confluence of legal orders and social fields. Through this, we can isolate the profession's authority from the State's but also see the value in their interdependence.

An isolation in the promulgation and enforcement of ethics norms for the medical profession means that it has some space to exercise its prerogatives without the overbearing regulation of the State that we now have. This is the historical function of medical ethics—law for physicians when there was no other law—but modern health care diminishes the need for or acceptability of a mostly autonomous profession that characterized the early years following the formation of the AMA.

The State regulates many aspects of health care, at both state and federal levels, to fulfill its many obligations to the population, including the licensing of physicians, other health care professionals and health facilities; the regulation of health insurance; and the development and financing of programs to provide health care or access to health care to different segments of society. The State does not currently regulate all areas of medicine or medical ethics; however, at times when it *does* regulate the State replaces the profession's ethical consensus with irrelevant or even harmful considerations, as happens in abortion and gun safety regulation. This is why the separation and confluence of semi-autonomous social fields is an important concept of legal pluralism that can inform the ideal role of professional self-regulation and medical ethics as a legal order.

The State does not have the capacity to replicate medical ethics. It can write the words into law, but ethics as designed by the medical profession is accompanied by more esoteric features, including a consideration of *who* controls its enactment. That the profession retains substantial authority and respect from society relates in no small part to its ethics and the understanding that physicians, more so than the State, owe their allegiance to patients. Medicine remains one of the

most trusted professions, a trust that the State cannot claim for itself.[25] If the profession is absolved of its self-regulatory obligations—if the State undertakes to fully regulate physicians—it is not unreasonable to predict that the trust in physicians built up over decades might also dissolve. Our health care system relies at base on concepts that are primarily ethical in foundation and arising from professional enactment, even if the State regulates the same issue in the same way.

The importance of medical ethics to the profession, patients and society does not mean that the State cannot or should not regulate. The expertise gap is an important indicator of what should be regulated by the profession, and how. Chapters 6 and 7 set forth areas of health care and ethics that permit a differentiation of State and professional roles. The profession has shown itself more adept at regulating many matters that are fundamental to the patient-physician relationship, such as respect for patient autonomy and promotion of patient health, while the State has on occasion placed other considerations—often political—ahead of its own obligations to promote and protect individuals' and the public health. Conversely, on matters such as conflicts of interest the State has become a font of expertise and authority while the profession has under-regulated despite a clear ethical mandate to adopt more stringent norms.

This differentiation again points to the utility of legal pluralism as a framework for exploring the past, current and future relationship between the medical profession and the State. The measure of *semi*-autonomy means that the profession might regulate physicians, through ethics, but does not do so alone. The profession is well-placed to regulate on the traditional values of health care,

[25] See e.g. Eliot Freidson, *Profession of Medicine: A Study of the Sociology of Applied Knowledge* (Chicago: University of Chicago Press, 1970) at 84; Gallup, "Honesty/Ethics in Professions", online: Gallup <http://www.gallup.com/poll/1654/honesty-ethics-professions.aspx>. Members of Congress are the lowest rated of the "professions" in this poll. *Ibid*.

but the expansiveness of our health care system and of physician self-regulation cautions against a completely isolated social field.

Like medical ethics, State regulation can also have a beneficent purpose aligned with traditional ethical values. State regulation can serve to dampen the profession's worst instincts, especially in matters of money and conflicts of interest. However, it can also dampen the effectiveness of a system meant to ensure that physicians act in a specific (ethical) way towards patients and others. The emphasis on "give" without a corresponding acceptance of "take" has made it more difficult to identify an effective normative system based in medical ethics as something other than a relic of the profession's past.

Of course, any advancement of medical ethics as a legal order is dependent on both the medical profession and State accepting the realities of medical practice and health care. For the State, legislators' deeply held beliefs in their supremacy as lawmaker, executives' broad powers to regulate in a variety of areas, and judges' discomfort with legal orders outside of the State's, are considerable barriers to overcome. These branches of the State must recognize that just because they *can* regulate in a certain way does not mean that they *should*. They must accept the expertise of those outside of the government in some circumstances.[26] The medical profession, for its part, must accept its fallibilities. It cannot be the final arbiter of all things it considers to be within the realm of ethics, if only because for certain matters its own judgment is compromised by self-interest.

[26] I realize that saying the State *must* do anything is an exercise in imaginative thinking, but there are fields of regulation that require the technical expertise of those being regulated and one job of State regulators is to determine when this is necessary.

Ethics is critical to physicians and the practice of medicine, and its existence as a legal order, independent but also considerate of State law, provides additional impetus to its authority. Given the exigencies of medicine and the role of the State in regulating many aspects of health care and physician practice, the shared nature of physician regulation necessitates what the business-oriented might call synergism, "a combination of known elements or functions that create a result greater than the sum of the individual elements or functions."[27] The profession has proven that it cannot rely on self-regulation alone, and the State has demonstrated that it needs the expertise of the profession on the technical and ethical aspects of medicine to regulate legitimately and properly. Legal pluralism suggests that the structures and relationships of the medical profession, State and medical ethics are eminently improvable, and can reach a synergy that incorporates the strengths of the profession and State and curtails their weaknesses.

[27] Bryan A Garner, ed, *Black's Law Dictionary*, 7th ed (St. Paul: West Group, 1999) at 1463.

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