The Impact of Bioethical Advice in Legal Frameworks: A Comparative Study of Guidance by National Bioethics Committees for Reproductive Sciences

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ABSTRACT

English

The purpose of this thesis is to explore the relation between law and bioethics for the specific regulation of reproductive health technologies. As traditional policy-making processes fall short in the face of the bioethical intricacies arising with novel assisted reproductive technologies, modern democracies increasingly rely on expert advice provided by National (Bio)Ethics Commissions, Councils, or Committees (NECs). Drawing from entities found in Europe and the USA, an in-depth analysis outlines the benefits of the distinctive functioning and methodology of NECs to inform law and policy-making on morally ambiguous subject-matter. Further, an empirical study reveals the de facto powers of these entities, which have surpassed their purely advisory functions and transformed into active players in the legislative process. Due to general hostility towards NECs found in the literature, this work also aims to dismantle concerns and prove the overarching value of this quasi-legal intervention.

Ultimately, the claim of this thesis is that law-makers must defer to NECs to bridge the knowledge gap between science and policy and bring about strong, reasoned, and socially beneficial juridical outcomes.

Français

Cette thèse traite de l'interaction entre le droit et la bioéthique pour assurer la réglementation des nouvelles technologies de la reproduction. Ne parvenant pas à résoudre les enjeux bioéthiques que posent ces avancées scientifiques avec les mécanismes traditionnels de réglementation, de plus en plus de démocraties modernes se fient à l'avis expert de Commissions, Conseils ou Comités Nationaux d'Éthique (NECs). En comparant les situations française et américaine, il s'agit d'exposer les atouts du fonctionnement et de la méthodologie de ces entités dans l'orientation du législateur. Par une étude empirique, je souligne ensuite les pouvoirs réels exercés par les NECs qui en font de véritables acteurs dans le processus législatif.

Enfin, au vu de l'hostilité doctrinale généralement éprouvée à l'égard de ces entités, cette thèse cherche à plaider l'utilité de cette intervention quasi-légale et démanteler les principales critiques.

Globalement, le but est de présenter les NECs comme des mécanismes opérant le lien nécessaire entre la science et le droit et garants d'une loi meilleure, plus performante et socialement acceptable.

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INTRODUCTION

The 21th century marks a research-oriented era in which scientific progress has reshaped almost every aspect of human life. All over the world, scientists continuously perform extensive research and regularly make new discoveries.[1] This evolution touches a large variety of fields with significant developments in biotechnology and medicine. Medical research in particular aims to lengthen, improve, and promote human life across the globe. Increased knowledge about the human body enables scientists to identify and treat more illnesses by creating new drugs and developing innovative cures, therapies, and procedures. The goal is to enhance all stages of human life, including its source: human reproduction. An entire branch of medicine – assisted procreation – is dedicated to the facilitation of human reproduction. Innovation in this field has developed at a remarkably rapid pace as procedures that were unthinkable a few decades ago are now common practice. Indeed, scientists perfected artificial insemination and laboratory embryo conservation or manipulation techniques to perform a series of so-called assisted reproductive technologies (ARTs).

Such advances trigger a dramatic expansion in the realm of possibilities and an unprecedented degree of control over the reproductive process.[2] By means of artificial insemination (AI), *in vitro* fertilization (IVF), surrogacy or other, more ground-breaking, methods (i.e. human embryo cloning), all natural boundaries disappeared: Heterosexual infertility can be overcome as well as the inability to conceive naturally affecting homosexual couples or single individuals. Not even death is a limit to procreation as widows can request posthumous

[1] *See* John K. Mason and Alexander McCall Smith, *Law and Medical Ethics* (London, UK: Butterworths, 1983) at 9.

[2] Carmel Shalev, "An Ethic of Care and Responsibility: Reflections on Third-Party Reproduction" (2012) 3:3 Med. Stud. 147-156.

insemination or gestate a frozen embryo. From a purely scientific perspective, virtually any reproductive desire can be fulfilled by means of medical assistance.

This progression has spurred significant public interest and mixed responses. While some welcome the gain in reproductive freedom, others fear the ramifications on the meaning of human life. ARTs defy traditional understandings of the most basic notions of human reproduction and challenge core societal beliefs and values. A sense of unease and apprehension can therefore be found within the medical profession and public opinion.[3] The tension between the promises and perils of ARTs ground a need for containment and regulation of novel practices. In fact, society turns to law and policy-makers[4] with a clear expectation for assisted procreation to become a subject of public policy. A coordinated legislative approach is meant to ensure the implementation of strong boundaries around the use of new ARTs[5] and ease the transition into a new reproductive reality.[6]

Despite an urgent need for regulation, most systems seem ill-suited to handle the continuous changes and respective moral ambiguities occurring in assisted procreation. Indeed, drawing the bounds of the permissible for reproductive medicine forms an intricate task and poses significant policy dilemmas. In addition to the technical and procedural obstacles, political pressure can disincentivize policy-making in this sensitive field of medicine. Since a framework is nevertheless required to contain the extensive reach of science, many pluralistic

[3] *See* Amel Alghrani, *Regulating Assisted Reproductive Technologies: New Horizons* (Cambridge, UK: Cambridge University Press, 2018) at 27; Sheila Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton: Princeton University Press, 2011).
[4] In this thesis, law is defined in relation to governmental intervention and therefore to policy-making. Law is to be considered as a policy instrument. Policy-making is thus related to law-making and policy embraces law. Additionally, the focus here lies on the legislative process (instead of the regulatory process) from a multitude of jurisdictions where legislative norms form a governing force in the field of bioethics.
[5] *See* Amel Alghrani, *supra* note 3.
[6] Canada, Royal Commission on New Reproductive Technologies, *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies* (Ottawa: Minister of Government Services Canada, 1993) at 10.

democracies found a common solution for decision-makers to deal with novel bioethical issues: a standardized deferral to national (bio)ethics committees (NECs) for bioethical advice. NECs draw from a multidisciplinary composition, autonomous operation, and a comprehensive methodology to provide bioethical advice and workable policy or guideline recommendations. This quasi-legal intervention forms a material recourse for policy-drafting on issues that fall outside the traditional legal scope. The advantages of a reliance on bioethical advice were progressively recognized and the deferral to NECs standardized. With this standardization, these entities progressively exceeded their theoretical advisory powers and transformed into active participants in the policy-making process. Since a recognition of normative activity for NECs revolutionized traditional legislative mechanisms, it elicited important scholarly debates that continue to destabilize the value of this expert intervention in the normative process. In fact, NECs intervene in a hostile environment where they are perceived as illegitimate actors or "*pseudo mini-parliaments*" replacing the legislator and posing a threat to democracy.[7]

Such findings trigger the need to assess the necessity of this form of involvement in the legislative process. Hence, my "problématique" can be summed up as follows: '*Are bioethical issues that arise with scientific advances beyond the grasp of the law so as to justify the intervention of quasi-legal institutions such as (bio)ethics Committees, Councils, or Commissions?*'

The aim for this thesis is to prove the effectiveness of NECs' involvement in the legislative process. In truth, expert bioethical advice serves as a powerful tool for policy-making in the field of reproductive medicine. The legislator relies on the input of these entities to tackle the bioethical intricacies that continuously arise with novel reproductive technologies. NECs ask

[7] *See* Klaus P. Rippe, *Angewandte Ethik in der Pluralistischen Gesellschaft* (Munich: Universitätsverlag, 1999).

crucial questions, examine possibilities, consider a plurality of viewpoints, and provide guidance in often uncharted waters. A systematic deferral to expert bioethical advice therefore contributes to strong, reasoned, and socially beneficial juridical outcomes. More than a technical facilitation of the policy-making process, the involvement of NECs serves a certain symbolic value: These entities represent a unique chance for a renewal of representative democracies.[8] By relying on multidisciplinary expertise, governments acknowledge and seek to overcome the knowledge gap between medicine and policy. Serving as a forum for a constructive exchange of alternative points of view, NECs represent an efficient tool for the establishment of responsible public policy that is respectful of the diversity found in public opinion.[9] Overall, NECs strike a valuable balance between conflicting societal beliefs on controversial bioethical issues arising with reproductive sciences and therefore represent the necessary intermediary between scientific and political legitimacy.

[8] *See* Teresa Kulawik, "Science Policy and Public Accountability in Poland: The Case of Embryonic Stem-Cell Research" (2009) Sc. Public Policy 469-482.
[9] Timothy Caulfield et al., "Law and Policy in the Era of Reproductive Genetics" (2004) 30:4 J. Med. Ethics 414-417 at 416.

STRUCTURE, METHOD, AND LITERATURE REVIEW

Scholars typically analyze this dependence on ethical advice through a general lens, focusing on the preparation of laws on a broad variety of topics within the scientific field. This thesis will draw from the themes found in the general literature around expert (particularly bioethical) advice to analyse its impact on policy decisions in the specific field of reproductive sciences. To examine the relation between bioethical advice and the law in reproductive sciences and highlight NECs' overarching effectiveness, I plan to organize my work around three main axes of analysis outlined below.

First, I depict the difficulty experienced by decision-makers when attempting to regulate novel scientific advances revolutionizing human reproduction. The focus lies with the legislative process instead of the regulatory and judiciary processes. Indeed, legislative norms generally emerge as the authoritative force in the field of bioethics. In the face of a growing need for efficient legislative frameworks, a set of examples drawn from civil law shows how the legislator struggles to adapt existing legal definitions and mechanisms to novel techniques (Part I).

Second, I explain how a standardized deferral to bioethical expertise on sensitive bioethical issues that arise with advances in reproductive sciences constitutes the best solution for efficient policy-making. Evidence will be drawn from the progressive institutionalization of bioethical advice in the USA (Presidential Commission for the Study of Bioethical Issues; National Bioethics Advisory Commission), France (Comité Consultatif National d'Éthique), and some other European countries (i.e. Luxembourg). With a comparative angle, I outline the functioning of NECs before revealing the benefits of bioethical expertise.

Ultimately, an empirical study highlights a correlation between certain NEC reports and actual policy decisions for reproductive sciences. NECs have exceeded their theoretical powers and transformed into active players in the policy-making process (Part II).

In the third part, I address criticism around quasi-legal advice by applying the teachings of general scholarly scrutiny of external involvement in the legislative process[10] to the specificities of the bioethical field.[11] Outlining these challenges seems important, yet I systematically discredit doctrinal concerns and prove the overpowering value of bioethical expertise. This process serves my overarching argument that expert NEC opinions are crucial to regulate public bioethical issues arising with novel technologies. Through a de-monopolization of normativity and reliance on public deliberation, NECs ultimately contribute to a new and improved form of democratic governance (Part III).

[10] *See* Frédéric Zénati, "La Portée du Développement des Avis" in Thierry Revet, ed, *L'inflation des Avis en Droit* (Paris : Economica, 1998) 101-115 at 109; Laurent Cohen-Tanugi, *La Métamorphose de la Démocratie* (Paris: Éditions Odile Jacob, 1989) at 182.

[11] *See* Carl Schneider, "Bioethics in the Language of Law" (1994) 24:4 Hastings Cent. Rep. 16; Dominique Thouvenin, "Les Lois de 1994 ou Comment Construire un Droit de la Bioéthique" (1995) D. 149 at 12-13; Sandrine Maljean-Dubois, "Bioéthique et Droit International" (2000) 46 AFDI at 87.

PART I: DIFFICULTY REGULATING ADVANCES IN REPRODUCTIVE SCIENCES

Reproductive medicine forms a striking example of the continuous evolution of science aimed at the promotion of human life. For centuries, procreation was reserved to fertile heterosexual couples. With the establishment of an array of novel techniques, scientists now have the power to fulfill virtually any reproductive desire: ARTs allow infertile heterosexual couples, homosexual couples, single individuals, as well as widows, to procreate. These technologies not only alleviate the burden of infertility, but also largely expand the pool of potential parents.

This expansion in the realm of possibilities comes at a certain cost. It poses novel risks for patient safety, raises healthcare coverage questions, and challenges core societal beliefs and values about the inviolability of human life.[12] Attitudes towards the development of ARTs vary substantially in different parts of the world and are largely impacted by scientific, cultural and religious differences. Without a definite determination of the most desirable course of action, a series of bioethical dilemmas arises. It could be argued that it is preferable to let practitioners and interested parties muddle through the difficulties these technologies pose, so as to let a sort of "moral equilibrium" emerge around ARTs. However, such a *laissez faire* approach seems inadequate. Indeed, addressing the issues underlying novel technologies with a variety of ethical standards would not lead to efficient results because these would never be fully accepted by all nor be coherent enough to lead to certain and predictable outcomes. Such uncertainty is incompatible with the importance of the issues at stake. In fact, the feeling of disorientation

[12] Studied *infra* Part 1.

within the medical profession and public opinion highlights a need for limitations and regulation of novel practices despite controversies on its source.[13]

In the result, society predominantly turns to law and policy-makers for guidance. It seems that the bioethical issues generated by novel ARTs are best solved with a series of neutral rules and proscriptions. Legal reasoning provides clear directives and thereby settles underlying dilemmas. Yet, most systems[14] appear ill-suited to handle the continuous changes occurring in reproductive medicine as technical obstacles and political pressure disincentivize policy-making in this sensitive field. Since a framework is nevertheless required to contain the reach of science, many pluralistic democracies found a common solution for decision-makers to deal with novel bioethical: a standardized (through law or repeated practice) deferral to national (bio)ethics committees (NECs) provides for ethical analyses as well as concrete policy or guideline recommendations.[15]

The first section of this part will outline common societal expectations of legal guidance through the bioethical disarray caused by scientific advances in the field of reproductive sciences. Only an efficient framework can allay public apprehension and entrench fundamental principles of human dignity and respect in the progression of scientific research (Chapter 1). The second section reveals how despite this being their role, law and policy-makers appear largely overwhelmed by the task and unable to guide human conduct (Chapter 2).

[13] *See* Avraham Steinberg, "The Foundations and Application of Medical Ethics" in Joseph G. Schenker, ed, *Ethical Dilemmas in Assisted Reproductive Technologies* (Boston; Berlin: De Gruyter, 2011) 1-13 at 12.
[14] The analysis of Part 1 has a general scope with arguments applicable to a variety of jurisdictions.
[15] *See infra* Part 2: The analysis of Part 1 prepares for the next part that addresses the solution found to this legislative shortcoming in many jurisdictions: a deferral to NECs.

Chapter 1: Expectation of Legal Guidance

The quick development of assisted procreation has improved human reproduction qualitatively by overcoming infertility and quantitatively by increasing numbers of families.[16] In turn, this evolution has spurred significant public interest and mixed responses. While some favor the boundless progression of science and welcome the gain in reproductive freedom, others fear a redefinition and a violation of traditional values attached to human life.

Reproductive technologies can indeed be perceived as a "*Pandora's box of bioethical issues*".[17] Ethical discussion focuses on matters of right and wrong, good and bad.[18] In a broader sense, ethics concerns fundamental values and bears on questions of human life and how we should structure our society.[19] As procreation has an inherent moral value, the aim of reproductive technologies seems immediately pertinent to ethical matters and must be addressed. The following questions arise: "*What attitude must humanity take in respect to these new powers over our destiny that science has given us?*" and "*Should every scientific development simply be welcomed or are there boundaries to be upheld?*"[20] Although pinpointing the exact limits of the ethically permissible is complex, it seems necessary to resist the systemic endorsement of every scientific development in this sensitive field. While the moral costs of ARTs differ with individual moral views, reproductive medicine bears a collective responsibility to address the moral perplexities arising from novel technologies. Indeed, the uncertainty around what anyone, practitioners and patients alike, ought to do fuels a sense of discomfort that can only

[16] In more economically advanced countries.
[17] Joseph G. Schenker, "Ethical Aspects of Advanced Reproductive Technologies" (2003) 997:1 Ann. N.Y. Acad. Sci. 11-21 at 11.
[18] David A. Jensen, "Human Reproductive Cloning: Ethical Perspectives" in Joseph G. Schenker, ed, *Ethical Dilemmas in Assisted Reproductive Technologies* (Boston; Berlin: De Gruyter, 2011) 297-307 at 298.
[19] *Ibid*.
[20] *See* Council of Europe, *Human Artificial Procreation* (Strasbourg: Council of Europe Press, 1989) at 8.

be eased through efficient regulation of scientific activity. For many years, the medical profession was entrusted with this task until the matter became subject to juridical oversight.

This section first explores ground-breaking reproductive techniques (Section 1) before revealing society's expectation of regulation by means of efficient legislative and/or regulatory policy frameworks (instead of professional guidelines) (Section 2).

Section 1: Ground-Breaking Techniques in Reproductive Sciences

In the realm of reproductive medicine, scientists developed numerous novel techniques and technologies. With the help of a variety of novel ARTs (II), natural boundaries can be overcome to fulfil virtually any reproductive desire found in society (I).

I. Growing Demand for Assisted Procreation

For centuries, procreation was reserved to fertile heterosexual couples as infertility shattered couples' dreams of having a baby.[21] This condition still affects a large portion of the world's population with studies showing that at least 50 million couples were affected in 2010.[22] Not only does infertility impede reproduction, it also represents a great emotional burden for those who are affected. Infertile women, specifically, are subjected to social stigma which can

[21] *See* the World Health Organization's definition of infertility: World Health Organization, "Infertility Definitions and Terminology", online: World Health Organization <www.who.int/reproductivehealth/topics/infertility/definitions/en/>: "*A disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse.*"

[22] Maya N. Mascarenhas et al., "National, Regional, and Global Trends in Infertility Prevalence Since 1990: A Systematic Analysis of 277 Health Surveys" (2012) 9:12 PLoS Med.

aggravate an already painful experience.[23] The overall burden of infertility affecting heterosexual couples spurred a strong demand for assisted procreation.

In recent decades, this demand expanded. With growing social and legal acceptance of same-sex couples and same-sex marriage, the idea of same-sex couples reproducing is now equally accepted and demanded. As they are biologically unable to procreate, same-sex couples rely on medical intervention. Similarly, with decreased stigma around single parenthood, more and more single individuals (including widowed partners) strive to overcome their biological inability to reproduce by requesting medical assistance.

The wish for parenthood progressively spread across all sections of society. Significantly, most people not only want to become parents, they want to establish a genetic filiation with their children and therefore place great hopes on reproductive medicine.[24] Combined with decreasing adoption possibilities worldwide,[25] scientists were increasingly pressured to develop human fertility treatments and increase the pool of potential reproductive agents.[26] Years of extensive research led to more knowledge and a greater understanding about the process of early human development and the causes of miscarriage and infertility.[27] Until today, various tests, studies, and laboratory manipulations are conducted to perfect uses of medical or pharmaceutical reproductive technologies.[28] Thanks to these advances, any reproductive wish from a couple or single individual can now be fulfilled through scientific intervention.

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[23] Nadine Taub, "Surrogacy: A Preferred Treatment for Infertility" (1988) 16:1-2 LMHC 89-95 at 93.
[24] Agnès Fine and Agnès Martial, "Vers une Naturalisation de la Filiation?" (2010) 78 Genèses 121-134 at 129.
[25] Karla King, "Why is the Adoption Rate Dropping?" (2014), online: Adoption.org <www.adoption.org>.
[26] Bernard M. Dickens, "Legislation for Assisted Reproductive Technologies" in Joseph G. Schenker, ed, *Ethical Dilemmas in Assisted Reproductive Technologies* (Boston; Berlin: De Gruyter, 2011) 15-28 at 15.
[27] *See* Ruth Deech, "Infertility and Ethics" (1997) 9:4 CFLQ 337-344 at 338.
[28] *See* John K. Mason and Alexander McCall Smith, *supra* note 1 at 32.

II. Review of Assisted Reproductive Technologies

Assisted procreation includes a variety of assisted reproductive treatments or technologies (ARTs). With a wide spectrum of possible treatments, physicians can bypass many natural barriers to human reproduction. Depending on the cause of the inability to procreate, the following (non-exhaustive list of) ARTs may be suggested to a couple or individual wanting to procreate: ovarian stimulation, artificial insemination (AI),[29] *in vitro* fertilization (IVF), preimplantation genetic diagnosis, intracytoplasmic sperm injection (ICSI), gamete intrafallopian transfer (GIFT), egg vitrification, as well as surrogacy.[30] Together these procedures are very successful with nearly ten million babies born worldwide as a result of ARTs.[31]

Artificial insemination (A) and IVF procedures (B) are the most widely practiced[32] and can lead to third-party reproductive collaborations (C). With growing demand for all forms of assisted procreation, innovation in this field is continuously evolving (D).

[29] Experts disagree on the exact definition and list of available ARTs as some exclude AI. However, AI is studied as an ART here.
[30] Quebec Science and Technology Ethics Committee, Position Statement, "Ethics and Assisted Procreation: Guidelines for the Donations of Gametes and Embryos, Surrogacy and Preimplantation Diagnosis" (2009) at 15.
[31] David Adamson et al., "International Committee Monitoring Assisted Reproductive Technologies: World Report on Assisted Reproductive Technology" (2018) 110:6 Fertil. Steril. 1067-1080: 8 million babies have been born worldwide as a result of IVF and other advanced fertility treatments.
[32] Fertility Answers, "IUI Versus IVF: What Are the Differences in these Common Treatment Procedures?", online: Fertility Answers <https://www.fertilityanswers.com/iui-versus-ivf/>.

A. Artificial Insemination (AI)

AI involves injecting sperm into the female reproductive system. Once sperm quality has been ascertained, it can be used along with, or without, ovarian stimulation. As there is no need for intercourse, artificial insemination can benefit couples or individuals with a range of needs. AI methods are continuously evolving with four different medical procedures commonly practiced, each progressing to a more invasive albeit performative form.[33] The procedure helps circumvent male incapacity or sterility and certain female conditions (including cervical factor infertility or endometriosis). More controversially, AI can also be used posthumously by widows hoping to conceive after a partner's death. Requests for AI are also formed by same-sex couples wanting to procreate by use of donor sperm.

B. In Vito Fertilization (IVF)

While AI helps circumvent male infertility, the inability to procreate often stems from the woman.[34] This explains the demand for IVF which refers to an extracorporeal fertilization method, performed using eggs from the woman being fertilized or from a donor, as well as the sperm of her partner or that of a donor. Once the gametes are collected, they are placed in a culture medium in order to facilitate their fusion, after which the resulting embryos are then transferred into a woman's uterus. Significantly, this can be the uterus of the biological, intended, or surrogate mother.

[33] AI can be intravaginal, intracervical, intrauterine, and intratubal.

[34] *See* John K. Mason and Alexander McCall Smith, *supra* note 1 at 38: A woman may suffer from anatomical problems such as a blockage of the fallopian tubes which will prevent her from conceiving by natural means.

C. Third-Party Reproductive Collaborations

As mentioned above, the success of AI and IVF techniques often relies on third party reproductive collaborations such as donation. The possibility of using donor sperm, eggs, or even embryos has considerably enlarged the realm of possibilities. Indeed, donations not only help heterosexual couples in cases of male and female infertility, it also accommodates single individuals' and female same-sex couples' wishes to procreate.

More significantly, novel treatments can lead to an uncommon social arrangement for the purposes of procreation in which a surrogate mother agrees to gestate a child for another person or couple. There are two types of surrogacy agreements:[35] traditional surrogacy in which the surrogate is artificially inseminated with the sperm of the intended father, making her both the genetic and gestational mother of the future child and gestational surrogacy where an embryo is formed through IVF from the gametes of the intended parents or a donor and then transferred into the uterus of the surrogate mother who carries and delivers the baby. In all of these arrangements, the surrogate mother is meant to give the child to the intended parents after giving birth. Surrogacy is commercial or altruistic, depending upon whether the surrogate receives financial compensation for her pregnancy. While surrogacy is used by many couples and individuals, it is of particular significance for male same-sex couples hoping to have a child.

[35] *See* Pikee Saxena et al., "Surrogacy: Ethical and Legal Issues" (2012) 37:4 Indian J. Community Med. 211-213.

D. Continuous Innovation

The above-mentioned advances in reproductive medicine are just the beginning. This field continues to evolve and new discoveries are made on a daily basis. Techniques that appeared to be figments of our imagination or fabrications of science fiction can become a reality tomorrow. Striking examples of this reproductive revolution include (but are not limited to) the possibility to control the sex and genetic markup of a future child as well as the science of human cloning. To further therapeutic research, scientists can also mingle human and non-human species to develop hybrid embryonic cells, which could lead to the creation of hybrid, half-human babies.[36] Other trailblazing technologies involve uterus transplantations that sever reproduction from the human body by enabling unisex gestation and gestation by dead or artificial wombs. While ectogenesis[37] (the gestation of a human fetus entirely outside the body by machines) has not yet been performed, partial ectogenesis has, as demonstrated by IVF and the gestation of premature babies in incubators.[38] Perpetually evolving and profoundly unsettling, the advancement of reproductive medicine requires oversight and restriction.

[36] Nicholas Wade, "Researchers Claim Embryonic Cell Mix of Human and Cow", *The New York Times* (12 November 1998) A4, online: The New York Times < https://www.nytimes.com/1998/11/12/us/researchers-claim-embryonic-cell-mix-of-human-and-cow.html >: The Advanced Cell Technology company developed a hybrid cell in 1998.
[37] Amel Alghrani, *supra* note 3 at 109.
[38] *Ibid*.

Section 2: Establishing a Need for Legal Guidance and Authority

Fertility practitioners manipulate embryos, enable unnatural pregnancies, and gift biological parenthood to those longing for it.[39] What was unthinkable a few decades ago, is now common practice: it is possible to circumvent heterosexual infertility as well as the inability to conceive naturally affecting homosexual couples or single individuals. Even widows can request posthumous insemination or gestate a frozen embryo. From a purely scientific perspective, nothing seems impossible as the array of existing and future procedures allows individuals to fulfill most reproductive desires. Although ARTs are only directly used by a minority of individuals, how these services are used deeply influences social attitudes and values. Hence, the infinity of possibilities raises a question of ethical permissibility and, with it, a need for regulation of scientific progress.

This idea of setting boundaries for novel scientific technologies is traditionally met with two conflicting positions in public opinion: First, a liberal view that firmly rejects the idea of regulating science to endorse all scientific discoveries (I). Second, a more restrictive view that requires regulation to achieve a balance between scientific advancement, patient safety, and respect for fundamental ethical principles. Amongst those who agree on the need for regulation, disagreement prevails on the source of authority as some praise self-regulation from within the medical profession (II), while others favor legislative policy intervention (III).

[39] Kimberley M. Mutcherson, "Disabling Dreams of Parenthood: The Fertility Industry, Anti-Discrimination, and Parents with Disabilities" (2009) 27:2 Law Inequal. 311-364.

I. Rejected Liberal View: No Right to Procreate

A liberal attitude towards medical innovation requires every scientific discovery to be welcomed by society and be made available to all individuals. Due to the undeniable benefits for humanity, the realm of scientific possibilities should not be questioned. On the contrary, science follows a natural order where any limitation would constitute an unjustified interference.[40] This "everything goes" approach is sought after in the reproductive field by practitioners and potential parents. Absolute scientific freedom entails full liberty for individuals to make use of scientific discoveries in their lives. In fact, individuals seeking fertility treatment increasingly formulate their requests in terms of "reproductive liberty" or "procreative autonomy".[41] Some authors[42] argue that procreative autonomy is as much a part of democratic liberty as freedom of speech and racial equality. Hence, reproductive choices should be made autonomously without any restrictions.[43] This desire for reproductive freedom grew in an era of unprecedented emphasis on autonomy and patient rights.[44] Ultimately, it led to the assertion of a "right to procreate"[45] to be construed as a negative right that forestalls interference and/or as a positive right that entitles individuals to all available forms of scientific assistance in procreation.[46]

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[40] *See* Ruth Deech, *supra* note 27 at 337.
[41] *See* Khiara M. Bridges, *The Poverty of Privacy Rights* (California: Stanford University Press, 2017) for a definition of procreative autonomy as "*the ability to decide whether to have a child without being subject to the government's power to compel the individual to act in alignment with the government desires.*"
[42] Ronald Dworkin, *Freedom's Law* (Oxford: Oxford University Press, 1996).
[43] John Harris, "Rights and Reproductive Choice" in John Harris and Søren Holm, eds, *The Future of Human Reproduction* (Oxford: Oxford University Press, 1998) at 5–37.
[44] Veronica English, "Autonomy Versus Protection – Who Benefits from the Regulation of IVF?" (2006) 21:12 Hum. Reprod. 3044–3049 at 3045.
[45] Other claims include the right to found a family composed of a person and a child, the free disposal of one's body, equality between single women and married women, or between same-sex couples and heterosexual couples.
[46] Elizabeth Brake and Joseph Millum, v° Parenthood and Procreation, in Edward N. Zalta, ed, *The Stanford Encyclopedia of Philosophy* (Stanford, USA: Metaphysics Research Lab, Stanford University, 2018).

While such claims are not wrong, they are commonly rejected in legal literature and were never recognized by the courts or legislature. Despite the importance of individual rights in today's society, there remains a strong need for balance through regulation to preserve public welfare and policy. A lack thereof puts the health of patients at risk and triggers a public sense of unease in the face of burgeoning reproductive technologies.

II. Intermediary View: Self-Regulation Within the Medical Profession

Drawing from a variety of democratic jurisdictions,[47] we note a strong belief that legislators are unable to deal with the ethics of medical practice. Abstract and general in nature,[48] the law is considered unsuitable to tackle the intricacies of bioethical issues. To avoid legislative intervention,[49] the choice was made to trust the medical profession to self-regulate.[50] Even as medicine developed, professional guidelines remained the primary source of regulation for physicians.[51] Hence, all novel social or ethical questions arising with the development of medicine, specifically reproductive technologies, were tackled through the individual or cooperative responses of professional medical associations and specialty societies.[52] No laws were passed to govern scientific conduct since professional guidance was considered the best source of up-to-date information available to practitioners.[53] Additionally, in the rare cases

[47] E.g.: USA and France.
[48] *See* François Terré, "La Crise de la Loi" (1980) 25 APD La Loi at 17 ; Comité Consultatif National d'Éthique, Avis n°129, *Contribution du Comité Consultatif National d'Éthique à la Révision de la Loi de Bioéthique* 2018-2019 (Paris: La Documentation Française, 2018) at 41.
[49] Bioethical issues were the domain of traditional authorities such as the church. With the rise of secularism, the medical profession as a whole was entrusted with the definition of the limits of science and medical practice.
[50] Joseph G. Schenker, *supra* note 17 at 11.
[51] *See* Brigitte Feuillet-Le Mintier et al., "Internormativité et Production de la Norme Éthique en Matière Médicale" in Brigitte Feuillet-Le Mintier, ed, *Les Lois « Bioéthique » à l'Épreuve des Faits. Réalités et Perspectives* (Paris: PUF Collection Droit & Justice, 1999) 1-9 at 5.
[52] Institute of Medicine, *Society's Choices: Social and Ethical Decision Making in Biomedicine* (Washington, D.C.: National Academies Press, 1995) at 7.
[53] *Ibid*.

where professional regulation fell short, physicians were trusted to self-regulate and resolve all ethical dilemmas in accordance with their personal experience, conscience, and belief system.[54]

This professional stance of self-regulation was taken in clear opposition to a legal approach to medical ethics. In this view, the law is considered an inadequate source of regulation for the day-to-day delicate ethical issues that arise in medical practice.[55] Nevertheless, this approach quickly appeared outdated. In relation to reproductive medicine in particular, self-regulation seems deficient.[56] Indeed, "*no policy is a policy*"[57] and without law, the market will decide, thus leaving individuals vulnerable to exploitation and public interest and values undefended.[58] This can lead to inequitable agreements, often between an indigent woman and a richer couple wanting to procreate, in which the weaker party agrees to the conditions of the contract involving their own body in the sole hope of compensation.

III. Dominant Restrictive View: Achieving Stability Through Law

To safeguard public interest, assisted procreation must become a subject of public policy and legislative boundaries must be implemented for the use of new ARTs.[59] Through prohibition and simple regulation, ethically satisfying standards of treatment are imposed (A) and public unease is alleviated (B).

[54] *See* Brigitte Feuillet-Le Mintier et al., *supra* note 51 at 339.
[55] John K. Mason and Alexander McCall Smith, *supra* note 1 at 10.
[56] Joseph G. Schenker, *supra* note 17 at 12.
[57] Patricia Baird, "Regulation of Reproductive Technologies" (2004) 9:2 Paediatr Child Health 91-92 at 92.
[58] *Ibid*.
[59] *See* Amel Alghrani, *supra* note 3 at 27; Sheila Jasanoff, *supra* note 3.

A. Regulating Medical Practice Through Law

Within the medical profession, the lack of legislative guidance obliges practitioners to operate in an atmosphere of uncertainty. Only clear laws can act as a "safe haven" and shield the profession from claims of unethical behavior and the risk of liability.[60]

The law also protects patient rights and well-being in the face of hazardous reproductive technologies.[61] In addition to common pregnancy risks, fertility drugs jeopardize patient health and the practice of multiple embryo transferral in IVF, meant to increase the chances of success, can lead to dangerous multiple births.[62] Combined with a risk of price exploitation[63] and the danger of human exploitation in ART agreements (for third party reproductive agents specifically),[64] the continuous advancement of reproductive medicine spurred the need for regulation by a stronger authority: law. Individuals using or engaging in ARTs must be assured that these services are provided in a regulated environment.[65] Despite a shared goal of regulating medical conduct (between self-regulation and legal regulation), only the law has the required legal authority. A comprehensive policy and pursuant legal framework can ensure the required accountability and compliance with standards from those working in the field.[66]

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[60] Veronica English, *supra* note 44 at 3044.
[61] *See* Patricia Baird, *supra* note 57 at 91; Lori P. Knowles, "Reprogenetics: A Chance for Meaningful Regulation" (2002) 32:3 Hastings Cent. Rep. 13.
[62] Veronica English, *supra* note 44 at 3046; Patricia Baird, *ibid.*: About 4 in 10 infants born after IVF are part of a multiple pregnancy.
[63] Veronica English, *ibid*.
[64] *See for instance*: Muriel Fabre-Magnan, *L'Institution de la Liberté* (Paris: PUF, 2018): Concerns about the underlying motivations of a donor or surrogate mother. In commercial surrogacy, there is a strong risk of human exploitation of vulnerable minorities.
[65] *See* Patricia Baird, *supra* note 57 at 91.
[66] Amel Alghrani, *supra* note 3 at 34.

B. Alleviating Public Concern Through Law

Laws on assisted procreation not only control professional conduct and patient safety. They also serve a broader purpose of easing public concern around this sensitive field of medicine.[67] While ARTs are increasingly perceived as routine, they have altered most basic understandings of human life. These techniques disrupt symbolic points of reference including common representations of family and blood relationships,[68] of the child,[69] of the human body,[70] and of the intrinsic value of the human being.[71] Evidence collected by authors analyzing public opinion shows how this disruption triggered public mistrust and concern surrounding the possible harms, risks, and ethical dilemmas associated with the use of ARTs.[72] As M. F. Fathalla phrased it, the following question cropped into the public mind: "*Is science a solution or a problem?*"[73] With growing fears of the mad scientist or alchemist in the public mind, public conceptions of reproductive sciences are commonly fraught with fantasies of futuristic horror. Lurid associations to fictitious examples found in written literature such as '*Brave New*

[67] *Contra*: Timothy Caulfield et al., *supra* note 9 at 415: "*Though moral unease may be a justification for caution and should be motivation for further analysis, it is an insufficient reason for the introduction of rigid prohibitions—particularly in an area where social mores have been seen to shift rapidly.*"; It could also be argued that laws, especially those forbidding certain practices, amplify public unease instead of easing it.

[68] ARTs dismantle traditional perceptions of family and parenthood through 3rd party reproductive collaborations, same-sex couple reproduction and conception by single individuals. Evidently, the traditional nuclear family model has disappeared. This leads to subsequent changes as the family is the building block of most relationships.

[69] A child will be the result of ART. It is crucial to weigh his/her interests and welfare against individual desires to procreate.

[70] ARTs destabilize the status of the human body by posing a significant risk of its commercialization. It seems unacceptable for any person to be treated as a convenience or a "bank of spare parts". Human dignity, worth, and autonomy must be preserved. This is particularly relevant in cases of surrogacy that raise concerns about equality and exploitation.

[71] As most ARTs involve laboratory embryo manipulations, discomfort grows. The question of the moral status of the human embryo is strongly debated as some view it is a mere cluster of cells and others attach great value to it. Specific concern around surplus embryos that could either be destroyed, donated to research or to another individual seeking to procreate.

[72] Amel Alghrani, *supra* note 3 at 22; Mahmoud F. Fathalla, "Current Challenges in Assisted Reproduction*"* in Current Practices and Controversies in Assisted Reproduction (Report of a Meeting on "Medical, Ethical and Social Aspects of Assisted Reproduction" held at WHO Headquarters in Geneva, Switzerland, 17-21 September 2011) [unpublished] at 9.

[73] Mahmoud F. Fathalla, *ibid*.

World' embryology, Nazi medicine, or *Frankenstein* experimentation lead public responses of unease and scepticism.[74]

Evidently, fertility benefits cannot justify an offense to society's codes of acceptability and the sanctity of human life. Under the impetus of religious outrage,[75] of feminist distrust,[76] or pure ethical inquiry,[77] questions arise as to the proper use of these new techniques. In other words, *what are the limits to assisted procreation?* While everything is scientifically feasible, it is not necessarily appropriate to grant every individual's desire.

This societal unease can be alleviated by law as it permits the ethical and prohibits the unethical.[78] Despite traditional uncertainty and controversy about the role of law in legal theory,[79] it is widely accepted that the law is meant to reflect public morality. Acting as "*safe pair of hands*", the law protects fundamental societal values and principles by erecting visible legal barriers aimed at safeguarding humanity.[80] It controls science in the interest of the community as a whole by ensuring the observation of fundamental rules of social conduct.[81] Through strict conditions, the law intervenes to either permit, regulate, condition, and, when appropriate, prohibit scientific practices and clinical activities.[82] Pursuantly, new medical

[74] Sheila Jasanoff, *supra* note 3 at 37.
[75] *See* Norman M. Ford, "A Catholic Ethical Approach to Human Reproductive Technology" (2008) 17:3 Reproductive BioMedicine Online 39-48.
[76] *See* Gerda Neyer and Laura Bernardi, "Feminist Perspectives on Motherhood and Reproduction" (2011) 36:2 Hist. Soc. Res. 162-176.
[77] *See* Trudo Lemmens et al., *Regulating Creation: The Law, Ethics, and Policy of Assisted Human Reproduction* (Toronto: University of Toronto Press, 2017).
[78] David Orentlicher, *Matters of Life and Death: Making Moral Theory Work in Medical Ethics and the Law* (Princeton: Princeton University Press, 2001).
[79] Controversy between Patrick Devlin, *The Enforcement of Morals* (Oxford: Oxford University Press, 1957) and H.L.A. Hart, *The Concept of Law* (Oxford: Oxford University Press, 1961).
[80] Patrick Devlin, *ibid*.
[81] John K. Mason and Alexander McCall Smith, *supra* note 1 at 10-11.
[82] *See* Patricia Baird, *supra* note 57.

technologies that are considered undesirable, can effectively be withheld or withdrawn from patients.[83]

Furthermore, ART-related controversies have fuelled a damaging relation of distrust between medical practitioners, medical institutions, patients, and society more generally. Legal intervention is required to re-establish a sense of trust between all intervening actors.[84] Indeed, only regulation can combat social misconceptions of science by guaranteeing that certain fundamental barriers of decency will not be crossed.[85] As the future will likely bring new developments in the ethically-charged field of reproductive sciences, it is crucial to improve these relationships.[86]

This is further emphasized by the flourishing effect a protective environment has on scientific progress. Whether it is justified or not, public mistrust can negatively impact science by giving reproductive technology a bad image, endanger the flow of public funding for research, and raise pressure for more extensive restrictions.[87] Ultimately, scientific progression is more protected when society trusts the work of scientists acting within a restrictive framework.[88]

[83] Joseph G. Schenker, *supra* note 17 at 12.
[84] Camille Bourdaire-Mignot and Tatiana Gründler. "La Bioéthique de Demain: Un CCNE Plus Fort et des Lois Moins Bloquantes" (2018) ADL 1-14 at 4, para 19.
[85] *See* Her Majesty's Stationery Office, *Report of the Warnock Committee of Inquiry into Human Fertilisation and Embryology* (London, UK: Her Majesty's Stationery Office, Cmnd. 9314, 1984).
[86] Camille Bourdaire-Mignot and Tatiana Gründler, *supra* note 84 at 4, para 19.
[87] Mahmoud F. Fathalla, *supra* note 72 at 9.
[88] Robert G. Edwards and D.J. Sharpe, "Social Values and Research in Human Embryology" (1971) 231 Nature 87-91.

Conclusion

With a realm of forbidden knowledge and experience upon which medicine and society must not trespass, public well-being ultimately supersedes individual urges.[89] ARTs must not develop without clear societal direction grounded in collective values. Yet, reserving the ability to regulate ARTs to the medical profession would constitute an improper derogation from an area of legitimate public concern.[90] As law represents public conscience[91] it constitutes a legitimate and effective mechanism used by governments to contend with social and ethical issues related to developments in assisted procreation.[92] Clear legislative boundaries are necessary to ensure patient safety and that practices remain within the bounds of what is broadly perceived as acceptable.[93]

It is however almost impossible to find solutions to the ethical problems in reproductive technologies that are acceptable in a pluralistic society. Extreme diversity renders the task of regulation extremely difficult.[94]

[89] Patrick Healy, "Statutory Prohibitions and the Regulation of New Reproductive Technologies under Federal Law in Canada" (1995) 40:4 McGill L. J. 905-946.
[90] John K. Mason and Alexander McCall Smith, *supra* note 1 at 10-11.
[91] *Ibid*.
[92] *See* Institute of Medicine, *supra* note 52 at 6; Brigitte Feuillet-Le Mintier et al., *supra* note 51 at 339.
[93] *See* Veronica English, *supra* note 44 at 3044-3046; Lori P. Knowles, *supra* note 61.
[94] Joseph G. Schenker, *supra* note 17 at 12.

Chapter 2: The Law's Inability to Provide Guidance for Underlying Bioethical Issues

Efficient frameworks are required for reproductive medicine.[95] To avoid a patchwork of standards and uses, this responsibility was progressively removed from the professional arena and placed as a primary focus of public scrutiny.[96] Indeed, comprehensive public policies are an efficient means of protecting patients and resolving underlying bioethical dilemmas.[97] Subsequent legislative intervention has imposed strict prohibitions and specific requirements to set the bounds of the permissible and regulate burgeoning reproductive techniques through all stages.[98]

While this may be their role, policy-makers appear largely overwhelmed by the task. When law is perceived as a policy tool,[99] the difficulty of regulating ARTs becomes apparent: Rapidly evolving techniques do not readily fall into existing legal categories and challenge traditional legal definitions and mechanisms.[100] These technical difficulties could be overcome through increased legal adaptability,[101] but resolving the sensitive issues at stake forms a more insurmountable obstacle. In fact, any policy stance on bioethical dilemmas is systematically met with strong opposition and rejection in public opinion. From a political perspective, it is therefore highly detrimental for the government and legislature to engage in this controversial field of law.

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[95] *See for instance* David Adamson, "Regulation of Assisted Reproductive Technologies in the United States" (2002) 78:5 Fertil. Steril. 932-942.
[96] Kathi E. Hanna and the U.S. Institute of Medicine, *Biomedical Politics* (Washington D.C.: National Academies Press, 1991) at 2.
[97] *See* Timothy Caulfield et al., *supra* note 9.
[98] *See* Patrick Healy, *supra* note 89.
[99] *See supra* note 12 explanation on premises for thesis analysis.
[100] *See* William P. Statsky, *Family Law: The Essentials* (Boston, Mass.: Cengage Learning, 2015) at 400.
[101] *Ibid*.: Incorporating provisions into legislations that permit subsequent fine-tuning or alterations after a specific time period.

This discomfort ultimately grounds the need for alternative modes of policy-drafting including a systematic deferral to expert advice provided by NECs to assist with the intricacies of reproductive sciences.[102]

Due to its conservatism and slow pace, the legislative process seems incompatible with novel issues arising with the continuous advancement of reproductive medicine (Section 1). More than a procedural struggle, the regulation of these sensitive matters also represents a dicey political responsibility because of the unavoidable public controversy and backlash that it triggers (Section 2).[103]

Section 1: Novelty of Issues

Policy-makers struggle to regulate advances as ARTs challenge traditional legal definitions and concepts (I) and almost immediately outrun new legislative frameworks (II). These challenged can nevertheless be remedied (III).

I. Challenges to Existing Legal Definitions and Frameworks

With the development of ARTs came clashes with existing laws that were fashioned before such revolutionary techniques were even considered. The core intention behind traditional concepts of law that did not foresee modern reproductive procedures.

[102] Studied *infra* Parts 2-3.
[103] The scope of this analysis is general and the arguments are applicable to a majority of jurisdictions.

Due to a deficiency in terms of structure, nature, and coverage of controversial subjects, existing rules and principles could not provide a legal basis for solutions to novel bioethical dilemmas arising with ART execution (A) and its practical consequences (B).[104]

A. Legal Gaps for ART Usage

To guarantee acceptable usage and execution of ARTs, a guiding framework is required. However, as soon as the first ART-related issues appeared, it became clear that long-standing laws would not provide such guidance.

A primary unresolved difficulty, in both codified legal systems, where codes define the scope of particular provisions, and Common Law systems, where precedents are expected to be followed, was determining the body of law (contracts, delicts or torts, family law…) by which ARTs are best approached.[105]

In addition, bioethical issues involve subject-matter that was entirely unknown in most jurisdictions. This is because most traditional legal categories are based on a core referential relation to biological facts. A significant change in biological reality, as induced by ARTs, therefore renders existing legal definitions and categories inadequate. Even the traditional *summa divisio* like that of means/ends or persons/things was outdated. For instance, as most ART procedures involve embryo manipulation, a determination of the legal status of the human embryo (A person? A thing? An ad hoc status?) became necessary to set a course of action, but was inexistent.

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[104] Council of Europe, Secretariat, *Human Artificial Procreation*, *supra* note 20 at 13.
[105] *See* Bernard M. Dickens, *supra* note 26 at 16.

In turn, ARTs challenge foundational concepts of property and rights in the human body[106] as questions of ownership of body parts, gametes, and embryos arise. With no clear assertion of a property right, the adequacy of various uses of human tissue, including commercialization, exposure to harm, or destruction was left undetermined.[107]

Further, when it comes to imposing restrictions for actions, treatments, or other interferences with physical autonomy that are commonly deemed unacceptable,[108] no clear prohibitions under threat of legal sanction could be found.[109]

B. Legal Gaps for Practical ART Consequences

Common legislative frameworks also fall short in the face of various practical and social consequences of ARTs. Challenges specifically arose in relation to old laws governing genealogical relationships and kinship. In most countries, legal concepts and definitions are built based on the "nuclear family model" (man-woman-child(ren)). However, with broader access to ARTs, largely permitted by third-party reproductive collaborations (donations and surrogacy), family models diversified.[110] As a result, the law of filiation and parentage failed to keep up. As a U.S. court notably commented: "[the] *technological fragmentation of the procreative process… has engendered a bewildering variety of possibilities which are not*

[106] Stacy Sutton, "The Real Sexual Revolution: Posthumously Conceived Children" (1999) 73:3 St. John's L. Rev. 857-932 at 860.
[107] *Ibid*.
[108] In many countries, the following practices are deemed profoundly unacceptable and must be prohibited by law: human zygote/embryo research related to ectogenesis, cloning, animal/human hybrids, the transfer of zygotes to another species, or the maturation and fertilization of eggs from human fetuses; the sale of human eggs, sperm, zygotes, fetuses, and fetal tissues, and advertising for or acting as an intermediary to bring about a preconception arrangement, receiving payment or any financial or commercial benefit for acting as an intermediary, and making payment for a preconception arrangement.
[109] *See* Patrick Healy, *supra* note 89.
[110] *See* Alan Brown, *What Is the Family of Law? The Influence of the Nuclear Family* (Oxford, Hart Publishing, 2019).

easily reconciled with our traditional definitions of "mother", "father", and "parent.""[111] Indeed, genetic lineage as a premise for legal parenthood seemed dysfunctional and even harmful to children born of ARTs as it leads to a problematic distinction between genetic parenthood and social and psychological parenthood.[112] As an increasing number of children were born as a result of ARTs, the need for new juridical modes of recognizing filial relationships emerged.

Additionally, the protection of the vulnerable third-party intervening in a reproductive collaboration grew urgent. Third-party interests (i.e. respect; anonymity) were opposed to those of the intended parents as well as those of the future child (well-being; dignity; identity rights). Surrogacy in particular forms a problematic phenomenon due to an increased risk of female exploitation and overall redefinition of traditional conceptions of motherhood.[113] Yet, due to the departure from traditional understandings of parenthood, there was no legal framework to determine parentage clearly in these contexts.

This non-exhaustive description of the law's prolonged inadequacy highlights the need for a process of "*legal acculturation*"[114] to resolve the array of bioethical issues that arise in relation to ARTs. While many legislators have successfully responded over the years, legislative voids remain a problem as new techniques develop. The law must continuously adapt to practical reality and anticipate future developments.[115]

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[111] *In re C.K.G.*, 173 S.W.3d 714, 721 (Tenn. 2005).
[112] Bernard M. Dickens, *supra* note 26 at 16.
[113] *See for instance* Martha A. Field, *Surrogate Motherhood: The Legal and Human Issues* (Cambridge, MA: Harvard University Press, 1990).
[114] Alain Pottage, "The Socio-Legal Implications of the New Biotechnologies" (2007) 3 Annu. Rev. Law Soc. Sci. 321-344 at 340.
[115] Sophie Monnier, *Le Droit des Comités d'Éthique: Éléments d'Analyse sur le Système Normatif de la Bioéthique* (Paris: L'Harmattan, 2006) at 429, para 775.

II. Continuous Developments: Failure of Traditional Law-Making Processes

The law is expected to be "*fit for purpose in the 21st century*".[116] With new discoveries come new policy choices[117] which require significant adaptability to review existing frameworks or create ART legislation.

This expectation of adaptability not only distorts the permanence of law (A), but also seems impossible to achieve due to the rapid pace of science (B).[118]

A. No Permanence of Law

Incessant change challenges traditional conceptions of law as permanent and consistent.[119] Abstract in nature, law is meant to withhold change by encompassing any new phenomenon.[120] This perception has progressively been abandoned.[121] Caught in the fast pace of scientific change, the legislator must be prepared to continuously adapt.[122] Although flexibility is necessary, it alters traditional understandings of the role of the legislator and destabilizes legislative legitimacy. As the idea of consistency fades,[123] the following question arises: 'If the law is no longer abstract and permanent, is it still an efficient and legitimate source of normativity?'

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[116] Amel Alghrani, *supra* note 3 at 19.
[117] *Ibid*.
[118] *See* Patricia Baird, supra note 57 at 92.
[119] *See* François Terré, *supra* note 48 at 17.
[120] *Ibid*.
[121] Sophie Monnier, *supra* note 115 at 419, para. 750.
[122] Brenda Hale, *From the Test Tube to the Coffin: Choice and Regulation in Private Life* (London: Stevens, Sweet and Maxwell, 1996) at 125; Sophie Monnier, *supra* note 115 at 420, para. 751.
[123] *See* Sophie Monnier, *ibid.*

B. Defeating Pace of Science

This acculturation is extremely difficult to achieve. Advances in reproductive medicine occur at a remarkably rapid pace with a constant flow of emerging possibilities. In the words of Robert Brownsword, "*the regulation of new technologies is an open agenda that invites on-going reflection*."[124] However, the workings of the law are characteristically slow-paced[125] and therefore make it impossible to quickly and adequately respond to new medical practices. Although some changes are successfully implemented, scientific developments continually require additional adaptations. Indeed, by the time the legislature develops a satisfactory framework for one type of procedure, a new technique has standardized. A striking example of this can be found in legislative responses to new IVF procedure tweaks: when legislatures finally tackled IVF, science introduced embryo cloning. Laws then needed to be amended to prohibit cloning and clarify that embryo manipulation is only acceptable when embryos result from laboratory fertilization.[126] The obsolescence of laws in this field is inevitable.[127]

Furthermore, the quality of law should not be jeopardized by useless attempts of catching up with science. Law-making requires long negotiations and extensive political work as a guarantee for quality and legitimacy. Hence, despite strong efforts of adapting the law to science,[128] the resolution of new bioethical dilemmas can ultimately not be guaranteed by

[124] Roger Brownsword, *Rights, Regulation and the Technological Revolution* (Oxford: Oxford University Press, 2009) at 28.
[125] John K. Mason and Alexander McCall Smith, *supra* note 1 at 9.
[126] Timothy Caulfield et al., *supra* note 9 at 416.
[127] Amel Alghrani, *supra* note 3 at 27.
[128] Sophie Monnier, *supra* note 115 at 419 para. 750.

traditional vectors. Overall, the steady progression of reproductive medicine confirms the need to rethink the current processes and look for alternative modes of policy-drafting.

III. Remedies

One attempted remedy found in many countries[129] was to govern reproductive sciences with "purpose-made" laws instead of general rules. This was intended to reduce the confusion that arises when trying to categorize novel ARTs.[130] Yet, determining the content of such specifically created laws remains complex as a technology-by-technology list of rules and prohibitions will only create an incoherent and chaotic patchwork of laws.[131]

As we will study below,[132] the most effective means of tackling the issues of reproductive medicine is branching out to para or quasi- legal actors. NECs constitute such entities and provide flexible, scientifically informed, and responsive oversight. If given a sufficiently flexible mandate by the enabling legislation, NECs can oversee, analyse, and resolve both current and upcoming bioethical dilemmas. While it is impossible for a law to encompass all future developments, external expertise can help shape strong and sustainable legal structures. Precisely, NEC intervention permits foresight and a deeper understanding of not only the science but also the social and ethical implications of ARTs.[133]

[129] *See Human Fertilisation and Embryology Act* 1990 (UK); Loi n° 94-653 du 29 juillet 1994 relative au respect du corps humain, JO, 30 July 1994, no 175; Loi n° 94-654 du 29 juillet 1994 relative au don et à l'utilisation des éléments et produits du corps humain, à l'assistance médicale à la procréation et au diagnostic prénatal, JO, 30 July 1994, no 175; Loi n° 2004-800 du 6 août 2004 relative à la bioéthique, JO, 7 August 2004, no 276.
[130] Bernard M. Dickens, *supra* note 26 at 17.
[131] Timothy Caulfield et al., *supra* note 9 at 416.
[132] *See infra* Parts 2-3.
[133] *See* Timothy Caulfield et al., *supra* note 9 at 416.

Section 2: Extreme Controversy: A Disincentivizing Factor in Policy-Making

As society struggles with the steady progression of reproductive sciences, public policy-makers face an arduous task. More than mere technical difficulty in the preliminary stages, decisions in the bioethical field constitute a heavy responsibility. "Bioethical decisions" form social issues of importance for policy with implications in terms of funding, legislative prohibition, regulation, moratoria, and health care financing. These decisions are inevitably subject to unmatched controversy in public opinion. Such disagreement can deeply affect the political longevity of decision-makers. The pursuant fear of political backlash further complicates and disincentivizes policy actions in the bioethical field.

While any policy decision is intricate, the field of reproductive sciences is particularly obstacle-ridden as the balance between competing interests is nearly impossible to achieve (I) and any decision is necessarily subject to extreme public backlash (II).

I. A "Balancing Act"

To regulate reproductive sciences, both the government and legislature hope to draw a framework by weighing competing interests and relying on an assumption of common agreement on core principles.

In practice however, this ideal of a commonly accepted policy in reproductive sciences (A) is typically squashed by extreme diversity found in public opinion (B).

A. The Policy Ideal

Policy-making refers to the authority resting with the government and legislator to guide human conduct through law or other forms of normativity.[134] There is an expectation of policy on novel bioethical issues.[135] As former U.S. senator Mark Hatfield said: "*In public policy, if there is a vacuum, government eventually will fill it, right or wrong, good or bad. We just can't let difficult bioethical matters evolve at will; we ought to help direct them*."[136]

From the outset though, policy-drafting in the field of reproductive sciences forms a difficult balancing act.[137] It requires careful balancing between two main competing public policy considerations: on the one hand, there is a common desire to encourage innovative research as increased scientific knowledge can lead to significant improvements for human health.[138] Reproductive sciences in particular are aimed at relieving human infertility and generally promoting the development of human life. On the other hand, it is necessary to respond to the need for regulation of scientific progress to prohibit unacceptable conduct, minimise harm, and allay public fears.[139] On this point, additional difficulty stems from extreme controversy on determining what must be considered unacceptable.

Ultimately, the goal is to weigh competing alternatives before finding a policy that embodies differing social and political values, yet agrees on core principles, and is therefore acceptable to all members of society.

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[134] Kathi E. Hanna and the U.S. Institute of Medicine, *supra* note 96 at 2.
[135] Kathi E. Hanna, "A Brief History of Public Debate about Reproductive Technologies - Politics and Commissions" in Lori P. Knowles and Gregory E. Kaebnick, eds, *Reprogenetics: Law, Policy, and Ethical Issues* (Baltimore, MD: Johns Hopkins University Press, 2007).
[136] Mark Hatfield, (Address at the U.S. Congress, Office of Technology Assessment (OTA), 1993) [unpublished].
[137] *See* Amel Alghrani, *supra* note 3 at 32; Roger Brownsword, "Regulating Human Genetics: New Dilemmas for a New Millennium" (2004) 12:1 Med. Law Rev. 14-39.
[138] Amel Alghrani, *ibid*.
[139] *Ibid*.

B. Extreme Diversity

In pluralist democracies, a variety of values and interests are heard and impact the decision-making process. Inevitably, the ideal of a commonly accepted policy seems unattainable as different stakeholders hold conflicting beliefs about the most desirable direction for scientific progress.[140] "*How can policy disputes be resolved in a society where there is no agreement, no shared faith, and no moral authority (e.g.: a church) to lead the way?*"[141]

In the field of reproductive sciences specifically, we note extreme diversity in social perspectives and opinion. Related to themes such as the beginning and the end of life that leave no one indifferent, ARTs touch a sphere of human life rich in emotional and symbolic values.[142] Each member of society addresses this issue in accordance with their respective belief systems – colored by culture, religion, heritage, personal history, preferences, and tastes.[143] With substantial differences among people and cultures, the answers to bioethical dilemmas are extremely diversified. Indeed, a public opinion poll on any issue would show a multitude of responses.[144]

Diversity is further entrenched by a strong reluctance and disdain for compromise.[145] While conflict about values are natural in any society, controversies around ARTs entail unique clashes between expertise and ignorance, encompassing ideals about rationality and progress,

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[140] Kathi E. Hanna and the U.S. Institute of Medicine, *supra* note 96 at 312; David Adamson, *supra* note 95 at 942.
[141] Tristram H. Engelhardt, "Integrity, Humaneness, and Institutions in Secular Pluralistic Societies" in Ruth E. Bulger and Stanley J. Reiser, eds, *Integrity in Health Care Institutions. Humane Environments for Teaching, Inquiry, and Healing* (Iowa City, Iowa: University of Iowa Press, 1990).
[142] John K. Mason and Alexander McCall Smith, *supra* note 1 at 13.
[143] Kathi E. Hanna, "A Brief History of Public Debate about Reproductive Technologies – Politics and Commissions", *supra* note 135.
[144] *See* Kathi E. Hanna and the U.S. Institute of Medicine, *supra* note 96 at 2; Timothy Caulfield et al., *supra* note 9 at 415.
[145] Kathi E. Hanna and the U.S. Institute of Medicine, *ibid.*

as well as challenges to traditional notions of legitimacy and authority.[146] As a result, fertility advances are systematically subject to protracted public debates.

II. Political "Hot Potatoes"

Strong public responses to the issues related to novel ARTs (A) have created political dilemmas in policy-drafting (B).

A. Strong Public Responses

Social diversity in views on sensitive issues in reproductive sciences never falls silent. In fact, strong public interest leads to a multiplication of advocacy groups or think tanks. Extremely polarized, they stick to their respective position and leave no room for conciliation. Each group sees its position as the only righteous and feasible one and wants it to be integrated into public policy.

Fuelled by religious institutions and leaders, public interest often transforms into public outrage. The Catholic church is particularly alarmed by ARTs due to its long history of exercising moral control over human conception.[147] Non-religious groups, also have been vocal. Some feminists[148] condemn these technologies for conditioning and manipulating women into motherhood while disability advocates warn about a new source of discrimination

[146] *Ibid*.
[147] *See* Norman M. Ford, *supra* note 75.
[148] *See* Catherine MacKinnon, *Feminism Unmodified: Discourses on Life and Law* (Cambridge, MA: Harvard University Press, 1987).

and ableism.[149] On the other hand, LGBTQ+ groups largely favor the development of these techniques and demand facilitated access.[150] As a result, even when a majority agreement is found, organized minorities are likely to object and will have their voices heard with the help of the media.[151]

The media plays a significant role as it picks up on discontent found in public opinion around ARTs and can fuel it. Drawing from the symbolic weight attached to the beginning of human life, ever since the first ART procedures were conducted, public media has engaged in sensationalized journalistic articles depicting a novel threat to the social and moral order.[152] Exaggerated media coverage of patient gamete theft, proposals for human cloning, exorbitant sums of money paid to egg donors, and septuplet and octuplet births, have fed the perception that these disturbing incidents represent the norm, or at least a pervasive risk, associated with in reproductive medicine rather than serving as exceptions.[153]

B. Political Dilemmas

With an urgent need for effective policy, the regulation of ARTs is on most political agendas. In the attempt to accommodate a plurality of viewpoints, legislators are often mired in painful and prolonged processes.[154] It can be politically challenging to set boundaries and a course of action.[155]

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[149] *See* John A. Robertson, "Procreative Liberty and Harm to Offspring in Assisted Reproduction" (2004) 30:1 JLME 7-40; Kimberley M. Mutcherson, *supra* note 39.
[150] *See* Michael Boucai, "Is Assisted Procreation an LGBT Right?" (2016) 6 Wis. L. Rev. 1065-1126.
[151] Kathi E. Hanna and the U.S. Institute of Medicine, *supra* note 96 at 312.
[152] Teresa Kulawik, *supra* note 8 at 475.
[153] David Adamson, *supra* note 95 at 932.
[154] Tristram Engelhardt, *supra* note 141.
[155] Diego Garcia, "The Intellectual Basis of Bioethics in Southern European Countries" (1993) 7:2/3 Bioethics 97 at 97-98.

This is primarily due to the entanglement of politics and bioethical issues. The diversity in public opinion is reflected in politics. Policy-makers are pressured from the outside but also from within the political arena as there is often no agreement to be found between parties. Bioethical issues therefore spur political tactics and power-play. This entanglement was notably revealed by past debates in the USA (and elsewhere) on the permissibility and legal framework for abortion. A party's or political leader's stance on abortion could determine political power, (re)-election, or the formation of a government.

The political turmoil around abortion extends to ARTs as "pro-lifers" strongly oppose fertility research advocates.[156] With an intense political focus on symbolic lines of conflict (instead of mere socio-economic interests), it seems clear that the regulation of contentious ART issues forms an insoluble problem. Not only is there is no fundamentally "right" answer, but any ART policy decision will necessarily trigger significant backlash from the respective group of individuals whose opinion was not followed.

Some political leaders (i.e. George W. Bush or Bill Clinton) were able to use controversies surrounding biotechnologies as an electoral advantage and other leaders simply decided to assert strict policies on sensitive technologies as soon as they developed (i.e. Germany's embryo policies). Nonetheless, most democracies struggle to regulate such advances. In fact, attempts to accommodate the plurality of viewpoints through discussion is systematically frustrated and policy making in this arena therefore represents a political "hot potato".[157]

[156] *See* David Adamson, *supra* note 95 at 932.
[157] Lori P. Knowles and Gregory E. Kaebnick, *eds, Reprogenetics: Law, Policy, and Ethical Issues (Baltimore, Maryland: Johns Hopkins University Press, 2007)*.

As a result of the intensity of the underlying conflicts, strategies of "non-decisions" develop to evade the issues altogether.[158] As both executive and legislative powers avoid controversy, there is a vacuum of public involvement in ART research and practice.[159] This would be unsatisfactory and potentially dangerous due to the previously outlined need for regulation in this sensitive area of medicine.

Conclusion

This section showed how scientific advances in reproductive medicine give rise to complexity upon complexity and render rational decision making exceedingly difficult.[160]

Social and political controversies surrounding ARTs should however also be perceived as a unique chance for a renewal of representative democracies.[161] The following question: "*Is it possible to plan better and to make more rational decisions in an irrational world where there are no absolute standards and where people hold diverse views?*"[162] must indeed be answered positively. It is possible for decision-makers to muddle through the complexity of controversial topics by employing quasi-legal tools such as a deferral to institutionalized and neutral bioethical advice. Indeed, NECs can satisfy the need for moral debate in policy-drafting[163] (that cannot be carried out within the general public). These entities serve as a forum for a constructive exchange of alternative points of view by actors that are open to the possibility of seeking compromising solutions and overall consensus. They therefore represent an efficient

[158] Teresa Kulawik, *supra* note 8 at 57; David Adamson, *supra* note 95 at 932.
[159] David Adamson, *ibid*.
[160] Kathi E. Hanna and the U.S. Institute of Medicine, *supra* note 96 at 2.
[161] Teresa Kulawik, *supra* note 8.
[162] *Ibid* at 321.
[163] *See* Timothy Caulfield et al., *supra* note 9 at 415.

tool for the establishment of responsible public policy that is respectful of the diversity in public opinion.[164]

In the next part, we will study how the work of NECs provides useful advice to public decision makers. Indeed, maximizing the use of ethical analysis facilitates hard policy choices on novel scientific advances and minimizes societal confusion.[165] We will also highlight that the purely symbolic nature of this intervention was surpassed and how these paralegal entities have become actively involved in the policy-making process. This diversification of sources of normativity has significant consequences, leaving traditional understandings of law and law-making forever modified.

[164] *Ibid* at 416.
[165] *See* Carl Schneider, "Moral Discourse, Bioethics, and the Law" (1996) 26:6 Hastings Cent. Rep. 37-39 at 38.

PART II: SOLUTION FOR EFFICIENT POLICY-MAKING: A STANDARDIZED DEFERRAL TO BIOETHICAL ADVICE

The healthcare environment is prone to the development of bioethical dilemmas due to recurring uncertainty about the most desirable course of action. Various levels of authority, ranging from the individual physician and healthcare institutions to the government, are tasked with the resolution of bioethical issues to allow the healthcare system to function. While all forms of bioethical decision-making are challenging, it is particularly arduous when the questions are of public concern and require authoritative policy intervention. As revealed in the first part, traditional policy-making processes fail to meet the urgent need for official guidance through the bioethical intricacies posed by novel reproductive techniques.

In the face of these shortcomings, a deferral to bioethical advice developed as a viable solution. Indeed, bioethical reasoning serves as a "*tool for answers*"[166] which contributes to efficient policy-drafting in the continuously evolving scientific field.[167] The growing need for assistance fueled the institutionalization of this deferral. Mirroring bioethics committees found on the local level (in-hospital and research ethics boards), national advisory committees[168] were established in multiple countries[169] to act on a broader scale and orient policy stances on public bioethical issues.

Over the years, increased reliance on this quasi-legal intervention led to a sort of standardization of NEC advice in the legislative process, which appeared beneficial to policy-makers. By means of a multidisciplinary composition, autonomous operation, and

[166] Fernando L. Stepke, *Acta Bioética* (Santiago: Editorial Universitaria, 2001) at 7.
[167] *See* Brigitte Feuillet-Le Mintier et al., *supra* note 51 at 339.
[168] Terms used interchangeably: commission, committee, council.
[169] This analysis is focused on Europe and the USA as these jurisdictions have emblematic, firmly established, and very active NECs.

comprehensive methodology, NECs bring about useful advice and facilitate the regulation of bioethical issues that fall outside the traditional legal scope. In addition to providing a material recourse for policy-drafting, these entities defuse the political tension that typically perturbs legislation in this arena. Such benefits have ultimately empowered NECs to the extent of exceeding their theoretical advisory powers and making them active participants in the policy-making process. In truth, a strong correlation can often be traced between NECs' opinion reports and actual policy decisions on the regulation of scientific progress.[170] Drawing from the themes found in the general literature around expert bioethical advice,[171] this part will analyze the effectiveness of NECs for policy decisions in the specific field of reproductive sciences.

The first chapter of this part will outline the progressive institutionalization of bioethical advice and provide an overview of selected NEC models found in Europe and the USA (Chapter 1). The next chapter will depict the benefits and prospects of NEC intervention for policy-making in the field of reproductive medicine (Chapter 2).

[170] Examples to be drawn from policies on reproductive sciences from the USA, France, and other European countries.
[171] *See for instance* Jean-Louis Baudouin, "Toward a Canadian Advisory Council on Biomedical Ethics, Study Paper" (1990) Law Reform Commission of Canada, Protection of Life Series; Brigitte Feuillet-Le Mintier et al., *supra* note 51.

Chapter 1: Progressive Institutionalization of Bioethical Advice

Growing societal interest in medical advances led to an expansion of bioethical activities in the late 20th century.[172] Along specialized bioethics scholarship and literature, committees proliferated on different levels of bioethical decision-making.[173] These committees can be defined as "*any group of persons whose primary task is to pass ethical judgment on, or undertake collective ethical consideration of, biomedical problems*."[174]

In many countries, the institutionalization of bioethical advice generated a multi-tiered system of ethics committees: Some committees act on the local level (HECs; IRBs) while others, called 'NECs' (and forming the point of interest of this thesis), were created on the national (or state) level. A focus on emblematic NEC models found in Europe and the USA reveals how these entities commonly operate as a source of bioethical advice for national decision-makers regarding issues of public concern such as novel reproductive technologies. Although different NECs present structural specificities, they typically apply the same analytical methodology. This special mode of operation fuelled the widespread success and standardization of the deferral process to quasi-legal advisory entities.

This chapter will outline a selection of well-established national advisory entities (Section 1) before focusing on their functioning (Section 2).

[172] Jean-Louis Baudouin*, ibid*.
[173] *Ibid*.
[174] Ronald E. Cranford and Edward A. Doudera, eds, *Institutional Ethics Committees and Health Care Decision Making* (Ann Arbor, Michigan: Health Administration Press, 1984).

Section 1: National Advisory Entities

The national regulation of scientific advances poses a series of public bioethical issues which challenge traditional policy-making procedures. Lacking the means to tackle underlying intricacies and provide satisfactory guidance, authorities rely on expert bioethical advice. Progressively, this interaction between law and bioethical expertise grew stronger and led to the national institutionalization of this advice: the establishment of NECs.

Europe (I) and the USA (II) provide examples of national advisory entities, permanently or temporarily set up, to reflect on bioethical issues, educate the public, and provide bioethical advice to national decision-makers.[175]

I. European NECs: Dominant French Model

France was the first country to establish a permanent NEC by governmental decree on February 23rd 1983:[176] The National Consultative Committee on Ethics for the Life and Health Sciences ("*Comité Consultatif National d'Éthique pour les Sciences de la Vie et de la Santé*" (CCNE)). At first, the CCNE was only competent for the ethics of medical research. In 1994, it was entrusted with the analysis of all ethical problems that generally arise with the progress of science, until it acquired its current mandate to "*give opinions on ethical problems and societal issues raised by progress in the fields of biology, medicine, and health.*".[177] In fact, this

[175] *See* Jean-Louis Baudouin, *supra* note 171.
[176] France, Order No. 83-132 of February 23rd 1983, providing for the creation of the Comité Consultatif National d'Éthique pour les Sciences de la Vie et de la Santé.
[177] Loi n° 2004-800 du 6 août 2004 *Relative à la Bioéthique*, JO, 7 August 2004, no 276.

committee's mandate was progressively enlarged until it was officially set up as a permanent and non-specialized advisory body.[178]

The CCNE cannot be abolished and uses its broad mandate to carry out two general missions: First, a mission of reflection: The thirty-seven CCNE members work together to reflect on bioethical issues that arise with scientific development, focusing on the fields of health and life sciences. This work often leads to the publication of opinion reports which, albeit non-binding,[179] are brought to the attention of the Ministers of Research and Health and spur particular interest within the French government and parliament. In 2004, the CCNE was officially recognized as an independent administrative authority ("autorité administrative indépendante")[180] and therefore operates independently despite certain institutional ties to the government.[181]

Additionally, the CCNE serves a mission of information[182] as it seeks to educate the public about current bioethical issues and encourages constructive debate.[183] Societal involvement provides a basis for the NEC's analytical work and strengthens general understandings of bioethical issues raised by scientific advances, including novel ARTs.[184] More precisely, the CCNE regularly holds open meetings, polls the public, and communicates transparently on its website.[185] It also organizes "annual ethics days" (états généraux de bioéthique) to host public information sessions and discussion groups on current issues.[186]

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[178] *See* Sophie Monnier, *supra* note 115 at 157, para 247; Claire Ambroselli, "France: A National Committee Debates the Issues" (1984) 14:6 The Hastings Cent. Rep. 20-21.
[179] Studied *infra* Part 2.
[180] Sophie Monnier, *supra* note 115 at 304-306.
[181] Studied *infra* Part 2.
[182] Studied *infra* Part 3.
[183] *See* Comité Consultatif National d'Éthique, "Presentation and History of the CCNE", online: Comité Consultatif National d'Éthique <www.ccne-ethique.fr>.
[184] *Ibid.*
[185] *Ibid.*
[186] *Ibid.*

The creation of the CCNE marked an important event in Europe.[187] As the first national advisory body tasked with the analysis and potential resolution of all bioethical issues arising with progress in scientific research, medicine, biology, and health care, it quickly inspired other European countries:[188] In 1987, Denmark created a bioethics commission, followed by Luxembourg in 1988, as well as Italy and Portugal in 1990. The trend also spread to traditionally reluctant countries, such as Germany, where an independent council of experts was finally created in 2001. Moreover, national bioethics advisory bodies are not a purely European phenomenon, with NECs acting in Argentina, Australia, and the USA. U.S. NECs, in particular, present interesting characteristics to be studied in more detail below.

II. U.S. NECs: A Continuum of Advice

Since 1974, the President and U.S. Congress set up numerous NECs on the federal level[189] to illuminate bioethical issues raised by scientific progress, including assisted procreation, and advise on public policy. Due to federal political and constitutional necessities, the consecutive U.S. NECs follow the temporary ad hoc model that were never meant to last indefinitely. Nevertheless, they were systematically recognized as official sources of advice and their activities form a sort of continuum of bioethical normativity for U.S. policy-makers.[190]

Until the mid-1980s, NECs were solely located within the executive branch of the U.S. government. The first was the National Commission for the Protection of Human Subjects of

[187] Claire Ambroselli, *supra* note 178.
[188] This is a non-exhaustive list.
[189] Similar entities can be found on the state level as the governments of New York and New Jersey established ethics commissions (New York State Task Force on Life and Law & New Jersey Bioethics Commission).
[190] *See* Kathi E. Hanna et al., "Finding a Forum for Bioethics in U.S. Public Policy" (1993) 12:2 Politics and the Life Sciences 205-219 at 206; Kathi E. Hanna, "A Brief History of Public Debate about Reproductive Technologies – Politics and Commissions", *supra* note 135.

Biomedical and Behavioral Research (National Commission), established in 1974.[191] While the Commission was created as part of the Department of Health, Education, and Welfare (DHEW), it operated independently and focused on issues related to research on human subjects as well as the laboratory handling of human embryos.[192]

When the National Commission's term ended in 1978, two recommendations were made: The first prompted the Ethics Advisory Board (EAB) (1978-1979) which focused on the ethics of research on fetal tissue transplantation.[193] The second recommended a National Council for the Protection of Human Subjects as a successor to the National Commission. This failed as Congress concurred and created a national bioethics body with a broader mandate: the first President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (President's Commission) in 1978.[194] Upon presidential request or on its own initiative, the President's Commission could advise different governmental agencies on a broad scope of issues. No longer restricted to research, the President's Commission reflected on various issues arising with medical practice and provided insight into the federal regulation of novel reproductive technologies. As soon as this commission was disbanded in 1983, there was significant push for its reestablishment.

After a period of political controversy,[195] Congress decided to locate the next NEC in the legislative branch and established the Biomedical Ethics Advisory Committee (BEAC) as a congressional body in 1985.[196] Unfortunately, its operations were cut short by 1989 due to political tensions, including sharp division on abortion.[197]

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[191] Established by the National Research Act of 1974, Pub. L. No. 348, 88 Stat 342 (1947).
[192] Studied in more detail *infra* Part 3.
[193] Kathi E. Hanna et al., *supra* note 190 at 206.
[194] The Biomedical Research Extension Act, Pub. L. No.95-622, 92 Stat 3412 (1978).
[195] Kathi E. Hanna, "A Brief History of Public Debate about Reproductive Technologies - Politics and Commissions", *supra* note 135.
[196] The Health Research Extension Act of 1985, Pub. L. No.98-158, 99 Stat 879 (1985).
[197] Kathi E. Hanna, "A Brief History of Public Debate about Reproductive Technologies - Politics and Commissions", *supra* note 135.

Subsequent requests for another President's Commission were effective. Indeed, since the 1990s, every U.S. president (except President Trump) established a NEC: In 1996, the National Bioethics Advisory Commission (1996-2001) was created by President Clinton to examine and advise on topics including human embryo cloning,[198] stem cell research, and research involving human subjects. In 2001, President Bush set up the President's Council on Bioethics (2001-2009), which issued reports on stem cell research, human enhancement, and reproductive technologies. President Obama's 2009 executive order generated the last commission which operated until 2017. While no new commission was established ever since, scholars and decision-makers hope for such an initiative in the near future.[199] Indeed, President Trump was repeatedly urged to call for his Presidential Bioethics Commission.[200]

Acting as intermediaries between society, political authorities, and science, NECs analyze and resolve various bioethical issues that arise with novel technologies. Their overarching purpose is to aid the government and legislature in ensuring that scientific advances rightfully progress with adequate regulation.[201] The next part will depict the functioning of NECs to help clarify how NECs proceed to perform their missions.

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[198] Studied in more detail *infra* Part 3.

[199] *See for instance* Alexander M. Capron, "Building the Next Bioethics Commission", *Goals and Practice of Public Bioethics: Reflections on National Bioethics Commissions*, Special Report (2017) 47:3 Hastings Cent. Rep. 4-9.

[200] *See for instance* Craig Klugman, "Dear Mr. President: It's Time for Your Bioethics Commission" (23 May 2017), online (blog): Bioethics.net < http://www.bioethics.net/2017/05/dear-mr-president-its-time-for-your-bioethics-commission/>.

[201] *See* 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>.

Section 2: Functioning of Selected National Advisory Entities

NECs are set up in different ways to provide guidance to the appropriate authorities on complex policy issues. To ensure a thorough understanding of the functioning of these institutions, it is useful to depict and compare selected NECs. With a broad range of national advisory bodies across the globe, NEC models found in Europe and the USA provoke an insightful comparison on structure (I) and methodology (II).

I. Comparative Structural Analysis

A comparative structural analysis can be drawn from this description of emblematic NECs found in Europe and the USA. It reveals fundamental differences between structural choices in terms of NEC standing (A), institutional affiliation (B), and composition (C).

A. Standing of NECs

While France and most European countries opted for a permanent NEC model, the USA consistently set up ad hoc NECs acting for a limited term.

As both types of commissions perform the same function of advising national authorities, the actual benefit of establishing a permanent instead of an ad hoc committee is subject to debate.[202] It may indeed seem questionable to allow a committee to exist indefinitely as it may artificially create new issues for analysis to ensure continued visibility.[203] However, due to the

[202] Kathi E. Hanna et al., *supra* note 190 at 215.
[203] *See* Sophie Monnier, *supra* note 115 at 156, para 245.

effort and length of the learning and acculturation processes necessary for an ad hoc NEC to function, a rapid dissolution seems wasteful.[204] Furthermore, as novel bioethical dilemmas are still emerging, it seems beneficial for governments to have a NEC in place to which latest problems can be readily referred.[205] NECs, as institutions, also benefit from a long-term existence because this guarantees consistency and credibility for all analytical activities.[206] Permanently set up NECs are actually more visible and exercise stronger authority in the political landscape.[207] Ultimately, NECs with open-ended terms seem to perform their missions more effectively and therefore form the preferable model.[208]

B. Institutional Affiliation of NECs

An additional distinction between NECs stems from the existence or absence of institutional ties with the national government, the legislature, or a political institution through financing, nomination, or other administrative arrangements. These ties suggest a certain political dependence and/or coloring[209] and trigger a question of NEC autonomy.[210]

Most NECs act under the authority of or are sponsored by the government or legislature. In the USA in particular, NECs are placed within U.S. Congress or are directly affiliated to the President. Conversely, the French CCNE is officially recognized as an independent authority, but it is also linked to the legislature and the executive. This link appears in the appointment procedure of its members[211] and the CCNE's composition which includes a member of

[204] Kathi E. Hanna et al., *supra* note 190 at 215.
[205] Alexander M. Capron, "Building the Next Bioethics Commission", *supra* note 199.
[206] Kathi E. Hanna et al., *supra* note 190 at 215.
[207] Jean-Louis Baudouin, *supra* note 171 at 43.
[208] *See* Alexander M. Capron, "Building the Next Bioethics Commission", *supra* note 199.
[209] Sanna Ahvenharju et al., "Comparative Analysis of Opinions Produced by National Ethics Councils – Final Report" (2006) Gaia Group Ltd. at 11.
[210] Jean-Louis Baudouin, *supra* note 171 at 44.
[211] The CCNE's chairman as well as 5 spiritual and philosophical leaders are appointed by the French President; 19 other members are appointed by various leaders from the executive and judiciary branches.

parliament and a senator.[212] It further reports to the Ministries of Health and Research and relies on the National Institute of Health and Medical Research for administrative and technical support.

These institutional ties do not however affect NECs' independent mode of operation. As long as the committee's roles, functions, and authority are expressly established by the legislation under which it is created,[213] it can remain autonomous. Indeed, members reflect on a broad variety of national issues without any political or ideological control.[214]

Balancing NEC autonomy and institutional affiliation is crucial. While political neutrality justifies NEC intervention, some form of institutional affiliation seems almost inevitable as entities that operate in complete independence are not officially and legally recognized sources of bioethical advice for the government or legislature. This is true for ethics committees hosted by non-governmental organizations without any institutional ties to the government or legislature. Although such independent committees are not official sources of advice, their impact should not however be underestimated. With a long tradition of public stands on controversial topics, NGO committees have gained some practical influence on governmental and legislative actions.[215] An example of this is provided by the U.S. National Academy of Medicine (NAM), an arm of the National Academy of Sciences (NAS), which operates as a private NGO. Due to its ability to convene well informed and impartial study committees, the organization is repeatedly commissioned by the federal government to advise on complex ethical issues such as assisted procreation.[216]

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[212] Art. L.1412-2 CSP.
[213] Jean-Louis Baudouin, *supra* note 171 at 44.
[214] Institute of Medicine, *supra* note 52 at 100-101.
[215] Duncan Wilson, *The Making of British Bioethics* (Manchester, UK: Manchester University Press, 2014) at 220-255.
[216] *See* Kathi E. Hanna et al., *supra* note 190 at 206.

C. NEC Composition

Drawing from practical reality,[217] it can be established that NECs typically have many members (22-30 approx.). While a plurality of members is beneficial for meeting attendance, it is important to determine what type of credentials or background are required to allow someone to make decisions on public and controversial bioethical matters.

In fact, efficient selection criteria protect NEC's institutional credibility and help form a membership that is representative of society and not just of organized bioethics.[218] When applied to reproductive technologies in particular, all those with a particular interest in the field should be invited to help develop regulations.[219] It would indeed seem out of touch with reality to simply entrust bioethical issues to individuals who are described as bioethicists.[220] In addition, NEC activity should always be part socialization (appreciation of the problems rooted in experience), and part theory (ethical, legal, and philosophical).[221] Hence, to ensure credibility and efficiency, NECs require a multidisciplinary composition.[222]

Multidisciplinarity is achieved when members represent scientific, medical, theological, ethical, social, economic and legal concerns and ensure an exchange between a variety of ethical approaches and a pluralist spectrum of opinions. Mirroring the discipline of bioethics itself, all fields of knowledge (as well as the opinions of lay people) should be represented to efficiently assess the ethical permissibility of revolutionary techniques from all angles.

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[217] *See for instance* the French CCNE's composition: It has 37 members: 5 members belong to the major philosophical and religious groups and are appointed by the President of France. 16 are selected for their expertise and interest in ethical problems with 2 parliamentarians, 2 representatives of the higher courts, and 12 people chosen by the various ministers concerned with ethical questions. The remaining 15 are researchers selected by their research institutions. All members are appointed for 2 years and half of them are replaced every 2 years.
[218] Kathi E. Hanna et al., *supra* note 190 at 215.
[219] David Adamson, *supra* note 95 at 942.
[220] Kathi E. Hanna et al., *supra* note 190 at 215.
[221] *Ibid*.
[222] Jean-Louis Baudouin, *supra* note 171 at 31.

Removed from the political arena, a plurality of viewpoints also ensures ideological pluralism and free expression of sectoral interests in finding the most acceptable resolution to contemporary issues.[223] In practice, this means that in addition to some bioethicists, members are (mainly) recruited among theoreticians and practitioners in health sciences, the humanities, and law.[224]

II. Comparative Methodological Analysis

After this structural comparative analysis, we aim to outline the commonalities found in the specific methodology applied by NECs in forming an ethical opinion. Far removed from ill-suited legalistic considerations, committees apply a distinctive approach to bioethical issues raised by advances in reproductive medicine.

The process can be summed as follows: Decisions (B) on bioethical subject-matter (A) are made on the basis of consensus (C).

A. Subject-Matter

As discussed above, NECs are generally competent to reflect on a variety of bioethical themes. However, as developments in the field of assisted procreation give rise to a large variety of questions, NEC intervention requires a circumscription.

[223] Kathi E. Hanna, "A Brief History of Public Debate about Reproductive Technologies – Politics and Commissions", *supra* note 135 at 197-225.
[224] Kathi E. Hanna et al., *supra* note 190 at 215.

The analytical activity is often limited by a request for a report on a specific question submitted to the NEC by a governmental body, the legislature, or an academic institution. This does not however affect the general mandate accorded to most NECs. Indeed, committees remain free to choose the specific issue to give an opinion on[225] and form their agendas on the basis of interest or political and/or social urgency. The only countries with NECs limited to a strictly reactive role are Czech Republic and Poland.[226]

B. Opinion Formation

NECs form a public moral judgment on bioethical issues which can be acted on by the relevant authorities and ideally lead to efficient policy. To achieve this, NECs follow specific steps. The first step is the identification and framing of the bioethical issue. As this is often difficult, members focus on the main elements of a given bioethical situation.[227] Only after gathering all relevant facts,[228] committees embark on a conceptual analysis.

An "opinion formation methodology" can be drawn from commonalities found in the specific area of reproductive medicine.[229]

First off, the issues of reproductive medicine exceed traditional bioethical theories.[230] Principlism,[231] for instance, is a dominant theory in bioethics where issues are approached on the basis of four main moral principles (autonomy, beneficence, non-maleficence and justice

[225] Sanna Ahvenharju et al., *supra* note 209 at 12.
[226] *Ibid*.
[227] Avraham Steinberg, *supra* note 13 at 4.
[228] Mary Warnock, "14 Ethics Committees" (1991) 5:3 Bailliere's Clinical Obstetrics and Gynaecology 761–777 at 772.
[229] Sanna Ahvenharju et al., *supra* note 209 at 37; Kathi E. Hanna et al., *supra* note 190 at 207.
[230] Canada, Royal Commission on New Reproductive Technologies, *supra* note 6 at 52.
[231] Tom Beauchamp and Jim Childress, *Principles of Biomedical Ethics* (Oxford, Oxford University Press, 1979).

(sometimes only three principles used – i.e. the Belmont Report)). To remedy the ambiguity of such a principle, it is important to subsequently engage in a process of specification to the particular circumstances of the case at hand. This theory would however be inadequate for NECs. While NECs evoke principles that ought to be followed such as autonomy, avoidance of causing harm, obligation to provide benefits, or fairness and non-discrimination,[232] their role is not to identify the leading moral principle on a given issue.[233] Similarly, the application of an utilitarian calculus[234] would not allow NECs to efficiently advise on bioethical issues. ART regulation, in particular, entails significant uncertainty about who or what should count among the "greatest number" whose interests outweigh all others.[235]

Instead of applying a known ethical theory or a single principle to a given bioethical issue, NECs provide a clear-sighted ethical analysis and draw a unique normative conclusion. Professor A. Capron's "*HEARD Model*"[236] helps summarize NEC methodology as follows:

Novel technologies make it difficult to see what features of a given situation are relevant to moral appraisal. Hence, for a successful analysis, the NEC starts by assembling all competing principles, interests, and viewpoints – the "**H**eritage" of a public bioethical issue. This is achieved thanks to the NEC's multidisciplinary composition which provides insight from various disciplinary fields (theological, ethical, economic, political, legal, medical, biological, and epidemiological).[237]

Once the NEC has established who has an actual interest in the dilemma, it weighs the overall "**E**nvironment", i.e. the context and consequences of scientific activity. This seems easy in

[232] Sanna Ahvenharju et al., *supra* note 209 at 37.
[233] Kathi E. Hanna et al., *supra* note 190 at 215.
[234] Peter Singer, *Practical Ethics* (Cambridge, Cambridge University Press, 1979).
[235] Mary Warnock, "14 Ethics Committees", *supra* note 228 at 774.
[236] Alexander M. Capron, Address (delivered at the Second Session 2 of the 22nd Meeting of the Presidential Commission for the Study of Bioethical Issues, "Reflecting on the Past, Present, and Future of Impact of National Bioethics Advisory Bodies", 31 August 2016) [unpublished].
[237] Institute of Medicine, *supra* note 52 at 1.

theory, but practice reveals that the specific consequences of novel ARTs are difficult to predict as they largely depend on the social and political setting in which the application takes place.[238] As a result, some NECs heavily rely on society as an "**A**udience" to the issue. This means that in addition to a multidisciplinary composition, NECs pursue strong societal involvement in their bioethical analyses. European NECs, particularly the French CCNE, recognize and benefit from public deliberation as a reflection of democratic pluralism and representativity.[239] Conversely, U.S. NECs historically struggle to effectively engage with the public. To remedy this, U.S. scholars have now set the increase of public deliberation as an actively pursued objective for future NECs.[240]

Furthermore, it is insufficient for NECs to find agreement on pragmatic consequences because the issues raised by ARTs require a preliminary determination of the moral status of certain elements such as the human embryo. Torn between sentiment, emotion, and religious attachment on the one side and medical benefit on the other, NECs are ultimately called to apply so-called categorical ethical arguments.[241] These will serve as a premise to all subsequent moral decisions. For instance, once the French CCNE defined the human embryo as an element of humanity (not a mere cluster of cells), it could recommend a set of guidelines for IVF procedures.[242]

Some might expect NECs to deliver certainty and definitive answers as to what constitutes the morally correct view. In truth, no entity is equipped to produce such an answer. Unlike algebra or geometry, bioethics is not an exact science.[243] Nevertheless, the NEC must decide on

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[238] Sanna Ahvenharju et al., *supra* note 209 at 37.
[239] Studied *infra* Part 3.
[240] *See* Amy Gutmann and Dennis Thompson, "Deliberative Democracy Beyond Process" in James S. Fishkin and Peter Laslett, eds, *Debating Deliberative Democracy* (Oxford: Blackwell, 2003) at 31-53.
[241] *See* Veikko Launis, "The Unbearable Lightness of Biomedical Principles" in Peter Herissone-Kelly et al., eds, *Philosophical Approaches to Bioethics* (New York & Amsterdam: Rodopi, 2006).
[242] *See for instance* Comité Consultatif National d'Éthique, Avis n°3, *Les Problèmes Éthiques Nés des Techniques de Reproduction Artificielle 1984* (Paris: La Documentation Française, 1985) ; Comité Consultatif National d'Éthique, Avis n°8, *Les Recherches et l'Utilisation des Embryons Humains In Vitro à des Fins Médicales et Scientifiques 1986* (Paris: La Documentation Française, 1987).
[243] Institute of Medicine, *supra* note 52 at 14.

potential "**R**esponses" to propose in its opinion. For instance, a practice may be considered morally unacceptable and ground a need for legal restriction. As science is quickly evolving, such medico-legal grounds may be inexistent and it is the NEC's role to push for novel legislation and legal standards where appropriate.[244]

In the final "**D**issemination" stage, the committee's working group, which was tasked with the issue, transfers a comprehensive summary of its analysis and list of alternative resolutions to all committee members. This is done in preparation for a subsequent deliberation process and finalization of the NEC's opinion.

Overall, each stage of a NEC's bioethical analysis forms a useful tool for public evaluation and governance of new reproductive technologies.[245] Instead of using "knock-down" arguments, discussion is meant to provide a forum for rational objective analysis and a systematic examination of underlying issues which effectively prepares for sound decision-making.[246] However, as mere conceptual analyses and explanations of possible resolutions to an issue are insufficient for policy-drafting, NECs members ultimately form a singular moral judgment on the basis of consensus.[247]

C. Consensus

When assisting policy-makers, NECs are not only asked to analyze a given question from all angles, they are expected to provide a concrete answer. Only when a single workable course of action is suggested by the NEC, can the advice be useful to policy-makers. With a multitude

[244] *Ibid*.
[245] Kathi E. Hanna et al., *supra* note 190 at 206.
[246] Marc D. Hiller, *Medical Ethics and the Law: Implications for Public Policy* (Cambridge, Massachusetts: Ballinger Publishing Company, 1981) at 7.
[247] Kathi E. Hanna et al., *supra* note 190 at 206.

of possible resolutions to an issue, NECs decide by means of self-imposed working guidelines and an efficient deliberation method which takes all competing interests into account.[248]

Consequently, most NECs function by consensus.[249] Consensus is a specific process which requires all members to unanimously agree. It must be opposed to a majority rule where the view of the majority overpowers any differing view found in a group.[250] Only consensus is appropriate for NECs as it is better adapted to social realities. Indeed, consensus reflects the pluralism found in society and thereby confers democratic legitimacy to the institution as a whole.[251] It would be pointless for a NEC to advise a policy that is bound to fail in later stages.

Conclusion

This analysis highlights the breadth of the institutionalization of bioethical advice. NECs now operate in many countries as advisory bodies to policy-makers regulating novel scientific practices such as reproductive technologies. NECs in Europe and the USA provide useful insight into the functioning of these entities. We note how despite structural differences in terms of standing and institutional affiliation, the advisory role commonly assigned to all national entities is carried out by applying a special methodology. Thanks to a multidisciplinary membership, the committee engages in detailed bioethical analyses before passing moral judgment on the basis of consensus. While commissioners cannot come up with a uniquely "correct" resolution to a dilemma, NEC consultation has become a crucial component to the

[248] Mary Warnock, *supra* note 228 at 768.
[249] Sophie Monnier, *supra* note 115 at 211-212.
[250] Jürgen Habermas, "La Souveraineté Populaire Comme Procédure" (1989) 7 Lignes at 34.
[251] Studied *infra* Part 3.

decision-making process in confronting ethical, legal, and social issues arising from scientific progress.

Chapter 2: Benefits and Prospects of NEC Involvement

Various advantages consolidated the quasi-legal intervention of NECs in the legislative process. This standardized deferral prompts a unique approach to public bioethical issues involving deep ethical analysis and a performative deliberative method. More than a material recourse for policy content formation, NECs' reflection work defuses political tensions about the regulation of reproductive medicine. Indeed, bioethical expertise can instil a sense of trust in the law-making process within society.[252] It ensures that scientific practices and policy proceed with awareness of and sensitivity to ethical considerations. This leaves political authorities in an advantageous position where the responsibility of making contentious policy choices is passed on to a neutral team of experts.[253]

Growing awareness of these benefits has empowered NECs to the extent of exceeding their theoretical advisory powers. While governing laws fix the advice as non-binding, empirical evidence reveals how actual policy decisions for reproductive sciences are often a direct product of NEC opinion reports. Hence, NECs have become active participants in the policy-making process.

This section will start by depicting the benefits of NECs' involvement in the policy-making process (Section 1). With increased recognition of NECs as an asset in the regulation of medical progress, these entities acquired significant practical influence (Section 2).

[252] Camille Bourdaire-Mignot et Tatiana Gründler, *supra* note 84 at 16.
[253] Jean-Louis Baudouin, *supra* note 171 at 49.

Section 1: Resulting Benefits for Policy-Making

Traditional policy-making processes fail to regulate novel reproductive technologies. With a pressing need for guidance, NECs developed as a useful quasi-legal mechanism to tackle the intricacies of the underlying public bioethical issues. This external involvement facilitates policy-drafting on sensitive topics in two main ways: From a material standpoint, bioethical analysis guides the decision-making process by unpacking underlying issues, highlighting crucial values and principles, and ultimately resolving the policy dilemma with an opinion or framework recommendation to follow. Additionally, this process presents a practical political advantage to both the government and legislature as a deferral to objective NEC advice neutralizes political responsibility and backlash.

An analysis of the material benefits of NEC involvement (I) will be followed by an overview of political advantages (II).

I. Material Recourse for Policy-Making

With a standardization of NEC intervention, the following question arises: *To what extent* "*does sustained attention to the moral underpinnings of health care contribute to better policy?*"[254] In other words: '*How does NEC activity contribute to policy-drafting?*'

[254] Kathi E. Hanna et al., *supra* note 190 at 207.

To answer these questions, we draw from Professor S. Hauser[255] identification of clarification (A) and orientation (B) as the dual input of NEC activity.

A. Clarification

First, the reflection work carried out by the NEC helps define and recognize what is important. Public issues that arise in relation to novel ARTs and their attempted regulation pose a variety of sub-issues which require broader analysis through a multitude of viewpoints, prolonged discussions, and deep ethical assessment. Bioethical principles such as dignity, liberty, autonomy, and solidarity must also be incorporated into the rule-making process.[256]
However, policy-makers do not have the capacity or resources to perform this type of analytical work. As underlying bioethical themes outreach the scope of law, a purely legalistic approach fails. These shortcomings explain political authorities' reliance on NEC intervention. NECs enlarge and compliment the policy-drafting process by presenting all relevant ethical considerations in relation to novel assisted procreation practices. By mastering the tools of bioethical reasoning, NECs are able to unpack and explain the bioethical dilemma, provide valuable insight, and suggest a resolution.

The purpose of a NEC's intervention is not to decide for the government or legislator what should or should not be done based on what is good or what is bad. Instead, the goal is to provide the necessary intellectual background to make satisfactory policy decisions.[257]

[255] Steve Hauser, Address (delivered at the Second Session 2 of the 22nd Meeting of the Presidential Commission for the Study of Bioethical Issues, "Reflecting on the Past, Present, and Future of Impact of National Bioethics Advisory Bodies", 31 August 2016) [unpublished].
[256] Camille Bourdaire-Mignot and Tatiana Gründler, *supra* note 84 at 4, para 15.
[257] Jean-Louis Baudouin, *supra* note 171 at 36.

Nevertheless, NECs often provide a helpful and unambiguous ethical framework which effectively orients the development of policy on ARTs.[258]

B. Orientation

Second, NECs serve as a forum to produce an independent national viewpoint of use to national authorities.[259] In accordance with their advisory functions, NECs are expected to decide by means of consensus on a practicable dilemma resolution. Indeed, their opinions orient and effectively push for policy action with concrete indications on how to guarantee ethical decision-making. Ideally, the suggested course of action is picked up by the government or legislature and transformed into concrete policy action. For the product of NEC work to be readily accessible to the relevant authorities, the opinion is published in an opinion report.

There seem to be two main types of opinion reports.[260] First, short opinions in which the NEC simply takes a stance on an issue justified with a few arguments. Second, long opinions which include thorough background information, elaborate ethical analysis, and consideration of future implications. While there is no rule, short opinions are usually produced by committees with less resources.[261] Additionally, some NECs opt for shorter opinions for practical reasons as these seem more likely to be considered by the relevant authorities.[262] However, despite their academic and theoretical tone, longer opinion reports can also have normative aspirations.[263]

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[258] Timothy Caulfield et al., *supra* note 9.
[259] Jean-Louis Baudouin, *supra* note 171 at 31.
[260] Sanna Ahvenharju et al., *supra* note 209 at 12.
[261] *Ibid*.
[262] *Ibid*.
[263] *Ibid*.

Often, NECs add a specific and more pressing recommendation to the general opinion. Recommendations form actual invitations to act, are presented as texts of law amounting to "white papers" or "model laws", and are ready to be submitted as a bill to parliamentary debate or directly enforced by the executive.[264]

Furthermore, when a NEC is asked or decides to provide a bioethical opinion on a given topic, its considerations are typically not limited to the present-time. In fact, the NEC is responsible to account for the future and probable incoming advances in assisted procreation. Even though such issues are not yet pressing, NEC advice often includes reflections about policies that will eventually need to be developed.[265] The hope is to thereby avoid confusion and panic of decision-makers in later stages.[266]

II. Political Tension Reliever

In addition to the material benefits of NEC opinion reports for policy-drafting purposes, this intervention presents considerable political benefits. As studied above,[267] bioethical issues that arise with novel scientific advances, particularly in the field of reproductive medicine, are extremely controversial. Polarization in society triggers political controversy and policy stances always entail significant risk for those in charge. Despite this tension, there is an urgent need for regulation which policy-makers seek to satisfy safely by relying on NEC intervention. Indeed, NECs not only assist by advising on a course of action, they are effectively handling

[264] Reality of NEC powers studied *infra* Part 2.
[265] Jean-Louis Baudouin, *supra* note 171 at 37-38.
[266] *Ibid*.
[267] Studied *supra* Part 1.

political hot potatoes in lieu of decision-makers.[268] With an aura of neutrality and objectivity, NECs provide external validation and reassurance of policy choices and defuse political tension about sensitive bioethical issues that arise with ARTs.[269]

More precisely, deferral to NECs serves as a sign of public concern (A), a source of technical legitimation for policy stances (B), and a guarantee for neutrality (C).

A. Deferral as a Sign of Public Concern

First off, to ease society's apprehension of novel ARTs, it is crucial for a government/legislature to officially recognize the urgency of the underlying issues.[270] A deferral to a NEC serves as a very public indicator of official concern. Assigning a sensitive topic to a special expert committee allows political authorities to reassure the public that it is given prominent attention.[271] According to Professor A. Capron, commissions act as "*a dumping ground for an issue that legislative or executive officials have to appear to treat seriously but really want to dispose of.*"[272]

[268] Lori P. Knowles and Gregory E. Kaebnick, *supra* note 157.
[269] Philippe Pedrot, "L'Influence des Avis du Comité Consultation National d'Éthique sur la Législation" in Brigitte Feuillet-Le Mintier et al., eds, *Les Lois « Bioéthique » à l'Épreuve des Faits. Réalités et Perspectives* (Paris: PUF Collection Droit & Justice, 1999) at 7.
[270] Eric M. Meslin and Harold T. Shapiro, "Some Initial Reflections on NBAC" (2002) 12:1 Kennedy Inst. Ethics J. 95-102 at 97; Alexander M. Capron, "Building the Next Bioethics Commission", *supra* note 199 at 7.
[271] Eric M. Meslin and Harold T. Shapiro, *ibid*.
[272] Alexander M. Capron, "Building the Next Bioethics Commission", *supra* note 199 at 7.

B. Technical Legitimation

Second, NECs act as technical experts in the field of bioethics. Since policy stances on reproductive technologies are systematically criticized in public opinion, NECs' intervention allows political authorities to push back and justify decisions on the basis of technical bioethical expertise. More specifically, this intervention confirms that all appropriate values were applied in the decision-making process and incorporated into the development of a policy.[273] While no choice will ever feel deeply or intrinsically "right", NECs are trusted to bring about the best possible outcome by applying their unique expertise and knowledge.[274]

C. Achieving Neutrality

More than backlash against policy orientations on ARTs, policy-makers encounter significant societal distrust. Society often seems unconvinced that decisions are made in their best interests and suspect all authoritative actions to be primarily driven by political tactics or power play.[275] In this environment, NECs are idealized as neutral policy experts acting above politics and partisanship.[276] Like a "*lightning rod*",[277] the commission absorbs the public policy shock by analyzing a public bioethical issue in an objective manner – focusing on the actual dilemma and offering a practicable resolution.[278] This image of a neutral authority bearing on the

[273] Philippe Pedrot, *supra* note 269.
[274] Bruce Bimber, *The Politics of Expertise in Congress: The Rise and Fall of the Office of Technology Assessment* (Albany, New York: State University of New York Press, 1996) at 6: Bimber's analysis of the OTA can be applied to NECs.
[275] Will Kymlicka, "Moral Philosophy and Public Policy: The Case of NRTs" (1993) 1 Bioethics at 8.
[276] Bruce Bimber, *supra* note 274 at 12.
[277] Alexander M. Capron, "Building the Next Bioethics Commission", *supra* note 199 at 7.
[278] *Ibid*.

complexities of politics[279] is fuelled by NECs' autonomous mode of operation and multidisciplinary composition.[280]

Overall, this deferral of difficult public decisions on reproductive medicine reassures the public that subsequent policies were objectively formed through expert involvement and therefore free from any political aspiration.[281] NECs have become instruments of "*true representative democracy insulated from power politics.*"[282]

Conclusion

The virtues of NEC involvement in the policy-drafting process are increasingly recognized by legislatures and governments worldwide. By applying a unique methodology, NECs produce bioethical opinion reports containing useful and practicable advice. This expert intervention not only helps decision-makers tackle the bioethical intricacies of regulating novel technologies, it also represents political benefits by deflecting public responsibility to a neutral expert. Over time, these entities have grown so successful that they seem to have effectively surpassed their mere advisory functions and gained significant power in orienting policy stances on complex public bioethical issues. Indeed, political authorities tend to make NECs the public face of a country's bioethics policy.

[279] Bruce Bimber, *supra* note 274 at 12.
[280] Will Kymlicka, *supra* note 275 at 8.
[281] Bruce Bimber, *supra* note 274; Christian Munthe, "Controlled Medical Research or Routine Medical Procedure? The Ethics and Politics of Drawing a Line" (Paper presented at the Conference *Are There Ethical Limits to Scientific Research?* held in Neuchâtel, Switzerland, 9-11 October, 1997) [unpublished] at 8.
[282] Bruce Bimber, *ibid* at 12.

Section 3: Increasing Power of NECs

In a democracy, only the elected legislator can produce new laws and the government can issue regulations. Hence, NECs can solely fulfil advisory functions and authorities remain free to apply or ignore the advice published in non-binding NEC opinion reports (I). These entities have however drawn from increased recognition and grown more influential (II). In fact, public authorities pay a lot of attention to bioethical advice and almost systematically incorporate it into law. Thus, NECs have effectively surpassed their symbolic nature to become essential sources of normativity in the eyes of the government, the legislature, and the public.

I. Theoretical Advisory Functions

According to the laws or regulations implementing and governing NECs, these entities intervene in the policy-making process as mere consultants without any authoritative or normative power. They advise on complex bioethical issues and suggest a course of action. Limited to strictly advisory functions, their advice is never binding and there is no obligation for authorities to follow it. For instance, according to the letter of French law,[283] the CCNE can merely advise on ethical problems and social questions that arise with scientific advances in the areas of biology, medicine and health. The CCNE acts as a non-authoritative mechanism producing non-binding advice. Indeed, French policy-makers always remain free to decide whether they choose to incorporate a NEC opinion entirely, only partially, or choose to ignore it entirely.[284]

[283] Loi n° 2004-800 du 6 août 2004 *Relative à la Bioéthique*, JO, 7 August 2004, no 276.
[284] Comité Consultatif National d'Éthique, *Rapport Éthique et Recherche Biomédicale 1984* (Paris: La Documentation Française, 1985) at 13.

A second example is provided by the U.S. law implementing the President's Commission.[285] Unlike the French CCNE, the President's Commission was granted "action-forcing authority". Accordingly, its intervention did not end with a mere suggestion, but obliged the receiving department or agency to publish the recommendations in the Federal Register and accept written comments on them from members of the public within sixty days. Then, within hundred-eighty days of this publication, the department or agency had to "*provide the Commission with, and publish in the Federal Register, a notice of* [its] *determination including an adequate statement of the reasons for the determination*" either to take the recommended steps or explain why such action was inappropriate.[286] Thus, although governmental authorities needed to be prepared to justify a refusal of advice, the Commission's opinion was not binding and could never actually be enforced.[287]

Furthermore, no type of NEC advice can affect policy-makers' freedom. Opinion reports typically contain a general opinion and occasionally include a specific recommendation. The opinion forms more of a consultative answer to a question, while the recommendation amounts to a more pressing invitation to act. Regardless of the degree, NECs never order, nor prescribe, nor oblige to anything.[288] In fact, NECs' analyses simply contribute to the general flow of ideas and cannot amount to legislation to be enforced.[289]

Significantly, this restriction to advisory functions is meant to benefit NECs.[290] These entities are known to act out of pure moral judgment and draw authority from technical expertise,

[285] The Biomedical Research Extension Act, Pub. L. No.95-622, 92 Stat 3412 (1978).
[286] The Public Health Service Act, Pub. L. No.95-622, 92 Stat 3412 (1978) §1802(b)(2).
[287] Alexander M. Capron, "Building the Next Bioethics Commission", *supra* note 199 at 8.
[288] Jean Michaud, *Rapport de la Cour de Cassation* (Paris: La Documentation Française, 1998) at 13.
[289] Anne Fagot-Largeault, "Les Liens des Comités Locaux avec le Comité Consultatif National d'Éthique" (1986), 6 Lettre d'Information du CCNE at 2.
[290] Jean Bernard, quoted in Comité Consultatif National d'Éthique*, Rapport Ethique et Recherche Biomédicale 1986* (Paris: La Documentation Française, 1987 at 231.

competence, and reputation. If NECs were to act as a "*supreme court of science whose opinions have force of law*"[291] or a supreme adjudicator of bioethical issues, they would lose all credibility and authenticity. A recognition of authoritative political power would pervert the institutions and should therefore be avoided.

II. Actual Powers - De Facto Powers

Despite the theoretical and legal restriction to mere advisory functions, NECs have gained significant influence and largely shape policy stances.[292] This observation leads to the following question: '*How have NECs secured a strong practical influence on policy-makers?*'

We will complete our analysis of the practical influence exercised by NECs (A) with an empirical study (B) drawing links between NECs opinion reports and actual policy stances found in Europe and the USA on a selection of topics, namely access to artificial insemination (AI), surrogacy, and human cloning.

A. Practical Influence of NECs

In practical reality, NECs exercise a certain normative authority. While it cannot amount to legal authority in terms of effectiveness, it does "prepare" the law.[293] Indeed, the work of the NEC often forms the first step towards the creation of a legal rule.

[291] Jean-Louis Baudouin, *supra* note 171 at 36.
[292] Brigitte Feuillet-Le Mintier et al., *supra* note 51 at 27.
[293] *Ibid*.

A primary factor contributing to the practical power of NECs is political disorientation in the face of complex public bioethical issues. As described above, traditional processes fall short in regulating novel advances which leads policy-makers to readily accept and incorporate external advice. Even when the NEC's opinion does not match the current political or social landscape, practical reality reveals that potential reluctance is typically overcome and expert advice is ultimately incorporated into law.

The wording of reports is revealing in this regard as it confers seemingly normative authority to NECs.[294] Indeed, with a concise and imperative voice, the opinions resemble judicial opinions. The organization of the reports also follows that of a legal syllogism – beginning with a factual context, followed by an analysis of the specific bioethical issue, and ending with a potential resolution.[295] Additionally, just like a legal or judicial decision, NEC opinions are always published.[296]

Furthermore, NECs draw from technical expertise to establish an aura of moral authority. Although the concept of expertise in bioethics is subject to debate,[297] NECs have a strong multidisciplinary composition and distinctive methodology which grants them knowledge and experience to tackle bioethical dilemmas in a comprehensive and useful way. This ability to perform moral judgments gives NECs considerable symbolic authority.[298] It would indeed seem wrong to ignore the ethically sound course of action that was formally outlined by a specialized committee.[299]

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[294] Sophie Monnier, *supra* note 115 at 262, para 466.
[295] *Ibid*.
[296] *Ibid*.
[297] Studied *infra* Part 3.
[298] Alexander M. Capron, Address, *supra* note 236.
[299] Comité Consultatif National d'Éthique and Lucien Sève, *Recherche Biomédicale et Respect de la Personne Humaine* (Paris: La Documentation Française, 1988) at 66.

Finally, NEC opinions are published and thus readily accessible to the public and subject to strong media coverage. Whether the NEC answers a special request or acts on its own initiative, the advice is explicitly directed at decision-makers. This direct address grounds a clear expectation for the advice to be effectively reflected in law. Hence, subsequent legislative frameworks are closely scrutinized and political authorities will be held accountable for their policy choices. Fearing the societal backlash that the neglect of expert advice would entail, policy-makers tend to reflect the orientation suggested by the NEC in law. Public opinion therefore strongly contributes to the practical power of NECs.

B. Empirical Study

As NECs' activity is continuously evolving, it is impossible to provide a full impact assessment.[300] Nevertheless, a plausible measure of NEC influence can be outlined by weighing NEC advice against subsequent legislative activity[301] in the field of ARTs in selected jurisdictions.[302]

For clarity and conciseness, this study is limited to a selection policy stances on public bioethical issues that were clearly driven by preliminary NEC advice. In Europe (1), this includes advice on access to AI and surrogacy issues, and, in the USA (2), this involves input on the handling of human embryos and cloning restrictions.

[300] Since legislation in this field in many countries has been passed in the last or even earlier decade, recent reports from some countries are not even available.
[301] In many countries assisted reproduction is regulated by legislation instead of regulation.
[302] Tom Murray, Address (delivered at the Second Session 2 of the 22nd Meeting of the Presidential Commission for the Study of Bioethical Issues, "Reflecting on the Past, Present, and Future of Impact of National Bioethics Advisory Bodies", 31 August 2016) [unpublished].

1. Europe

A look at legislation passed in the field of reproductive medicine reveals a tendency to follow NEC advice. Indeed, most countries allow ARTs and welcome new reproductive techniques, but incorporate some NEC-proposed limitations into public policy.

An example of this is provided by French law governing access to AI. In France, AI was limited to heterosexual infertile couples for many years. However, with the acceptance of same-sex marriage and decreased stigma around single parenthood, this limitation was increasingly questioned. Hence, in 2017, the CCNE pushed against this historical reluctance and deemed both options desirable and requested a change in legislation.[303] This orientation was successful: The French law on bioethics was scheduled for amendment in 2019 and the modification proposal entailed an extension of assisted procreation to same-sex female couples and single women. On October 15th 2019, broader access to AI was first voted in Parliament and the bill was adopted by the Senate on February 4th 2020 and now awaits final examination and promulgation by Parliament.[304] This process clearly reveals the CCNE's influence on the legislature. Indeed, the commission's recommendation inspired the French political authorities to make a change and satisfy a growing demand for AI.

Another example is provided by the handling of public bioethical issues posed by surrogacy agreements. European NECs have often addressed the issue of surrogacy agreements:[305] Due

[303] Comité Consultatif National d'Éthique, Avis n°126, *Sur les Demandes Sociétales de Recours à l'Assistance Médicale à la Procréation (AMP) 2017* (Paris: La Documentation Française, 2018) at 18-26.
[304] Projet de loi n°2187 du 24 juillet 2019 *Relatif à la Bioéthique*.
[305] *See for instance* France, Comité Consultatif National d'Éthique, Avis n°110, *Relatif aux Problèmes Éthiques Soulevés par la Gestation Pour Autrui (GPA)* 2018 (Paris: La Documentation Française, 2019); Luxembourg,

to socio-ethical reasons including the psychological and biological costs of pregnancy, possible conflicting interests of natural and genetic mothers, as well as the threat of surrogate motherhood becoming commercialised, many commissions deem surrogacy unacceptable and with the result that subsequent legislation effectively banned the practice.[306]

However, a problem arises with cross-border practices. Indeed, many couples from restrictive jurisdictions travel to a permissive jurisdiction to conceive a child through surrogacy before returning to their home country where they ask the state to recognize a filiation through adoption. For years, restrictive jurisdictions such as Luxembourg have extended their general rejection of surrogacy and refused to officially recognize these children as citizens. In 2016, the Luxembourgish Ethics Commission condemned this legislative refusal and pointed to an inequality between children. While a ban on surrogacy is deemed necessary, states have a duty to recognize cross-border surrogacy arrangements and protect the interests of resulting children.[307] This recommendation was heard by the Luxembourgish legislator: In 2017, a bill[308] was proposed, which specifically allows the recognition of children born from a foreign surrogacy agreement but residing in Luxembourg.

2. USA

In the USA, evidence can first be drawn from the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission), which dealt with the ethics of research generally and specifically analyzed laboratory practices involving the human embryo. The 1975 report, "*Research on the Fetus*" formed the basis for later

Commission Nationale d'Éthique, Avis 26.2016, *PMA, GPA, Accouchement Anonyme : Autant de Défis Éthiques Pour la Société* (Luxembourg: Commission Nationale d'Éthique, 2016).

[306] France, Germany, Luxembourg, and Italy ban surrogacy.

[307] Commission Nationale d'Éthique, Avis 26.2016, *supra* note 309.

[308] Luxembourg, Projet de loi n°6568 du 25 avril 2013 *Relatif à la Réforme du Droit de la Filiation*.

regulations[309] on research and assisted procreation practices, specifically IVF, which require extensive laboratory handling of embryos. While the Commission did not define the status of the embryo or fetus, it recognized its genetic heritage and vulnerability and affirmed that it should be treated respectfully and with dignity, regardless of its life prospects. These recommendations largely translated into subsequent policies on assisted procreation practices in the USA.[310]

Furthermore, the National Bioethics Advisory Commission (NBAC) published significant analyses on human cloning practices upon a request formed by President Clinton in 1997.[311] The issues at stake included safety concerns, individuality, family models, reification of children, and human dignity. These were weighed against individual desires of reproduction and the medical fight against infertility. The Commission concluded that the use of this technique for procreation purposes would expose the fetus to unacceptable risk and open the door to a form of eugenics. Deeming reproductive cloning practices overall unethical, the Commission recommended public policies that prohibit the creation of children through cloning in both federal and privately funded sectors.[312]

President Clinton forwarded a bill to Congress based on that recommendation.[313] This bill was followed by others, but due to constitutional challenges,[314] none achieved the recommended nationwide ban on cloning. Nevertheless, even without a federal prohibition on human cloning, the NBAC's advice contributed to a widespread agreement that cloning-to-produce children should be prohibited and may not be endorsed by the federal government. Hence, all federal

[309] 45 CFR §46, SubPart B (2009).
[310] *Ibid*.
[311] U.S. National Bioethics Advisory Commission, *Report on Cloning Human Beings* (Rockville, MD: U.S. Government Printing Office, 1997) [Cloning Human Beings Report].
[312] *See* Harold T. Shapiro, (Letter to President Clinton, June 9, 1997), reprinted in the Cloning Human Beings Report.
[313] *See* US, Bill HR, *Cloning Prohibition Act of 1997*, 105th Cong, 1997.
[314] Lori B. Andrews, "Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning" (1998) 1:3 Harv. J.L. & Tech. 647-676.

funding of human cloning is strictly prohibited[315] and many states prohibit the practice through state healthcare regulation.[316]

Conclusion

The goal here is not to draw comparisons between the various ethical statements and resultant laws on specific issues related to reproductive medicine. Instead, this analysis aims to highlight the widespread and commonly recognized effectiveness of NEC intervention for policy-drafting. While there are exceptions to this phenomenon (i.e. in the context of embryo research in the USA where the advice of NECs was not followed), the argument of this section draws from European and American laws on AI, surrogacy, and cloning, which were largely shaped by NECs' opinions and recommendations. Even when the advice is not wholly incorporated, laws in the area of assisted procreation typically follow the general orientations of NECs' opinion reports. Political authorities clearly depend on bioethical advice to draft policies on the public bioethical issues raised by these practices. Similarly, this reliance on expert intervention is equally strong concerning other assisted procreation practices as well as other scientific practices raising bioethical issues (such as medically assisted dying or genome mapping). Empirical evidence almost systematically reveals a strong resemblance between NEC opinion reports and legal stances on bioethical subject-matter.[317]

Increased reliance on NECs further reveals a widespread attempt to make ethics a source of law. By intervening in the preliminary stages of law-making, NECs ensure the integration of

[315] *See* Transcript of Clinton Remarks on Cloning, U.S. Newswire (1997) *available in* 1997 WL 571115; *See also* US, Bill HR, *Cloning Prohibition Act of 1997*, 105th Cong, 1997; US, Bill HR, *Human Cloning Prohibition Act*, 105th Cong, 1998, s 1574; US, Bill HR, *Prohibition on Cloning of Human Beings Act of 1998*, 105th Cong, 1998 s 1602.

[316] Seven states – Arizona, Arkansas, Michigan, North Dakota, Oklahoma, South Dakota, and Virginia – ban all forms of human cloning.

[317] Sophie Monnier, *supra* note 115 at 484, para 880.

ethical principles and norms into the regulation of novel scientific advances.[318] NECs represent the perfect tool for pluralist democracies striving for a "complimentarity" between ethical and legal normativity[319] and a new and improved form of democracy.[320]

However, the magnitude of this *de facto* power has triggered a doctrinal debate and scholarly scrutiny of the legitimacy of NECs' external involvement in the decision-making process.[321] While some remain convinced that the source of law must not be diversified, others perceive benefits from this new form of democracy. The next part will analyze this debate and demonstrate the overarching effectiveness of NEC intervention.

[318] *Ibid*.
[319] Philippe Pedrot, *supra* note 269 at 7.
[320] Studied *infra* Part 3.
[321] Controversies studied *infra* Part 3.

PART III: OVERARCHING VALUE OF BIOETHICAL EXPERTISE

The recognition of normative activity of NECs revolutionized traditional legislative mechanisms and became the subject of scholarly scrutiny. More specifically, controversy arises with the following question: '*Does the quasi-legal intervention of NECs in the legislative process harm or benefit modern democratic societies?*' In the responses of the literature, two main conflicting positions can be identified: First, the intervention of NECs is heavily criticized. A number of scholars[322] denounce an unjustified interference in the legislative process and thereby fuel an atmosphere of hostility towards NECs. Second, a defense of expert involvement arises with scholars praising NECs as valuable instruments for efficient policy-making.

Taking the latter view, this thesis aims to rebut concerns around NEC intervention and demonstrate the overarching effectiveness of quasi-legal advisory entities for policy-making in the scientific field. This argument is further supported by authorities' practical dependence on quasi-legal expertise to resolve bioethical intricacies and help bring about operative regulatory frameworks.

Finally, this study goes beyond a mere rebuttal of scholar criticism as we address the conceptual, yet profoundly democratic, changes for governance brought about by the involvement of NECs in the legislative process.

The first section of this part will review the main elements of criticism found in the literature against NEC involvement in the legislative process. Each argument will be met with a counter-

[322] *See* Klaus P. Rippe, *supra* note 7 at 31.

argument to discredit concerns (Chapter 1). This systematic dismissal serves the next section which will reveal the modernization of governance triggered by NECs (Chapter 2).

Chapter 1: Overcoming Challenges of Expert Involvement in Policy-Making

While the intervention of multidisciplinary expertise is particularly significant in the bioethical field, it constitutes a wider phenomenon. It is therefore useful to apply the teachings of general scholarly scrutiny of external involvement[323] in the legislative process[324] to the specificities of the bioethical field.[325] Many scholars criticize the deferral process and denounce the growing reliance of political authorities on theoretically non-binding advice.[326] More specifically, the *de facto* power of advisory entities is contrary to traditional conceptions of democracy where any exercise of authority draws legitimacy from citizen vote. These scholars do not want the source of law to be diversified and alert to the unjustified replacement of the democratically elected legislator. Evidently, NECs fall short of such positivist or formalist expectations (Section 1).

In addition to disapproval of the whole deferral process, scholars challenge the specific aptness of commissioners in terms of technical expertise and the preservation of political and/or religious neutrality. Partisanship would pervert bioethical analyses and impede the forging of consensus (Sections 2&3).

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[323] Commissions are often asked to provide expertise in matters of pure science and/or medicine.
[324] *See* Frédéric Zénati, *supra* note 10 at 109; Laurent Cohen-Tanugi, *supra* note 10 at 182; Bruce Bimber, *supra* note 274.
[325] *See* Carl Schneider, "Bioethics in the Language of Law", *supra* note 11; Dominique Thouvenin, *supra* note 11; Sandrine Maljean-Dubois, *supra* note 11 at 87.
[326] *See* Frédéric Zénati, *supra* note 10 at 109; Laurent Cohen-Tanugi, *supra* note 10 at 182; Bruce Bimber, *supra* note 274.

In this hostile environment, the following questions arise: '*Does active NEC involvement represent an unjustified interference in the policy-making process? Alternatively, can challenges be overcome to pave the way for a new and improved form of democracy?*'

To serve the argument of this thesis, challenges to NEC involvement will systematically be discredited to prove the overpowering value of bioethical expertise for regulatory frameworks for innovation in reproductive sciences.

Section 1: Democratic Legitimacy Debate

The reality of the power exercised by NECs in the decision-making process triggered scholarly scrutiny of the democratic legitimacy of such external involvement. While some authors perceive benefits from this intervention, others remain convinced that the source of law must not be diversified.

This part will focus on the latter argument which portrays NECs' involvement in policy-drafting as an unjustified interference (I). Although such concerns are valid, they can effectively be challenged (II).

I. Rejection of an Unelected Authority in the Legislative Process

According to traditional conceptions of democracy, a principle of popular sovereignty must be respected. Hence, for the source of power to remain with the people, any authority-exercising entity must be democratically elected.

As studied above,[327] NECs exercise considerable influence. These entities gained a strong practical power and actively shape new laws in the medical field. However, despite a transformation of NEC opinion reports into an actual source of normativity, the functioning of these entities lacks traditional guarantees of democratic legitimacy.

In the face of this transformation, some authors[328] raise the following question: "*Is it appropriate to remove the issues associated with reproductive [medicine] from the oversight of democratically elected officials?*"[329]

Drawing from positivist[330] or formalist[331] theories, scholars, such as Klaus P. Rippe,[332] alert to the unjustified replacement of the democratically elected legislator. Since the people asserted their sovereignty when they freely elected the legislator, law-making must be reserved to the representatives in parliament.[333] Accordingly, NECs appear as inefficient "*pseudo-mini-parliaments*"[334] and their intervention in the legislative process is unjustified. This is because commissioners are unelected and appointed. Further, even though NECs aim for representativeness in their composition, this is very different from traditional understandings of political representation. Selection criteria for commissioners aim for knowledge, experience, skill, and a representation of dominant interest groups in society. Not only can this be perceived as elitist, it also fails to guarantee a universal representation of citizens.[335] Clearly, these entities do no benefit from the type of democratic legitimacy that grounds the authority of traditional

[327] Studied *supra* Part 2.
[328] *See* Timothy Caulfield et al., *supra* note 9 at 416.
[329] *Ibid*.
[330] H.L.A. Hart, *supra* note 79.
[331] Frederick Schauer, "Formalism" (1988) 97:4 Yale L. J. 509-548.
[332] Klaus P. Rippe, *supra* note 7 at 31.
[333] *See* Bruce Bimber, *supra* note 274 at ix.
[334] Klaus P. Rippe, *supra* note 7 at 31.
[335] Sophie Monnier, *supra* note 115 at 182, para 302.

democratic institutions by means of free elections. As a result, politicians may feel uncomfortable to give up their regulatory powers to an external committee.[336]

Furthermore, the need for expert advice in a democratic creation of legislative frameworks is subject to controversy. Kathi E. Hanna challenges the reliance on NECs by raising this question: "*How could legislators or citizens retain firm control of the reins of social enterprises like government when experts held sway over society's most essential knowledge—the reach and limits of its technology?*"[337] Even though elected officials always retain the authority to exercise power over NECs – by disregarding their advice, or making policy during a commission's time of deliberation – the previously outlined impact of quasi-legal advice is democratically questionable. According to the literature, a systematic deferral to NECs, renders sensitive subject-matter inaccessible to elected political authorities. Expertise should however not be transposed into political power and the ultimate policy tune must be called by the legislator. Knowledge on a specific topic can never be so vast that only specialized experts can provide guidance. Such an affirmation would not only diminish the role of the legislator, but also destabilize the fate of democracy as a whole.[338]

[336] Timothy Caulfield et al., *supra* note 9 at 416: In the USA specifically, this discomfort translated into a reluctance to establish NECs.
[337] Kathi E. Hanna and the U.S. Institute of Medicine, *supra* note 96 at 326.
[338] *Ibid.*

II. Counter-Argument: No Threat to Democracy

Concerns around the lack of democratic legitimacy of NECs' involvement are valid.[339] The functioning of these entities undeniably differs from traditional democratic political institutions. However, the specificities of NECs should not be decisive and discredit the overall input of these institutions. As long as there is sufficient transparency in the institutional process as well as continued oversight and accountability by elected officials, the power of NECs can effectively be checked and balanced. [340]

Finally, NECs pose no threat to democracy as public policy persistently stands upon a foundation of the public will.[341] Although policy drafting in sensitive arenas such as reproductive medicine is facilitated and largely oriented by NECs' advice, the government and legislator remain the ultimate sources of authority. This is primarily because NECs only receive mandating authority through governmental decree or legislative act. They are also restricted to a specifically defined sphere of competence or jurisdiction. Hence, despite an undeniable degree of practical influence, final policy decisions remain in the hands of the legislature.[342]

Section 2: Bioethical Expertise Debate

The involvement in the legislative process of NECs, and the appointed commissioners specifically, cannot be justified as the expression of the will of the people determined by means

[339] Timothy Caulfield et al., *supra* note 9 at 416.
[340] *Ibid.*
[341] *See* Bruce Bimber, *supra* note 274.
[342] Lucien Sfez, "Science et Pouvoir: La Question des Experts", in Lucien Sfez et al., eds, *Système et Paradoxe : Autour de la Pensée d'Yves Barel* (Paris: Seuil, 1993) at 169.

of free elections. Nevertheless, the practical influence of these entities stems from an expectation of technical expertise in the field of bioethics.[343] Indeed, due to their expert composition, NECs are considered to be best placed to guide human contact through novel scientific advances and orient policies in this arena.

In the face of this reliance on NEC advice for the regulation of scientific advances, scholars[344] question the general concept of expertise and challenge the specific bioethical expertise of commissioners acting on NECs. This type of argumentation aims to invalidate the current level of quasi-legal participation in the legislative process (I), but can be dismantled as a product of a misunderstanding of bioethical expertise (II).

I. Scepticism Around Bioethical Expertise

The concept of expertise in bioethics is widely rejected.[345] Indeed, there can be no individual expert in bioethics as no single person can be given the authority to distinguish right from wrong. This type of criticism is regularly directed at individual bioethicists which put themselves out to be experts in the field after years of practical training and/or academia.[346]

Concerning NECs, it is important to remember that the multidisciplinary membership is comprised of only a limited number of bioethicists acting alongside practitioners and scholars from a variety of disciplines including theology, law, sociology and ethics, as well as some laypeople.[347] It is from this distinctive composition that these entities strive for expertise in the field of bioethics, not from proficiency in moral philosophy.

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[343] Studied *supra* Part 2.

[344] Luc Ferry, "Tradition ou Argumentation? Des Comités de "Sages" aux Comités de Délibération" (1991) 56 Pouvoirs 5-21 at 17; Hubert Doucet, *Au Pays de la Bioéthique, L'Éthique Biomédicale aux États-Unis* (Geneva: Labor et Fides, 1996) at 184.

[345] Mary Warnock, "14 Ethics Committees", *supra* note 228 at 772.

[346] *Ibid*.

[347] NEC Composition studied *supra* Part 2.

Nevertheless, some scholars extend their general disdain for the discipline of bioethics to the bioethical expertise attributed to NECs. Just like there can be no individual expert in bioethics, there can be no class of individuals specially qualified to pass the kind of moral judgments provided by NECs.[348] Without such thing as a truth to be imposed in bioethical dilemmas,[349] many authors perceive these issues as matters of personal judgment.[350] Hence, NEC opinions should not be portrayed as the single national voice on bioethics expressed by a group of a "*bioethics elite*".[351] There can be no single solution in bioethics and a group of carefully selected individuals cannot come up with the rightful resolution to public issues. NEC opinions are perceived as a mere formulation of one possible course of action for a public bioethics issue. By voiding the technical expertise of these entities, their intervention and practical influence seems unjustified. In other words, as expertise in bioethics is considered inexistent, there is no reason for the advice of NECs to be systematically followed by political authorities.

II. Counter-Argument: Underlying Misconception of the Concept of "Expertise"

It seems clear that no individual or group of individuals can rightfully assert absolute authority as the voice of truth in bioethics. Nevertheless, the disdain for the concept of expertise in this field stems from a misunderstanding. In truth, bioethical expertise should be understood as expertise based on the existence of a particular ethics skill and knowledge.[352]

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[348] Mary Warnock, "14 Ethics Committees", *supra* note 228 at 772.
[349] *See* Jean-Louis Baudouin, *supra* note 171.
[350] Luc Ferry, *supra* note 344 at 17; Hubert Doucet, *supra* note 344 at 184.
[351] Kathi E. Hanna et al., *supra* note 190 at 214.
[352] Yvette Lajeunesse and Lukas K. Sosoe, *Bioéthique et Culture Démocratique* (Montréal & Paris: Harmattan, 1996) at 213.

When applied to NECs, this definition helps clarify that these entities do not aspire to any moral authority, instead they exercise actual bioethical expertise.[353] This expertise refers to commissioners' expert skill and knowledge in terms of bioethical theory and analytical method.[354] Indeed, as Mary Warnock explains, NECs' "*authority is that of the considered view based on the fullest information available and formulated without undue haste*."[355] Due to their characteristic multidisciplinary composition, commissioners draw from an array of backgrounds to give reasoned and complete consideration to the questions submitted to them. NEC members are also well-informed about novel technologies and have both the analytical tools and the time to understand and resolve complex problems.[356] This clarification of analytical skill exercised by NECs for bioethical subject-matter provides for a new and more appropriate understanding of the concept of expertise in the field. Hence, the systematic deferral to NEC advice can be justified. Lacking the knowledge and the time, political authorities rely on NECs to understand the bioethical intricacies posed by public policy on medical innovation.

Section 3: Neutrality Debate

One of the main justifications for NEC involvement in the regulation drafting process for novel medical technologies is an expectation of neutrality.[357] Far-removed from the political arena and composed of a multidisciplinary team of experts, it is often assumed that these entities are equipped to provide objective advice. This neutrality is sought for decision-making on sensitive

[353] Alastair V. Campbell, "Committees and Commissions in the United Kingdom" (1989) 14:4 J. Med. Philos. 385-401 at 392.
[354] Mary Warnock, "14 Ethics Committees", *supra* note 228 at 775.
[355] Mary Warnock, *A Question of Life* (Oxford, UK & New York, NY, USA: John Wiley & Sons, 1985) at 96.
[356] Bruce Bimber, *supra* note 274 at 2.
[357] Studied *supra* Part 2.

issues arising with novel medical technologies. However, because NECs work on highly controversial topics, this controversy can reflect internally among members of the body. Such repercussions pushed some authors[358] to question NECs' aura of neutrality. More specifically, the bioethical analyses and subsequent policy recommendations are suspected to be biased by the political or religious ideology of commissioners.

Although bias can never be entirely avoided on advisory panels (I), it can be overcome as long as members present sufficient ideological flexibility (II).

I. Bias and Partisanship Suspicions in NECs

Unlike purely scientific expert panels, which provide factual recommendations, it is more difficult for bioethics commissions to be (or be seen to be) neutral.[359] These commissions engage with factual matters of science, law, and economics, as well as value questions of ethics. Hence, scholars, including Alastair V. Campbell,[360] legitimately raised the following question: "*Are such advisory committees a source of dispassionate and non-partisan advice?*"

Commissioners are undeniably exposed to certain forms of bias which could strip NECs of their aura of neutrality. Partisanship in NECs creates a risk of ideological coloring of resulting policy recommendations (A) and, in more extreme cases, it can block the commission's consensus-based deliberations (B).

[358] Christian Munthe, *supra* note 281 at 8.
[359] Eric M. Meslin and Harold T. Shapiro, *supra* note 270 at 100.
[360] Alastair V. Campbell, *supra* note 353 at 387.

A. Neutrality-Perverting Bias

As long as the commission is bound to a mission of pure bioethical analysis, its neutrality is easier to preserve. However, with NECs being transformed into policy-making bodies the problem of manipulation and bias arises.[361]

These entities are often exposed to political (1) and/or religious bias (2) which could distort the NEC's activity (3) and subsequently impact policy stances on sensitive topics, including novel reproductive technologies.

1. Political Bias

NECs are meant to act above politics and the tactical power play it involves.[362] Due to their multidisciplinary composition, distinctive methodology, and analytical skill NECs are expected to serve as a neutral authority to bear on policy.[363] This aura of neutrality largely justifies their intervention and serves as legitimation of controversial policy stances.

Despite this general aspiration for impartiality in bioethical deliberation, some authors[364] contend that these entities are exposed to a risk of expert politicization. In other words, it is by no means certain that the decision-making of a NEC will not be vulnerable to political tactics.[365] Concrete evidence of this politicization is provided by cases of correspondence

[361] Christian Munthe, *supra* note 281 at 8.
[362] Bruce Bimber, *supra* note 274 at 12.
[363] *Ibid* at 4-5.
[364] *See* Institute of Medicine, *supra* note 52 at 14; Christian Munthe, *supra* note 281 at 8.
[365] Christian Munthe, *ibid.*

between experts' agendas and political agendas.[366] The results of the expert intervention are then predictable in their support for a particular political position.

A potential politicization of bioethics commissioners can be traced back to a variety of factors: First, members may have some kind of personal political interest or predisposition which orients their positions during deliberations.[367] This bias is further fuelled by a tendency of governments as well as the legislator to favor opinions of experts who share the current political power's preferences.[368]

Second, NECs with a significant affiliation to the legislature or government have a stronger tendency toward a politicization of members.[369] For instance, due to its links to the executive power, the U.S. Presidential Commission for the Study of Bioethical Issues struggled with political bias of members and sustaining its independence. The NEC was therefore accused of providing false assurance on bioethics policy stances taken in relation to scientific advances.[370] The U.S. example further reveals how the traditionally short term of ad hoc NECs amplifies detrimental politicization tendencies.[371] Indeed, the standing of these commissions is intrinsically linked to politics as they are often disbanded and recreated with the tide of political elections.

Third, there is a risk of diversion and capture of commissioners by advocacy and/or sectarian groups, or by financially self-interested parties.[372] Even though the input of such groups can be

[366] Bruce Bimber, *supra* note 274 at 15.
[367] Kathi E. Hanna, "Whose Advice? Expert Committees Get a Makeover" (2002) 32:6 Hastings Cent. Rep. 13.
[368] *Ibid*.
[369] Bruce Bimber, *supra* note 274 at 15.
[370] Jonathan Montgomery, Address (delivered at the Second Session 2 of the 22nd Meeting of the Presidential Commission for the Study of Bioethical Issues, "Reflecting on the Past, Present, and Future of Impact of National Bioethics Advisory Bodies", 31 August 2016) [unpublished].
[371] Alexander M. Capron, Address, *supra* note 236.
[372] Institute of Medicine, *supra* note 52 at 14.

an important asset for NEC deliberations, this possibility must be carefully monitored.[373] Indeed, NEC studies on any given public bioethical policy problem must stem from disinterested analysts. Members should act as actual experts and avoid intervening as highly informed advocates.[374] If an opinion is the product of advocates "cloaked" in the authority of expertise, the advice has no value and could even be counterproductive.[375]

2. Religious Bias

The issues arising with advances in reproductive medicine are often heavily intertwined with religious belief systems. While bioethical reasoning must not be directed by religion, it can draw from it. This is because, even in secular countries, certain groups in society have strong religious attachments, which cannot simply be ignored. Hence, NECs are expected to incorporate religious considerations into their analyses to render well-thought-out and inclusive opinions.[376] For a complete representation of all viewpoints found in society, the membership of NECs (e.g. France) therefore includes representatives of the country's main religious orientations.

However, evidence shows that the views defended by religious commissioners are likely to be held with great confidence and tenacity and effectively silence any other view.[377] Indeed, many religious communities consider their positions to be rooted in the divine will and therefore outweigh all others. For instance, ARTs are typically condemned by religious leaders as they

[373] *Ibid*.
[374] Bruce Bimber, *supra* note 274 at 12.
[375] *Ibid*.
[376] Jean-Louis Baudouin, *supra* note 171 at 31.
[377] Institute of Medicine, *supra* note 52 at 4.

bring about pregnancies that are deemed unnatural. These techniques also rely on laboratory manipulations that are considered unacceptable due to the sanctity attributed to the human embryo.

In light of NECs' practical influence on novel policies, the fear is to see reproductive technologies excessively condemned and restricted in accordance with conservative religious beliefs advanced by religious commissioners. While such extreme positions are typically balanced out by other non-religious commissioners, an undeniable risk of religious bias remains. Indeed, religious commissioners can be very persuasive and impact the opinion report of the NEC.

3. Distortion of NEC Activity

Ultimately, an ideological coloring of commissioners can distort bioethical advice. NEC analyses and opinions must not be subjected to a manipulative promotion of a political or religious agenda. The analyses of NECs are meant to follow a distinctive methodology and perform objective bioethical decision-making. Hence, commissioners' bias deprives NEC activities of their analytical and advisory purposes. This is damaging in democratic societies because these entities are expected to speak freely, even when their position opposes the general orientations of the current government or legislative power[378] or those of the Church.[379] In cases of political bias, it gives political authorities absolute control over new policy orientations under the guise of seeking independent expert advice.[380] Alternatively, in cases of religious bias, sensitive bioethical questions arising with reproductive medicine would not be

[378] Jonathan Montgomery, Address, *supra* note 370.

[379] In most Western democracies, the Catholic Church serves as the main religious authority. Other religious orientations also come into play (Protestantism, Islam, etc.).

[380] Kathi E. Hanna, "Whose Advice? Expert Committees Get a Makeover", *supra* note 367.

objectively analyzed and all policy recommendations are likely to be extremely restrictive. Any form of bias undermines NECs' aura of neutrality and objectivity. If the advice is no longer objectively formed, it is of no use to policy-makers.[381] Since no benefit can be drawn from a deferral to a biased advisory entity, authorities should ignore the advice and draft policy on the basis of their own knowledge and skill.[382]

B. Impediment to Consensus

So far, we studied the fear of biased commissioners distorting NEC discussions and analyses in order to serve an ideological agenda. An additional issue arises with extreme partisanship in NEC membership at the moment of deliberation. Indeed, some scholars argue that partisan commissioners could ultimately impede the entity from finding consensus on controversial issues.[383] Due to the above-mentioned phenomena of political or religious biases, individual commissioners often hold unyielding positions on controversial topics. To honor outside commitments, they could choose to block consensus that would otherwise be forged among "reasonable persons".[384] The risk of such a detrimental polarization of commissioners is heightened in areas already staked out by well-organized interest groups (e.g.: laboratory embryo manipulation).[385]

The failure to find consensus reduces the overall utility of NECs' intervention for policy-makers.[386] This is because the expectation of success of this deliberation method largely

[381] *Ibid*.
[382] *Ibid*.
[383] Kathi E Hanna et al., *supra* note 190 at 216.
[384] *Ibid*.
[385] *Ibid*.
[386] *Ibid.*

justifies the deferral to an expert committee's advice.[387] Indeed, it is on the formulation of a NEC's consensus that subsequent laws could potentially be founded.[388]

Nonetheless, the will to find consensus must not be overpowering and divert from the goal of finding the best solution to an issue. Although extreme partisanship is detrimental, excessive avoidance and agreement could lead to harmful passivity in NEC dynamics. Indeed, the desire to find an agreement could lead commissioners to underestimate objections, ignore unpopular viewpoints, and fail to consider alternative information.[389] NEC members are therefore often perceived as "*bien-pensants*" individuals, who tend to avoid conflict and advance "*predictably acceptable views*".[390] Such consensus-oriented dynamics should not drive NEC deliberations because forging consensus among moderate forces is ultimately useless.

In reality, power struggles between commissioners are necessary to bring about a satisfying resolution. As François Malherbe pointed out, NECs should base their procedure on a "*rational consensus*" instead of a merely strategic one.[391] In other words, it is important not to actively ignore ambiguities and variations in interpretation by settling for the "*lowest common denominator*" just to use a simple formula all members easily agree on. Bioethical decision-making requires work, reflection, and dialogue to find the "*highest common denominator*".[392] Only a group of sufficiently open-minded commissioners can produce satisfying results through careful consideration of all interests at stake.

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[387] Studied *supra* Part 2.
[388] Mary Warnock, "14 Ethics Committees", *supra* note 228 at 775-776.
[389] Institute of Medicine, *supra* note 52 at 13.
[390] Mary Warnock, "14 Ethics Committees", *supra* note 228 at 776.
[391] François Malherbe, "Orientations and Tendencies in the French-Speaking World" in Corrado Viafora and Alberto Bondolfi, eds, *Vent'anni di Bioetica: Idee, Protagonisti, Instituzioni* (Padova: Fondazione Lanza/Gregoriana Libreria Editrice, 1990) 199-235 at 227.
[392] *Ibid*.

II. Counter-Argument: Ideological Flexibility

These suspicions raise the following question: '*Can the government or legislator elicit advice from experts that is unshaded by partisanship or ideology?*'[393]

First off, it is important to note that some form of bias is inevitable and even desirable for NECs. It is an institutional phenomenon[394] that necessarily accompanies the multidisciplinary membership of NECs.

Nevertheless, ideology must not form the basis of bioethical decision-making and NECs should strive for ideological flexibility.[395] These entities cannot function with unduly dogmatic or fundamentalist commissioners[396] and require a balance of opinions and approaches.[397] As long as commissioners are willing to engage in shared moral decision-making,[398] potential biases do not discredit or block the intervention of NECs. Throughout all stages of NEC activity, from analysis to consensual deliberation, members must be willing to look beyond their individual interests, set aside their views, and be flexible and open to an equal assessment of all viewpoints. Efficient bioethical analysis requires open-minded commissioners, who do not camp on views, but represent valuable contributors with unique knowledge and experience.[399] To achieve this ideological flexibility,[400] it is important to appoint members for their independence and originality.[401] While it is difficult to lay out a set list of requirements for appointment, it seems preferable for candidates to have strong communication skills and an ability to work in a group. Overall, commissioners are not expected to be moral relativists

[393] *See* Bruce Bimber, *supra* note 274 at 4-5.
[394] Alastair V. Campbell, *supra* note 353 at 397.
[395] Kathi E. Hanna et al., *supra* note 190 at 215.
[396] Mary Warnock, "14 Ethics Committees", *supra* note 228 at 775-776.
[397] Jean-Louis Baudouin, *supra* note 171 at 43.
[398] Alastair V. Campbell, *supra* note 353 at 397.
[399] Institute of Medicine, *supra* note 52 at 5.
[400] Jean-Louis Baudouin, *supra* note 171 at 43; Kathi E. Hanna et al., *supra* note 190 at 215.
[401] *Ibid*.

(viewing no moral judgment as absolute or universal), but they must look beyond their individual positions to work toward objectives that serve the national good.

Further, NECs can develop formal procedures and an organizational culture intended to demonstrate neutrality.[402] If commissioners follow a norm of non-partisanship in the bioethical analysis of issues, use neutral language and concepts, avoid rigid arguments drawn from pure ideology, and equally weigh an all interests, NECs can preserve their autonomy and neutrality. Many NECs rely on specific criteria to guide internal appointment and work processes and seem to have achieved flexibility.[403] Indeed, a majority of commissioners seem to be willing to openly participate in ethics deliberation.[404] This argument largely debunks scholars' apprehension of negative repercussions of commissioners' bias on policy.

Conclusion

This non-exhaustive list of concerns[405] undeniably undermines governmental and legislative reliance on institutionalized bioethical advice. Technical and democratic legitimacy questions remain and commissioners' influence can be challenged. However, such criticism leads to overly pessimistic conclusions and therefore seems inadequate.[406]

In truth, despite numerous challenges, NEC intervention is still valuable for modern pluralistic democracies. The overall goal is to strive for a balanced composition of commissioners

[402] Bruce Bimber, *supra* note 274 at 82.
[403] Institute of Medicine, *supra* note 52 at 5.
[404] *Ibid*.
[405] *See* Camille Bourdaire-Mignot et Tatiana Gründler, *supra* note 84 at 11, para 50; Tom Murray, Address, *supra* note 302; Jonathan Montgomery, Address, *supra* note 370; Kathi E. Hanna et al., *supra* note 190 at 215: A number of additional concerns arise in relation to NECs' distinctive mode of operation. Problems include the difficulty encountered by commissioners when bounding the bioethical issue, a lack of legal knowledge and procedural rigor, and uncertainty around the portability of the advice (must have a practicable form which makes it applicable to a variety of circumstances).
[406] Bruce Bimber, *supra* note at 274.

bringing the collective expertise to consider and deliberate all facets of an issue before delivering a set of recommendations. The perfectly constituted bioethics committee does not exist and a deferral to external bioethical expertise remains the most pragmatic solution to the law's inability to provide guidance for novel scientific advances.

Chapter 2: NECs for a Modernization of Governance

NECs are imperfect institutions and their shortcomings necessarily spark criticism within the literature. We have nevertheless studied how negative assessments are often the product of misconceptions and/or exaggerations.

The atmosphere of hostility is also highly inopportune in light of policy-makers' urgent need for NEC interventions. In fact, despite various concerns, these entities contribute to the rule of law. Novel technologies, including ARTs, challenge legal systems and lawmakers given that existent juridical principles and tools may not be equipped to respond to innovative practices that affect human health and wellness. The methods of the past appear outdated and modern democracies must change their approach to policy-making to efficiently tackle continuous scientific advances. Quasi-legal entities represent the most accessible tool to shape new regulatory frameworks on sensitive subject-matter.

Significantly, the systematic deferral and growing reliance on bioethical advice generates more than purely procedural changes to governance. Indeed, the reliance on bioethical advice also spurs a de-monopolization of normativity, such that legal reasoning is completed with bioethical analysis. Furthermore, NECs provide a forum for public deliberation and exchange on public bioethical issues. With a multidisciplinary composition and special consideration for

viewpoints found in society in their analyses,[407] the increased influence of NECs indirectly pushes governments to move towards a more deliberative form of democracy.

Overall, the regulation of advances in science, and reproductive medicine specifically, presents a task of such magnitude for policy-makers that a reform or rethinking of the system becomes necessary. NECs help achieve this goal by de-monopolizing traditional sources of normativity (Section 1) and supporting a more deliberative form of democracy (Section 2).

Section 1: Necessary De-Monopolization of Normativity for the Regulation of Novel Technologies

Traditionally, norms must originate from the legislator that was democratically elected by the people.[408] The source of all rules was also purely legal. In disregard of other forms of normativity, human conduct was to be regulated in accordance with existing legal principles and mechanisms.

At the present time though, it is commonly accepted that the continuous advancement of science outruns the legislator and justifies a deferral to quasi-legal entities.[409] Yet, increased reliance on NECs not only procedurally replaces the role of the legislator, it further reveals an attempt to make ethics a source of law. As studied above,[410] a purely legal approach fails to tackle the bioethical intricacies arising with new technologies. This failure justifies a "*de-monopolization*" of normativity.[411] By intervening in the preliminary stages of law-making,

[407] Studied *supra* Part 2.
[408] *See* H.L.A. Hart, *supra* note 79; Frederick Schauer, *supra* note 331.
[409] Studied *supra* Part 1.
[410] Studied *supra* Part 2.
[411] Sandrine Maljean-Dubois, *supra* note 11.

NECs ensure the integration of ethical principles and norms into the regulation of novel advances.[412] Indeed, as rules in the medical field are based on this bioethical advice, many democracies are moving towards a sort of "*complementarity between para-legal norms and legal norms*".[413] Each source of normativity could not function on its own as the norms of ethics lack legal authority and legal norms lack wisdom and consensual legitimacy.[414] Hence, the most effective democracy establishes a reciprocal influence between ethics and law. While these two orders not necessarily match, an interactivity can be achieved as one relies on the other to perform.[415] Many democracies strive for such an interactivity between orders of normativity and hope to achieve it through the establishment of NECs. Indeed, strong reliance on NEC intervention allows a system to benefit from such an entanglement between forms of normativity.[416]

However, some nations resist such an entanglement between ethical and legal forms of normativity due to the uncertainty it causes. This is because all boundaries are blurred as the author of the law becomes a mystery, norms lose their traditional significance, and the hierarchy that governs them is rearranged.[417] Regardless, an abandonment of traditional conceptions might just be what society needs in the face of novel medical technologies. Old conceptions of normativity must be left behind in order to tackle the continuous advancement of science.

[412] *Ibid*.
[413] Sophie Monnier, *supra* note 115 at 421, para 754.
[414] *Ibid.*
[415] Philippe Pedrot, *supra* note 269 at 7.
[416] Sophie Monnier, *supra* note 115 at 421, para 754; Philippe Pedrot, *ibid.*
[417] Sophie Monnier, *ibid* at 421, para 755.

Section 2: Accepting NECs as Vectors for an Improved Form of Democracy

External expert involvement in the legislative process poses a series of concerns when opposed to traditional conceptions of democracy. As we have studied above,[418] authorities' reliance on expert advice for policy-making is often criticized. The literature describes unelected experts, including NECs advising on bioethics, as undemocratic because they fail to represent popular society. Due to this lack of democratic legitimacy, the only justification for their involvement is that it guarantees objectivity rooted in knowledge and expertise during the legislation-drafting process. Hence, NECs' influence is tolerated because their advice helps the disoriented legislator solve bioethical intricacies and the ultimate authority remains in the hands of the elected officials.[419] Deferral to NECs represents a mere facilitation of the policy-drafting process without their involvement causing any conceptual changes to governance.

However, in this paragraph we will go beyond this general conception and opt for a more controversial perspective on NEC involvement in the legislative process. A closer look reveals how NECs stand out among other expert panels as these entities constitute a forum for public deliberation. Via various techniques, including open communication and public meetings or events, NECs encourage constructive debate between experts and the general public. While public deliberation primarily aims to inform and educate the public on bioethics, NECs simultaneously draw from these exchanges to incorporate a variety of viewpoints into their opinions. These entities therefore act as a procedural venue to enhance and facilitate

[418] Studied *supra* Part 3.
[419] Studied *supra* Part 3.

deliberation on bioethical issues.[420] In other words, NECs constitute deliberative forums where large numbers of people are included in discussion to eventually arrive at a most justifiable solution on public bioethical issues.[421] When policy-makers incorporate NEC opinions into law, they indirectly move toward a deliberative form of democracy.

In light of NECs' strong reliance on societal involvement and practical role as a forum for public deliberation on bioethical issues (I), these entities can legitimately be described as vectors for a new more deliberative form of democracy (II).[422]

I. NECs as a Forum for Public Deliberation

NECs encourage active citizen involvement in bioethical discussion. Despite variations in the execution of this mission between NECs (i.e. France vs. USA), most now strive to act as a forum for public deliberation on complex bioethical issues.

Public deliberation on such issues triggers an exchange of viewpoints (A), which ultimately serves the bioethical analysis performed by NECs (B).

[420] *See* Simone Chambers, "Deliberative Democratic Theory" (2006) 6 Annual Review of Political Science 307-326.
[421] *See* James S. Fishkin and Peter Laslett, eds., *Debating Deliberative Democracy* (Oxford: Blackwell, 2003); Simone Chambers, *ibid*.
[422] *See* Frédéric Zénati, *supra* note 10; Stuart L. Hart, "Managing Knowledge in Policy Making and Decision Making" 8:1 Sci. Commun. (1986) 94-109 at 95.

A. Encouraging Public Deliberation

An increasing objective for NECs, actively pursued by the French CCNE,[423] is to serve as a forum for public deliberation. An important element of this is the practical organization and encouragement of public discussion. Indeed, NECs host public debates by inviting members of society to the table for an exchange of viewpoints on complex bioethical issues. For such debates to be constructive, NECs first strive to educate and inform the public. While the population may have some degree of knowledge on bioethical issues, public information often stems from the media and is therefore incomplete or incorrect.[424] NECs hope to remedy common misconceptions by providing accurate and accessible explanations of the issues at hand by means of presentations and publications. Once the public is sufficiently informed about a given bioethical issue, it is invited to engage in a free exchange of viewpoints and ideas.[425]

In practice, we note some disparities in execution of this active public involvement ideal between NECs. In the USA specifically, there has been significant variation in how commissions have approached this objective as some merely provided public notice of their meetings or made their meeting minutes available to the public, while others more actively tried to hold public meetings and encourage public deliberation.[426] However all attempts show that public involvement was never maximized.[427] Conversely, the French CCNE seems to have mastered this element. Along with a strong dissemination of information and open communication channels available on its website, the CCNE regularly organizes "annual

[423] *See* Comité Consultatif National d'Éthique, "Presentation and History of the CCNE", *supra* note 183.
[424] Jean-Louis Baudouin, *supra* note 171 at 34-35.
[425] *Ibid*.
[426] Mary Darby, "How to Elevate Bioethics Deliberations to a National Level" (2015), online: The Blog of the 2009-2017 Presidential Commission for the Study of Bioethical Issues: <www.blog.Bioethics.gov.>.
[427] Eric M. Meslin and Harold T. Shapiro, *supra* note 270 at 99.

bioethics days" (états généraux de bioéthique).[428] On these occasions, the CCNE holds workshops and symposiums before sounding the public and encouraging active involvement of both experts and laypeople for stimulating discussions on any given bioethical issue.[429] The CCNE therefore provides a perfect example of a NEC serving as a forum for experts and the general public in which to exchange ideas and provide the public with an opportunity to express its views and feel heard. This NEC continuously seeks out the opinions of individuals and groups found in the general population for richer and more intense bioethical reflection.

B. Societal Involvement as a Component for Bioethical Analyses

Active citizen involvement fuels public reflection on and understanding of complex bioethical issues.[430] Simultaneously, this societal participation serves the work of the NEC. Indeed, our analysis of NEC methodology revealed a dominant concern for the "Audience" of bioethical opinions.[431] This is because societal input serves as a precious source of information and a starting point for bioethical analysis. The orientations collected through deliberation highlight crucial angles and approaches for any given issue. More precisely, NECs gather the pluralism of opinions found in society during public debates and attempt to reflect these in their analyses and subsequent opinions. When it comes to advances in reproductive medicine specifically, it appears crucial to assess community attitudes towards novel techniques.[432] An analysis performed in total disregard of the views found in society would appear out of touch and inadequate. NECs seek to adapt their work to the state of science and accompanying public

[428] *See* Comité Consultatif National d'Éthique, "Presentation and History of the CCNE", *supra* note 183.
[429] Eric M. Meslin and Harold T. Shapiro, *supra* note 270 at 99.
[430] *See* Jean-Louis Baudouin, *supra* note 171.
[431] Studied *supra* Part 2.
[432] *See* Eric M. Meslin and Harold T. Shapiro, *supra* note 270 at 99.

opinion at any given time.[433] These entities also strive to develop a national viewpoint.[434] Instead of imposing a dogmatic opinion on a given issue, the goal is to foster the expression of various views found in society and establish a diverse, yet common and national viewpoint on controversial issues.

NECs engage with the public to improve the quality of their analyses and resulting opinions and recommendations. Nevertheless, this process triggers an important change in governance due to the practical influence exercised by these entities. In other words, NECs serve as a deliberative democracy procedure which facilitates communication about contentious policy issues even in agonistic political contexts.[435]

II. Resulting Transition to a Deliberative Form of Democracy

According to a significant school of thought,[436] democracy should no longer be defined as a system where the majority's decision-making power conditions new laws.[437] Instead, the democratic decision-making process should be a deliberative practice based on discussion and common construction;[438] in other words, a process in which citizens publicly discuss new laws. The literature often draws from Jürgen Habermas, who revived the idea of deliberation and gave it a democratic foundation.[439] According to this theorist, the fundamental source of legitimacy is the collective judgment of the people which is to be found in a disciplined set of

[433] *See* Sophie Monnier, *supra* note at 115, para 469.
[434] Jean-Louis Baudouin, *supra* note 171 at 34-35.
[435] *See* Teresa Kulawik, *supra* note 8 at 469.
[436] *See* Dominique Rousseau, Droit du Contentieux Constitutionnel (Paris: Montchrestien, Domat, Droit Public, 2001); Jürgen Habermas, *The Theory of Communicative Action* (Boston: Beacon Press, 1984).
[437] Dominique Rousseau, *ibid.*
[438] *Ibid* at 482.
[439] Jürgen Habermas, *The Theory of Communicative Action*, *supra* note 436.

practices defined by the deliberative ideal.[440] Concerning the regulation of novel medical technologies specifically, the time has come to implement a more deliberative form of democracy to "*provide the most justifiable conception for dealing with moral disagreement in politics.*"[441]

To this end, some authors welcome the standardization of NEC intervention in the legislative process. [442] The hope is to abandon systemic deficiencies and move towards a more deliberative form of democracy by means of an increased reliance on the advice of these quasi-legal entities.[443] In fact, a deliberative system relies on a specific decision procedure to function.[444] NECs act as such a venue for deliberative justification and accountability of novel policies.[445] To clarify this argument, we will show how NECs serve each of the purposes generally attributed to a deliberative democracy.[446]

First, a deliberative democracy aims to promote the legitimacy of collective decisions.[447] When it comes to difficult policy choices, such as those arising with novel medical technologies, authorities face significant disagreement. Thus, to make hard choices more acceptable in the eye of the public, it is necessary to demonstrate consideration for the relevant conflicting moral claims in the decision-making process.[448] In practice, a deliberative system relies on a specific decision procedure to function.[449] Deferral to NECs constitutes such a procedure as it reassures

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[440] *Ibid*.
[441] Amy Gutmann and Dennis Thompson, *Why Deliberative Democracy?* (Princeton: Princeton University Press, 2009) at 10.
[442] Dominique Thouvenin, *supra* note 11 at 12-13; Chantal Mouffe, *Le Politique et ses Enjeux. Pour une Démocratie Plurielle*, (Paris: La Découverte – MAUSS, 1994) at 32 ; Dominique Rousseau, *supra* note 436.
[443] Dominique Rousseau, *ibid*.
[444] *Ibid* at 18.
[445] *See* Simone Chambers, *supra* note 420.
[446] Amy Gutmann and Dennis Thompson, *Why Deliberative Democracy?*, *supra* note 441 at 10.
[447] *Ibid*.
[448] *Ibid* at 10.
[449] *Ibid* at 18.

the general public that sufficient consideration was given to the plurality of viewpoints found in society. In fact, NECs not only provide a forum where all views can be heard, it also uses these perspectives for subsequent bioethical opinion formation.

The results of public deliberation feed NECs' bioethical analyses. This phenomenon plays into the second purpose commonly attributed to deliberative democracy: encouraging a public-spirited perspective on policy issues through cooperation.[450] Indeed, a deliberative process relies on public-spirited perspectives on public issues.[451] Public forums, such as NECs, are deemed essential to bring citizens together to discuss bioethical issues and gather a variety of viewpoints.[452] NECs actively rely on this societal involvement for their bioethical analyses and incorporate the public-spirited perspectives that emerge during debates into their opinion reports.[453] Thus, from a procedural approach to deliberative democracy,[454] NECs render the legislative process more deliberative as citizens are given the opportunity to discuss and contribute to the finding of a legitimate outcome for modern policy dilemmas.[455] Indeed, thanks to a strong practical influence, policies are often the indirect result of the public deliberation performed by NECs.

Third, deliberative democracy intends to remedy the general misunderstanding around novel advances found within society as well as among officials.[456] In fact, many scholars[457] contend that deliberation can broaden perspectives, promote toleration and understanding between

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[450] *Ibid*.
[451] *Ibid* at 10.
[452] *Ibid* at 11.
[453] *See* Comité Consultatif National d'Éthique, "Presentation and History of the CCNE", *supra* note 183.
[454] *See* Simone Chambers, *supra* note 420.
[455] *See* Jürgen Habermas, *The Theory of Communicative Action*, *supra* note 436.
[456] Amy Gutmann and Dennis Thompson, *Why Deliberative Democracy?*, *supra* note 441 at 11.
[457] Seyla Benhabib, *Situating the Self: Gender, Community, and Postmodernism in Contemporary Ethics* (London, UK: Routledge, 1992); Amy Gutmann and Dennis Thompson, *ibid*, John S. Dryzek, *Deliberative Democracy and Beyond: Liberals, Critics, Contestations* (Oxford: Oxford University Press, 2000).

individuals, and encourage a public-spirited attitude. Via the intervention of a deliberative forum, such as NECs, both individual and collective comprehension of new medical technologies can be increased.[458] Indeed, as we have mentioned above, public discussions engaged by NECs aim to inform and educate the public and thereby encourage individuals to take broader views on bioethical issues.[459] Public deliberation forums trigger an expansion of knowledge and recognition of misapprehensions.[460]

Ideally, NECs contribute to the creation of a novel form of democracy. Specifically, in countries (i.e. France) with entities that heavily rely on societal participation, the democratic system is improved. The use of NEC opinion reports renders the legislative process pluralized, heterogeneous, and diverse.[461] Hence, even without traditional guarantees of democratic legitimacy conferred by election, NECs promote an improved deliberative democratic system in which decision-making "*has become less an analytic endeavor than a process of mediating among parties with differing levels and types of knowledge – a kind of "knowledge management."*[462]

Conclusion

The aim of this part is to overcome doctrinal criticism of NECs and prove the overall effectiveness of their intervention. Despite some shortcomings, these entities form a valuable resource to policy-makers faced with the intricacies of regulating novel scientific advances. It is indeed necessary to adopt a pluralistic approach and de-monopolize traditional sources of

[458] *See* Jean-Louis Baudouin, *supra* note 171 at 34-35.
[459] *Ibid.*
[460] *See* Simone Chambers, *supra* note 420.
[461] *See* Frédéric Zénati, *supra* note 10.
[462] Stuart L. Hart, *supra* note at 422.

normativity. By deferring to NECs, authorities strike a valuable balance and implement a complementarity between ethical and legal reasoning for policy-drafting on complex and sensitive scientific subject-matter. More significantly, traditional hostility should be replaced by a recognition of NECs as key players in the development of a new and improved form of democracy. Commissioners are attentive to the needs and attitudes of society and incorporate a variety of viewpoints into their opinions. In fact, modern democratic societies benefit from the involvement of public deliberation forums as a procedural venue for a more deliberative decision-making process.

CONCLUSION

The last decades marked the development of a series of assisted reproductive technologies. By means of medical intervention, all natural barriers can be overcome and no reproductive desire appears out of scientific reach. Despite the obvious advantages for human fertility, this unfathomable progression poses new risks for patient safety and challenges core societal beliefs and values. Indeed, significant moral controversy arises as to the proper use of these technologies. Without a definite determination of the most desirable course of action, numerous public bioethical dilemmas appear. Due to this disorientation, the medical profession and, society more generally, hope for legal guidance to alleviate concerns and ensure the development of ARTs with clear direction grounded in collective values. However, traditional policy-making processes seem outdated and fail to grapple with the moral ambiguity that accompanies medical innovation. This is because traditional legal definitions and concepts were fashioned before such revolutionary techniques were even considered and most attempts to "acculturate" the law are outrun by the defeating pace of science. Furthermore, these topics are subject to extreme controversy in public opinion and are often entangled with politics. This makes it politically challenging to set boundaries and a course of action.[463]

Lacking the means to tackle underlying intricacies and provide satisfactory guidance on public bioethical issues raised by ARTs, authorities rely on expert bioethical advice. Progressively, this form of advice was institutionalized with the creation of NECs across many countries. With the help of a team of interdisciplinary experts, legislators can efficiently regulate innovation in reproductive medicine. Drawing from a selection of well-established NECs – specifically from France and the USA – we were able to depict the distinctive functioning and methodology applied by these entities. Despite some structural differences, these expert

[463] Diego Garcia, *supra* note 155.

commissioners engage in detailed bioethical analyses before passing moral judgment on the basis of consensus. The standardization of NECs' intervention reveals the reality of the legislator's reliance on bioethical advice to inform legal and policy developments in sensitive areas, such as reproductive medicine. The empirical study conducted in this thesis highlights a strong correlation to be found between an entity's recommendation and subsequent policy stances. This proves how NECs progressively surpassed their mere advisory functions and transformed into active players in the legislative process.

The overarching goal of this work was to emphasize the effectiveness of the involvement of quasi-legal institutions in the policy-making process. NECs can withstand the criticism that arose with the standardization of their involvement and continue to gain influence. These entities have proven their worth to both the legislator and society as a whole. Indeed, more than a procedural facilitation, this external intervention contributes to the rule of law by providing objective resolutions through ethical reasoning and expertise. The intervention of a multidisciplinary team of experts guarantees strong juridical outcomes. It also fuels a modernization of governance as we move away from a strictly legal source of normativity by adding bioethical reasoning into the preliminary stages of law-making. The intervention of NECs ultimately renders the legislative process more deliberative due to a strong consideration for the plurality of viewpoints found in society when conducting bioethical analyses.

While this thesis focused on the policy-making processes found in countries having established NECs, further research could be performed on the situations of countries functioning without the advice of such institutions. For instance, Canada never established a NEC to advise on bioethical issues despite strong scholarly arguments in favor of the creation of Canadian

advisory council.[464] In truth, scientific innovation knows no boundaries and most countries host rapidly evolving reproductive technologies. It therefore seems interesting to assess how policy-makers handle the bioethical intricacies underlying these advances, in the field of reproductive medicine or in other areas, without the help of a national institutionalized team of multidisciplinary experts in bioethics. Specifically, the analysis of the process behind the recent regulation of medical assistance of dying in Canada would provide for a fascinating research topic. The focus could lie on the preliminary stages of law-making to understand which procedures were used, which actors intervened, and how these factors shaped the ultimate legislative outcome for Canada.

[464] *See* Jean-Louis Baudouin, *supra* note 171.

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