Biolaw and Bioethics: Convergences and Divergences

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Abstract This chapter addresses the convergences and divergences between bioethics and biolaw. Bioethics and biolaw are normative discourses that give reasons for action, whose particularity consists in necessarily interacting with other disciplines and social practices at the time of their elaboration and application, and especially with life sciences and related technologies. Both terms are constructed with the prefix *bio*, which points to the common field of application of each of these normative disciplines. With the prefix *bio*, life sciences are included in these terms, as well as biomedical and clinical research, their technological applications, and the practice of medicine through these new technologies. Throughout this chapter, the author will show that the relationship between bioethics and biolaw is still an area to explore, due to the complexities of their scope of application, which invites us to rethink the traditional discussion about the relationship between ethics and law.

1 Introduction

In this chapter, I will reflect on the convergences and divergences between bioethics and biolaw. Both are recent disciplinary fields in moral philosophy and legal sciences, respectively. In spite of their short time of evolution, they have acquired epistemological and methodological characteristics that cause problems to their disciplines of origin and, consequently, to the relation between them. This forces us back to the old debate on the relationship between ethics and law, but also leads us to question the theoretical terms in which it was established and to rethink it from a more practical perspective.

Bioethics and biolaw are normative discourses that give reasons for action, whose particularity consists in necessarily interacting with other disciplines and social practices at the time of their elaboration and application, and especially with life sciences and related technologies. While both are social and communication systems endowed

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with distinct functions, they are also mutually dependent. Each one of them is constructed taking into account the other in its disciplinary field. But what is, in principle, an epistemic strength can also be a source of confusion. While in the theoretical field there is the tendency to reduce one discipline into the other, in the practical field there is the distrust of medical professionals and researchers in front of law or, conversely, of the authority (governmental or parliamentary) in front of their self-regulation.

Both terms are constructed with the prefix *bio*, which points to the common field of application of each of these normative disciplines. With the prefix *bio*, the life sciences are included in these terms, as well as biomedical and clinical research, and their technological applications, and also the practice of medicine through these new technologies. It is still a matter of discussion whether this field is restricted to technoscience applied to human *bios* or it also extends its scope to non-human *bios* (animals and plants) including the environment (Macer 1998).

When bioethics became institutionalized during the 1970s, it concentrated its field of study and action, almost exclusively, on the ethical implications of the life sciences applied to the human being, especially the old and new problems of medical ethics and biomedical research. It was at the height of public and academic debates about the new technologies of clinical application that influenced the birth of bioethics (e.g. hemodialysis, organ transplantation, life support mechanisms, assisted human reproduction techniques, etc.), when law begins to assume these new biomedical problems and to respond to them.

From then on, law intervenes in bioethical and public debates through different instances. Jurists participate in the development of the first patient rights charters (Annas 1975), in technical commissions for the selection of patients for a treatment with the new hemodialysis technique (Seattle Committee, 1962) or to define brain death (Harvard Commission, 1968), and in relation to the latter, in the design and elaboration of laws relating to organ transplantation. Also, they had a place in the special commissions destined to the protection of the subjects that participate in the biomedical research, as was the case of the United States National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974), elaborated the well-known *Belmont Report* (1978), which was motivated by a series of scandals in medical research between the 1940s and 1960s (Beecher 1966).

On the other hand, the courts begin to establish jurisprudence on bioethical issues. For example, US courts, the first to confront these new problems of medicine, applying constitutional principles in the absence of specific legislation, issued sentences that until today are emblematic for the study of bioethics and biolaw: *Canterbury* versus *Spence* (1972) on informed consent, *Quinlan* case (1976) or *Cruzan* case (1985) on limitation of life support treatment, or *Baby M* case (1986) on surrogacy and assisted reproduction techniques. And when in vitro fertilization began to be used as medical treatment, the legal response was not long in coming. Expert committees, including jurists, were set up in some European countries to deal with the ethical and legal consequences of the application of this technique, especially assessing the implications for constitutional law and civil family law (see, for example, *Warknock Commission* in UK, 1982, *Benda Commission* in Germany, 1985, and *Palacios Commission* in Spain, 1988).

The term biolaw was born in the 1990s in the context of the "European legal culture" (Kemp 2000: 235), coined first in French (*biodroit*) and soon afterwards in English (*biolaw*), extending later to other European languages (*biorecht, biodiritto, biodireito*). The term replaced others previously used like *biomedical law* or *lois de bioéthique*, that were more equivocal and less inclusive of the phenomenon of the interrelation between sciences of life, biotechnology, ethics and law. Indeed, the concept of biomedical law has a more restricted scope than that of biolaw, since it refers only to the "legal implications of the biomedical sciences and biotechnologies linked to the health of the human being" (Romeo Casabona 2011: 189). On the other hand, it is more linked to the traditional medical law and health law, whose emphasis is placed on the duties of health professionals and health organizations, and not on the legal rights of those who may be affected by biomedical advances (Jacob 1983).

Throughout this chapter, I will show that the relationship between bioethics and biolaw is still an area to be explored, due to the complexities of its scope and application as well as the accelerated pace of biotechnological advances and the necessary social and cultural adaptation to these in the context of globalization. This, from the beginning, invites us to rethink the traditional discussion about the relationship between ethics and law. To advance in this field, I propose to go beyond the traditional positions that have approached the bioethical-biolaw relationship in terms of disciplinary extension, suggesting the need for a paradigm shift towards a more dynamic interdisciplinarity. In this sense, I will hold a systemic view of biolaw that makes it a perfect test field for the transformation of the legal sciences and legal systems in the context of a globalized and technological society steeped in growing scenarios of social, political and environmental uncertainty.

2 Towards a Systemic View of Biolaw

2.1 A Return to the Debate on the Relationship Between Ethics and Law

Although prior to the institutional birth of bioethics there was a relationship between ethics and law in the specific field of medical practice and clinical research, through *Medical Ethics* and *Health Care Law*, the focus of each of these sub disciplines was far from the interdisciplinary complexity that will characterize bioethics and biolaw and the relationship between them. This is due to several reasons. First, the focus of *Medical Ethics* and *Health Care Law* are not the ethical and legal implications of complex biomedical and biotechnological advances. Second, its content is given by the duties and responsibilities of medical professionals and not primarily by the interests and rights of people who may be affected by new health technologies. Third, they are not disciplines in a strict rigor but sub disciplines, inasmuch as they do not propose an epistemic and methodological approach specific to their problems. In this sense, medical ethics are taxed on a deontological ethics (expressed in codes of

professional ethics) and sanitary law (within which the medical law is included) is subject to administrative law. And fourth, there is not even an interdependence and disciplinary co-evolution between them as has happened and continues to occur with bioethics and biolaw.

The above points to the fact that the theoretical debate about the relationship between ethics and law, in the terms that emerged in the period of positivism with Kelsen, Ross, Hart and others, still remains, to put it softly and in a metaphorical way, "out of play", when law in all its expression (doctrinal, jurisprudential and legal) is challenged by new concrete social phenomena with strong ethical implications that are the result of the applications of biomedical sciences and biotechnologies. New biomedical practices stir up conflicts, generate tensions and moral disputes about values that are extremely sensitive to individuals and the community, affecting at the same time, basic legal rights such as life, privacy, health, freedom, free development of personality, among others, opening up new facets and dimensions of these legal goods previously unthinkable for traditional law.

With different philosophical foundations, the natural philosophers argue essentially two theses, first, that "there are universally valid moral principles and justice accessible to human reason" and, second, a conceptual thesis of law, "according to which a normative system or a standard cannot be described as 'legal' if they contradict those moral or justice principles" (Nino 2003). On the other hand, the different positions of legal positivists coincide in the conceptual thesis that "the concept of law should *not* be characterized by value properties but taking into account only descriptive properties," so that a legal system or a legal rule should not be identified as such by virtue of its suitability to moral principles. In other words, the concept of law does not imply a necessary connection with morality.

For the question that interests us in this chapter, I must take a step forward introducing those theses that overcome the dichotomy of connection and separation between law and morality, as was posed by the extreme positions of legal positivism and natural law. In order to do so, I will make a brief reconstruction of one of the moderate representatives of positivism, Robert Alexy, and from there I will argue that the answer he offers even though it overcomes the weaknesses of the conceptual thesis of legal positivism outlined above is unsatisfactory to deal with the relationship between bioethics and biolaw.

For Alexy, the question about the necessary relations between law and morality is so broad that it encompasses the whole conception of law and its practice, which in his view would explain why a satisfactory answer to that question has yet to be found, despite the enormous theoretical efforts that have been made to address it. Alexy's thesis argues that there is a necessary conceptual relationship between law and morals. Therefore, he believes that legal positivism, which opposes such a relationship, would fail as a general theory of law (Alexy 1993).

Alexy proposes two argumentative strategies to establish the necessary connection between moral and law. The first is called the argument of injustice (the strong thesis) and the second, the argument of correction (the weak thesis). The argument of injustice evaluates law as a system of norms, from the perspective of an observer and through a defining connection. I will not dwell on Alexy's reasons for rejecting

this argument, both to evaluate a particular norm and a system of rules, and we will go directly to the argument of the correction on which he bases his thesis on the necessary connection between law and morality.

The correction argument evaluates law from the perspective of the concepts of procedure, participant and legal ideals, showing that, in the procedures of creation and application of law, the participants necessarily have a claim of correction that includes a claim of moral correction, with which it wants to demonstrate the necessary link between law and morality. This argument is based on two theories, the theory of pretension and the theory of discourse. Regarding the first one, Alexy shows that, if from the perspective of the participants (that is, legislator or judge) a rule is approved or a judicial decision is taken by undermining the legal correction, a performative contradiction falls, specifically the one in which one incurs when, at the moment of asserting a proposition, the content of it contradicts the rules of the act of enunciating such a proposition, that is, the rules of argumentative discourse. For example, to issue a constitutional rule that in its content denies the claim of justice of a constitution or a judicial decision whose content contradicts the institutional act of enunciating a sentence.

However, for Alexy, this claim of correction, necessarily included in the concept of law, does not prove that there is a necessary conceptual relationship between morality and law. In order to prove that this claim has such a need, he resorts to discourse theory, in terms of the procedural ethics of Habermas or Apel's discourse, which allows the claim of justification to be linked to that of correction. A legal norm or judicial decision can be described as morally acceptable, appealing critically to higher levels of justification, provided that in the critical evaluation the ideal rules of practical argumentative discourse are respected, which requires conditions of equality and symmetry of the affected, as budgets of a universally valid ethic. Thus, if for Alexy a legal argumentation is a part of practical argumentation and it is not distinguished qualitatively from it, then law can necessarily be linked to a universal procedural morality.

2.2 Biolaw as an Open System: Social Morality, Civic Dialogue and Regulatory Policies

From the formal point of view, the necessary connection between morality and law is established. Nevertheless, at the same time, it is exposed to the limitations of the theory of foundation that Alexy uses. If discursive ethics can guarantee the necessary conditions for the relationship between bioethics and biolaw, it is not a theory that ensures sufficient conditions to respond to many of the tensions between the two, especially if we think of the growing contexts of uncertainty of our globalized capitalist society where biotechnological advances, biomedical practices and bioeconomy do not recognize boundaries nor the structural asymmetries between societies and others. I will then indicate what the strengths and weaknesses of this ethical theory

are as a source of justification for confronting the relationship between bioethics and biolaw.

Among the valuable aspects to be recognized in this ethics are the following. First, it establishes the necessary conditions for a bioethical dialogue in open and pluralist societies, since it can base social consensus because of the normativity and inherent universality of dialogic reason and establish ideal conditions to rationally criticize these factual consensuses, allowing distinguishing between validity and efficacy. Second, it allows establishing an inseparable link, according to Habermas's thesis (1998), between the rule of law and deliberative democracy. That link is the supposition for: (i) legitimizing moral consensus in modern societies that are axiologically and culturally plural; and (ii) validating a civic dialogue within a deliberative democracy in the foundations of a rule of law, whose democratic politics cannot invade the private areas of autonomy by virtue of the constitutional principle of respect for the free development of the personality and whose judicial policy based on the constitution cannot stifle the legislator's will.

However, the relationship between bioethics and biolaw, based on a discursive ethical theory, finds important limitations that must be corrected with a systemic view about the interdependence between these two disciplinary fields and their necessary opening to other disciplines. One limitation has to do with the lack of legitimacy in the relations between national States, the growth of legal pluralism as well as the overcoming of the nation-state as an essential source of normative production, due to the greater preponderance of international organizations with normative capacity. Another limitation is the rise of autonomous intra-state entities, and transnational consortia that establish normative guidelines and, consequently, point out the problem of legitimacy in the face of *regulatory competition* in the scenario of globalization (Santos 1998). Moreover, it is insufficient to confront the asymmetries of global capitalism (Pogge 2008) and to give space, in its idea of intersubjectivity, to the recognition of a concrete *other* instead of an abstract or generalized one (Benhabid 1978).

Law, already in the initial phase of bioethics, converged with it through institutionalized mechanisms (national ad hoc commissions or permanent bioethics commissions) for the discussion and generation of regulatory policies in the area of biomedical and clinical research. In these instances, law uses extra-juridical knowledge, either in terms of scientific and technical knowledge or in terms of normative and methodological knowledge of moral philosophy. What is characteristic in these cases is that law does not translate into product or result (rules, judicial decisions, or system of rules and principles), but in a process or activity of interpretive and argumentative practices, as Dworkin (1978) points out, where the distinction between the legal and the moral is more diffuse than law seen in the static sense. It is what Alexy calls the perspective of law from the point of view of the procedure, the participant and the legal ideals. In addition, despite the unified perspective of law as a system and as a process tends to separate in theory, they are indispensable in practice because there is no legal result without processes of interpretation and application (Van Der Brug 2001).

Hence, a model of law as a closed system—as posed by Kelsen's positivism, though later moderated by Hart, Ross, and Raz—is not viable for these new scenarios. In addition, it is arguable that the functional model of Luhmann's law, as a functionally differentiated subsystem of the social system, is adequate. Hence, if the legal system is operatively closed as a unit, by virtue of the self-referential or autopoietic process of the system[1] is that which gives its elements the juridical-normative character (legal/illegal), any external communicative process, including non-legal regulations, is a subsystem environment reduced to its minimum expression (Luhmann 1983).

3 Approaches of Law to Bioethical Problems: Sources of Biolaw

Next, I will analyze the different approaches of law to moral questions that have been addressed in the discipline of bioethics since its origin. I will carry out so through the revision of some of the sources of biolaw, ranging from *soft law* sources (guidelines or recommendations of international bodies for research ethics and human rights declarations on bioethical issues) to legally binding instruments (treaties, constitutions, legislation and jurisprudence), highlighting in each of them the points of convergence and divergence between bioethics and biolaw.

3.1 Biolaw in the International Law of Human Rights

A first antecedent of the relationship between bioethics and law was the *Nuremberg Code* (1948), emanating from the Nuremberg trials to the Nazi physicians, one of whose essential principles, free consent to participate in an investigation, soon passes to an International Treaty (*International Covenant on Civil and Political Rights*, 1966, article 7). In that same period, the World Medical Association, an international non-governmental organization, taking into account the principles of the Nuremberg Code, drafted the *Declaration of Helsinki* in 1964 (with several modifications until 2013), in order to specify, expand and update those general principles.

The *Declaration of Helsinki* generated considerable adherence and consensus within the international research community until the controversy over the "double ethical standard in research" was unleashed in the 2000s. in relation to post trial access to treatment in medical research in developing countries (Macklin 2004). This was provoked by the growing internationalization of the investigation, which gave rise inside the organization to a controversial process of modifications to the document, which has been denominated "the battle of Helsinki" (Wolinski 2006). In the early 1980s, another international non-governmental organization (WHO),

[1] Luhmann borrows from the biology of complex systems the concept of *autopoiesis.*

established jointly with the UNESCO, developed ethical guidelines in 1982 (revised 1993, 2002 and 2016) for research with human beings, emphasizing the protection of the subjects and vulnerable groups of the underdeveloped countries, which was driven to a large extent by HIV research.

The importance they have had, especially the last two documents to which I have referred, in the ethics research committees is undeniable and, even more so, when the evaluation of protocols takes place in a context of legal or regulatory void or a certain normative deficiency due to the lack of clarity of the legislator or the regulator. It is also worth recognizing the value of these documents to guide the process of producing legal norms related to these issues. Many legislations expressly mention them in the motivation of the legal bodies dedicated to these matters.

However, the application of its principles and recommendations runs up against difficulties of a different legal order. First, they are norms or guidelines that lack legal enforceability, so they cannot replace internal legal rules that go in a contrary sense. An example of this is given in Chilean legislation regarding the absolute prohibition of carrying out an investigation with persons with mental disabilities that makes them incompetent to consent, which, in the ethical guidelines in question, is instead authorized through representation and compliance with certain conditions. Second, these ethical guidelines, especially those of Helsinki, have been subject to profound changes that have not generated an international ethical consensus, so their implementation at the national level is problematic. For this reason, the strategy of some countries to incorporate adherence to their principles by legal means is not adequate.

The dispute over the value of the *Declaration of Helsinki* as an international instrument of consensus led some Latin American countries to prefer (in the *Cordoba Declaration* of 2008) the United Nations instruments, namely UNESCO. Also, in the case of the United States, for opposite reasons, led it to withdraw from the Helsinki sphere of influence and opt for adhering to a more technical than ethical consensus instrument of the leading countries in the pharmaceutical industry (Guide to Good Clinical Practices ICH).

At the beginning of the 1990s, UNESCO prioritized in its agenda, creating a special Program and a Committee, the discussion on the dignity, rights and freedoms of individuals in the face of biomedical scientific developments, especially in relation to genetic research and its technical applications, which at that time burst into social debate with the cloning of mammals. In 1997, one year after the cloning of Dolly the sheep by Wilmut and Campbell, the *Universal Declaration on the Human Genome and Human Rights* was approved. Its principles are established in order to protect the human genome, especially against medical practices and research activities in both national and international contexts.

With the discussion that this instrument aroused, the contradiction between different ethical approaches to the biomedical and biotechnological social phenomena could already be seen in the nascent national and international biolaw. On the one hand, a reactive and protectionist approach that uses law as a mechanism of control of social fear, and, on the other hand, a more open-minded approach to co-evolution between science and society. While the legalization of new interests in categories

of human rights contemplated by this instrument, such as genetic rights, was useful in guiding national legislation (the rights of individuals to informed consent, non-discrimination, privacy and confidentiality, among others), on the other hand, it generated confusion. The instrument included open categories, such as the "human genome as a world heritage", which has not always been adequately interpreted, developed and applied, resulting in the risk of excessive legal intangibility of the good. Knoppers, who proposes to interpret it as a "bio common" in the same way as the common good "sea" is interpreted in international public law, suggest an interpretative key that can define its meaning and operationalize the category.

In the same year the instrument of UNESCO was promulgated, the Council of Europe approved the first International Treaty on legal questions concerning the applications of biology and medicine, the *Convention on Human Rights and Biomedicine*, informally called Convention of Oviedo. This Convention is the first legally binding instrument at the international level, open to European and non-European States, which enshrines new human rights, namely the protection of the in vitro human embryo and the human genome. It has been extended through additional protocols in areas such as the ban on human cloning (1998), human organ and tissue transplantation (2002), biomedical research (2005) and genetic analysis for purposes of health (2008). The other treaty, recently approved by the European Council in biolegal matters and open to all States, is the *Convention against Trafficking in Human Organs* of 2015.

The Oviedo Convention highlighted one of the problems of biolaw in terms of the legitimacy of its sources. From the discussion phase of the Treaty, tensions between the ethical and legal consensus reached at international level and those obtained at the national level in matters that are so ethically sensitive for each society were manifested. For example, the United Kingdom or Belgium did not sign the Convention because the protection afforded to the embryo was excessive, while Germany and Ireland did not sign it because they considered that protection was insufficient. Despite this, the Convention was a very significant advance for the international biolaw, because it guaranteed rights with sufficient flexibility to adapt to the coming changes, contemplating mechanisms of revision and reservation. However, a clear weakness was the role granted to the European Court of Human Rights, only of an interpretative nature, without a judicial protection of the basic rights that it contemplates.

In the following years, the International Committee on Bioethics of UNESCO continued to do a great deal of work in integrating the problems common to bioethics and biolaw. In 2003, following the previous declaration of 1997, a new instrument that further specifies human rights in the field of genetic research, entitled International *Declaration of Human Genetic Data*, was approved. During the same period, the instrument that framed the two previous ones began and established the general biojuridical principles within the international system of human rights: the *Universal Declaration of Bioethics and Human Rights*, approved in 2005.

While this Declaration is a very relevant milestone for the interface between bioethics and biolaw at the global scale through the language of human rights, its approach to this interrelation is rather deficient in the conceptual field. First, it mis-

takenly introduces the word bioethics in its title, despite it is a legal document that is not about a normative discipline like bioethics. If this were so, it would be an open contradiction, since a normative system such as international law cannot be applied to another normative system such as bioethics. Second, it falls back into the same error when it sets the object of the Declaration in these terms: "it deals with *ethical issues* related to medicine, life sciences and related technologies applied to human beings." In addition, the same happens when it expresses one of its objectives in this way: "to provide a universal framework of principles and procedures to guide states in the formulation of legislation, policies or other instruments *in the field of bioethics*" (italics are mine).

This confusion, which is quite common in the specialized literature and leads to include a normative system within the other (bioethics within the biochemistry and vice versa as well), not only supposes a regression in the understanding of the Interrelationship between bioethics and biolaw, but also detracts from the same instrument, one of whose objectives is for national states to be able to generate legally binding regulations, using as a basis and framework for interpreting human rights. It should also be borne in mind that human rights in the field of biolaw play a vital role in the production and application of specialized legislation, since they have the function of guaranteeing constitutional values. This certainly implies a generative function of new categories of rights based on traditional human rights, an interpretative function of legal rights and a distributive function of goods that are the result of scientific advancement.

In spite of these conceptual confusions, the Declaration, in essence, is a very new and valuable instrument as a framework for biolegal principles aimed at guaranteeing the practice of medicine, biomedical research and its biotechnological applications at the international level. At the same time, it is an instrument of protection of underdeveloped countries' people against the bioeconomic domination of the most scientifically developed countries. In addition, its approach to the problems of such practices is broader than it was in previous decades in the context of bioethics and international instruments of biolaw, was restricted to clinical, and research. In fact, the Declaration incorporates new bio-legal principles such as social responsibility and health, respect for cultural diversity and pluralism, protection of future generations, the environment, the biosphere and biodiversity, and management of technoscience in accordance with the precautionary principle, of international cooperation and the shared benefits of its progress.

Despite the limitations of human rights contained in *soft law* instruments, they make it possible to promote their progression in legally binding instruments and, in turn, to provide an interpretative framework for national legislation in biolegal matters. However, the importance of human rights is not only limited to the influence on the development of international biology, international and constitutional jurisprudence, and national legislation, but on the evolution of academic and institutional bioethics itself (Lenoir and Mathieu 2004; Annas 2005).

3.2 Biolaw in Contemporary Constitutionalism and in the Legislation

Under the influence of international human rights law's progress regarding biomedicine, human genome and biotechnologies, contemporary constitutional law has begun to develop new fundamental rights in these matters, opening up specific areas of competence for the legislator. For example, the Swiss Constitution of 1999 introduced a number of articles on health protection, transplantation, reproductive medicine, non-human genetic engineering and the human environment. However, the level of comprehensiveness of its constitutional norms in these matters, especially in reproductive medicine, make it an exception within constitutional comparative law, and also raises a very relevant issue for biolaw. The matter is the reasonable adjustment between extension of normative content and the level of hierarchy of the rule that consecrates the said content. In the case of Switzerland, for example, it is highly debatable that such specific issues, as the immediate transfer of in vitro embryos to women, are subject to a constitutional change rather than to a legal one.

The Constitution of Portugal (1997) and Greece (2001) also included fundamental rights relating to the protection of dignity, health and genetic identity, but with more general rules than those of the Swiss Constitution. For its part, Germany incorporated in its constitution a very broad principle on these matters, guaranteeing "the natural bases of life" in connection with the principle of responsibility for the future generations. Many other constitutions in the world contemplate one or another principle or constitutional rule related to bioethical questions. To give some examples: the requirement of informed consent to participate in scientific or medical experiments (in constitutions of some countries of the former Soviet Union), preservation of the genetic integrity of the country (Brazil, Ecuador), regulation of biosafety of genetically modified organisms (Ecuador), and respect for future generations (Brazil, Japan, Norway).

The study of comparative constitutional law has been another relevant legal approach to the understanding of bioethical issues in society and a valuable source for analysis, discussion and proposals for regulation that ad hoc commissions or permanent national bioethics commissions pose to legislators in various biojuridic subjects, as well as for the decisions of the courts in these matters. Within the functions that constitutional law plays in the controversial issues that bioethics assumes, I expose the most influential ones. On the one hand, it is a source of basic principles and rights with respect to problems at the beginning and end of life or issues related to arbitrary discrimination (e.g. genetics) or health protection (life and social equality), giving legal solutions in the absence of special legislation or replacing its indeterminacy. On the other hand, it is a powerful juridical tool to interpret tensions between individual and collective decisions, pondering conflicting fundamental rights and reconciling value pluralism and religious denominationalism within a society.

However, what may be an advantage of the constitutional text, it can lead at the same time to a stalemate in bioethical social debate if constitutional principles and values, such as dignity, life, integrity, equality, or health, are used by very different

ideological positions to achieve diametrically opposed interpretations. Issues such as the decriminalization of abortion or postcoital pill distribution policies in conservative Catholic societies raise bitter controversies that end in the constitutional courts whose judgements do not always evidence the usual social practice and the less radicalized moral visions (Bascuñán 2004).

In these cases, legislation can be a useful instrument for reflecting social moral consensus as well as an instance for integrating scientific evidence with due rigor, by designing relevant legal institutions (informed consent, surrogate decision, advance directives, etc.), clear and flexible legal rules, and non-jurisdictional instances of consultation for difficult decisions (e.g. ethical committees of care). This should allow the expression of the axiological plurality that a democratic society must integrate. However, the problem comes when, dealing with these complex matters, the state institutions fail to establish the procedural conditions of minimum standards to discuss, design, apply and revise biolegal legislation that reflects social moral consensus, respects axiological pluralism and generates adherence in the community.

3.3 Biolaw in International Constitutional Jurisprudence

Constitutional and international jurisprudence has also played an important role as a source of biolaw. In this respect, it is necessary to emphasize at the outset the difference that, in principle, *common law* and *civil law* systems maintain as well as the points in which they converge regarding biolaw.

In the *common law* system, in which the judicial precedent plays a preponderant role, the beginnings of biolaw were marked by the study of the jurisprudence—the *Casebooks* are the ones in which the bioethical relationship and law in paradigmatic judicial cases are discussed (Menikoff 2000). However, over time, the creation of a specialized statutory right has gained more importance, due to the need to provide legal certainty to the agents involved in the relations of biomedical and clinical fields. hence, it is necessary to recognize specific rights and procedural rules of evaluation and control (e.g. in laws relating to assisted human reproduction, patient rights, biomedical research, genetic privacy, use of human biological material, etc.).

Before this statutory law was established with specific legal rules, this system had the advantage of being able to respond more flexibly to the challenges of biomedical scientific advances, thereby reducing the structural gap in biolaw regarding these advances. However, at the same time, it was able to push the creation of a *statutory law*. An example of this was the jurisprudence of the US Supreme Court in the matter of decisions at the end of life (*Quinlan* case and *Cruzan* case), which influenced the legislation regarding the rights of patients (autonomy rights, representation, decision and the institution of the vital will) and the creation of health care ethics committees (Baron 2007).

Conversely, in the countries of the *civil law* system, although the impulse of the first specialized laws marked the topics of the discussion about the relation between bioethics and law, the same production of legal norms led to rigidities and impasses

that have ended up being unblocked by means of constitutional jurisprudence or international courts. An example of this has been the influence of the judgments of the European Court of Human Rights on European legislation on assisted reproduction (*S.H and Others vs. Austria* case and the *Pavan vs. Italy* case). Another example on this same subject, now in the jurisdictional system of the Inter-American Convention on Human Rights, is *Artavia Murillo* et al. versus *Costa Rica* (Brena 2012).

Both systems of law are mutually influenced and transformed when bioethical issues have entered their sphere of production and application of legal norms. The extensive jurisprudence of the European Court of Human Rights applied to both *common law* and *civil law* countries on bioethical issues demonstrates the diffuse boundaries of both systems. Although the Court has repeatedly recognized that, in sensitive matters such as beliefs about human life, States enjoy a great deal of discretion, it has also, in various judgments, limited that margin through concepts such as inhuman treatment, avoidance of abuse, and privacy, among others. An example of this is the evolution of the Court with regard to decisions at the end of life, especially assisted suicide[2] and suspension of treatment.[3]

However, there are many risks in legislating and applying law in biolegal matters, instances where the relationship between bioethical discourse and legal discourse is highlighted. For example, the tendency to avoid social discussion and tensions of moral dissent; the tendency to intervene hastily with legal norms to respond to the social fear of biotechnological progress; to legislate without adequate scientific evidence; to legislate for the parliamentary majority that does not correspond to the opinion of the citizenry; to produce deficient norms in its legislative technique that tend to generate legal uncertainty; and to legislate exhaustively without considering non-jurisdictional instances of interpretation and enforcement, among others. These are the types of questions that, beyond the evaluation of the sources of biolaw, require thinking about what the conceptual reference frames in which biolaw has shifted are, and in what its relation to bioethical discourse is.

4 Reference Frameworks for Biolaw and Their Relationship with Bioethics: A Plurality of Models

4.1 Reference Frameworks and Models in Biolaw

One of the features of law that I have highlighted, with respect to its degree of adaptability to the phenomenon of biotechnological progress in complex social contexts

[2]From the *Pretty* versus *UK* case, 2002—the Court dismisses the violation of the right to private and family life, to *Koch v. Germany*, 2011, and *Gross* versus *Switzerland* 2012 cases—the Court in both cases estimated that the State violated the right to private and family life.

[3]*Lambert and others* versus *France* case—the Court argues in favor of the laws authorizing the suspension of treatment, so that a medical decision correctly taken would not violate the right to life as sustained by the claimant family.

(axiological pluralism) and under the tension of extra moral forces (impulse of technological innovation, market forces and globalization), is its structural mismatch to regulate this phenomenon. Although this gap can be explained by the nature and social function of law, that is, giving legal security through principles, rules and procedures that guarantee autonomous decisions as well as protect the most vulnerable and distribute benefits and burdens equitably, the ethical-scientific and ethical-social debate on new biomedical advances is given simultaneously with a legal analysis that adds recommendations at the level of best practice policies and calls to international regulatory harmonization (Dove et al. 2014).

The way how new health technologies, such as cell therapy with iPS cells and gene expression, using the CRISPCas9 technique have been addressed, shows this convergence and simultaneity of bioethical and biolegal arguments. However, this process is still in the scope of the ethical recommendations of scientific organizations and not in the processes of generation of legally binding norms that always require longer analysis and decision.

However, the co-evolution between bioethics and biolaw has been much more problematic and risky, ranging from two opposing tendencies that persist in many societies characterized by scarce channels of citizen participation and by the lack of an ad hoc institutional framework to channel the biomedical regulatory process. On the one hand, it is possible to identify a tendency towards a model of anomie in biolaw, in the sense of avoiding or delaying the discussion and adoption of legal norms in these sensitive and complex matters from the moral point of view, a question that obeys very varied causes, as I shall point out later. On the other hand, a tendency towards a protectionist model in biolaw can be identified, in the sense of an overregulation, both in normative and procedural content, in response to the social fear interpreted by the normative authority or in response to different kinds of ideological pressures (confessional, secular, political, etc.).

The motivations behind these extreme trends in biolaw are always very heterogeneous. Therefore, before characterizing their respective models, I will give a brief presentation of the various frames of theoretical-philosophical reference that may be behind those tendencies. The frames of reference are related to different philosophical perspectives that bioethics has taken on to confront axiological conflicts in pluralistic societies: the libertarian model, the liberal model, the utilitarian model, and the personalistic model (Palazzani 2016).

The libertarian model asserts that the intervention of the State in matters of bioethics is inadequate because it interferes in areas that should be reserved for the free self-determination of individuals and the technical decision of health professionals. In addition, because it can obstruct the free development of research and discourage self-responsibility. Finally, because it is inefficient to control at the international level the prohibition of certain practices (e.g. cloning, use of embryos in research, etc.). This model is associated with what has been called "Highly Inappropriate Legislation" (HIL), a current that postulates that law is inappropriate for the spaces of intimacy and personal freedom in matters concerning morality (Nielsen 2000). This position can find its philosophical foundation in Nozick's political theory (*Anarchy, State and Utopia*, 1974) and Hayek *(Law*, *Legislation and Freedom*, Vol.

1 Rule and Order, 1973), and in Engelhardt Jr. (1996), who postulates the impossibility of building consensuses between moral strangers in contexts of plurality of moral visions and multiculturalism. Under this model, the State must guarantee the maximum sphere of competence for free decision-making and promotes the self-regulation of professionals through codes of ethics or good practices.

The liberal model admits a minimal intervention of the legislation in these matters, reduced to establish procedural rules that allow resolving the conflicts of interests, so that personal moral decisions are guaranteed in a context of axiological pluralism in the society. In this context, biolaw must be neutral with respect to individual moral options and only limit them if they affect the interest of third parties. Biolaw is then reduced into the role of norm setting that recognizes constitutional principles such as arbitrary freedom or non-discrimination and the regulatory function that determines mechanisms for free decision-making (e.g., informed consent, advance directives, ethical committees, etc.). A good expression of the philosophical foundation of this model is found in Charlesworth (1993) who argues that in a liberal society the legal sphere should not deal with matters of personal morality since there is no possibility of a social consensus on essential values. Instead, it should only guarantee personal autonomy in decisions related to medicine and biotechnology.

The utilitarian model has had a relevant influence on bioethics. It is used as a criterion for understanding and applying the principle of beneficence and nonmaleficence (Beauchamp and Childress 2013) and it is also a conceptual and procedural framework for analyzing bioethical conflicts, as can be seen in one of the contemporary most prominent utilitarians, Singer (1993). However, it is also well known that, since the origin of utilitarianism (Bentham and Mill), legislation has a prominent moral function in this theory, which is a social instrument aimed at ensuring the best possible outcome in relation to social efficiency, increasing the quality of life and well-being of the largest number of people, by reducing the suffering of individuals. It is possible to identify this frame of reference in the field of applied ethics and research ethics, but also successfully applied to the areas of public health, distribution of health resources, and health emergencies, among others. When it comes to assessing the incorporation of new biotechnologies into society, one can appeal to the utilitarian criterion of "public interest" as a guarantee of the legitimacy of legislation that gives the greatest benefit to the greatest number of people. The personalist model in biolaw puts the emphasis on law as a limit for technology in order to protect the dignity of the human being. Guided by this concept, biolaw would have the function of fixing "the insurmountable limits of the dangerous attempt to subjugate technoscience to individual will, to arbitrary politics or to the contingent novelty of extemporary social needs (Palazzani 2016)." The philosophical justification of this model is found in Kantian ethical theory, which expresses the idea of dignity in the second formulation of the categorical imperative: "Act in such a way that you always treat humanity, whether in your own person or in the person of any other, never simply as a means, but always at the same time as an end" (AA, IV, 429). This idea has been widely used in the discourse of bioethics as a requirement of non-instrumentalization of people in diverse biomedical contexts and technological applications. The indiscriminate and sometimes uncritical use of this concept has led some philosophers to

postulate the uselessness of the same for the bioethical discussion (Macklin 2003) or even to qualify it as risky for society because it is ideologically designed to stop biotechnological advances that can go to the benefit of people (Pinker 2008).

Beyond this controversy, there are authors who, with detail and rigor have distinguished the uses that this concept has, especially, in the human rights instruments. Beyleveld and Bronwsword have argued that the diverse uses of this concept in human rights instruments can be traced back to two opposing conceptions: (i) "dignity as empowerment," which is used in classical human rights with the traditional sense of individual autonomy and free development of personality, and (ii) "dignity as constraint", which is used in the recent human rights instruments related to bioethics. In this last sense, dignity works rather as a limit to autonomy. The authors consider difficult to defend this meaning rationally since it depends on contingent cultural provisions and contexts. From a Kantian perspective, these authors believe that in the field of biolaw, the use of the concept of dignity can be defended rationally, not only as a requirement of being treated as an end and not as mere means, but as a practical virtue which indirectly supports respect for human rights, without falling into a concept of paternalistic dignity understood as a limitation of autonomy (Beyleveld and Bronwsword 2001).

With these different philosophical frames of reference in mind, I return to the extreme models of biolaw to make a more detailed description and conclude with a presentation of the moderate models that are in the middle of each other. With respect to the trend I call *the model of anomie in biolaw*, it can identify two motivations apparently opposed in the ideological field, which finally end up being complementary. On the one hand, legal abstention can be related to the libertarian model that privileges freedom in the health market or biomedical innovation, and whose normative source is professional self-regulation and individual decisions. On the other hand, it is related to a morally conservative socio-political context, in which the social debate is very polarized and lacks adequate institutional channels to build consensus to serve as a basis for legislating.

Nielsen (2000) calls this abstentionist approach to biolaw individual *control—the private ordering approach* and although he considers that it fails in central aspects regarding the role of biolaw in society, it may have advantages when we think that it is better not to have a law than to have a bad law. The author points to the Italian situation of deregulation of assisted reproductive techniques (prior to the 2004 law), which had strong public tensions over the practice and a *laissez-faire* state of reproductive medicine, a scenario that is perfectly transposable today to Latin American countries that are without legislation in the matter as Chile, for instance. Regarding assisted reproduction in Italy, Zatti (2000) pointed out that the lack of legislation was due not only to contingent political causes, but to a legislative practice that lacks technical and preparatory work of purely verbal compromise. On the one hand, and to think of law, paradoxically, as an instrument for the proclamation of values, rather than as a mechanism for resolving conflicts. On the other, all of which leads, finally, to opt for the legislative vacuum rather than for a socially and politically legitimized regulation.

At the other end, *the prohibitionist model of biolaw* is characterized by the fact that in matters so delicated around life, society must anticipate the risks of free choice of people and the lack of control of biomedical practices, through a clear system of prohibitions and sanctions. Although it is a model diametrically opposed to the previous one, it is at the same time, complementary, because many societies, due to the lack of social moral consensus, pass to prohibitionist legislation pretending it replaces a not achieved social consensus. The frame of reference of this model is, in particular, personalistic. In its arguments to legitimize law, the idea of dignity as the ultimate ratio is used to put limits to decisions that go against the "sanctity of life" (for example, in subjects such as protection of the preimplantation embryo, surrogacy, euthanasia and assisted suicide, among others), which, after all, leaves no room for other moral choices in society.

Although it is evident that a model of this type provides stability and legal certainty against morally controversial scenarios of biomedical practice, by imposing a single moral vision, legal or regulatory anticipation excludes all the beneficial possibilities that the same practice implies. Due to that reason, a prohibitionist strategy ends up opening the dam of legal containment with successive modifications. The cases of Germany, Austria and Italy, countries that have developed very conservative legislation on in vitro fertilization and embryo protection, show how the initial legal restrictions have been reduced to include other legitimate interests such as the mother's right to health or the right to have a healthy child, against the intangibility of the in vitro embryo.

On the other hand, such a regulatory strategy has certain advantages, because "it gives the possibility of provoking an open debate in the legislative stage, whose results can sustain the legitimization of acta as well as favor circuits of political responsibility and democratic accountability (Casonato 2006). However, this is not always the case, especially if democratic institutions are not mature enough to channel such debates, which may lead to a divorce between law and reality. Therefore, it is not a good strategy to start with a prohibitionist model and then to open it little by little, if the conditions for legislative change are not there. In fact, the changes in the Italian and Austrian legislation referred to above did not come from the legislative branch but were a consequence of the constitutional and human rights courts' case law.

A middle way between the two models discussed above are the liberal model, which is a more adequate and pertinent approach to face the legal challenges that point out moral and social scopes of biomedicine. A good way to characterize these intermediate models, which I might also call permissive legal intervention model and enforcing law model, respectively, is the one made by Lord W. Kennett at a conference on legislation and regulation in Europe. He distinguished two attitudes to face the questions that pass from ethics to law. The first attitude towards biomedical challenges feels that "if it is wrong, I must legislate at once. Let us forbid it in the Penal Code, or at least write it into the Civil Code, and if I can't do either of those, then let us outlaw it in some other code or body of law, such as the Public Health Code". The English say that this is the *French way*. The other attitude facing the same challenges feels that if it is wrong, let us educate everybody to know that it is

wrong, and that will surely solve the problem. At the very most, let us hope that the professionals will regulate it in their codes of practice, medical, nursing, and so on, and above all, no new law. The French say that this is the *British way* (Fluss 2000).

The permissive intervention model is framed within a liberal model that, on the one hand, privileges the function of recognition of basic values and fundamental rights that guarantee the respect of autonomy and the free development of the personality in the clinical and biomedical decisions. On the other, it fosters the regulatory role of institutions and procedures (ethical, welfare and research committees, advisory committees and regulatory agencies) that can arbitrate conflicts of interest with respect to those decisions. In this sense, basic values such as human dignity are legally recognized, for example, in the context of complex decisions on beginning of life beginning and end of life, in terms of *dignity as empowerment*, namely, as the ability of individuals to determine their own good regarding their body, privacy and health.

In the context of legal intervention, the permissive model tends to generate an institutionality that can channel the opinions and arguments that are made in the society regarding a subject to legislate, for which privileges the formation of ad hoc committees integrated in a plural and interdisciplinary way. An example of this was the *Warnock Committe* in the United Kingdom, in charge of laying the foundations for an assisted reproductive law, taking into account, as expressed by the chair of that commission, that affirming rights is a social act that requires recognition of positions shared in public opinion (Harris 1985: 129–135). Following the same example of this commission, the model of an independent agency was born (*Human Fertilization and Embryology Authority*) with functions of control and regulation recognized within a law (*Human Fertilisation and Embryology Act*, 1990) that is broad enough to guarantee the legal sustainability of the same in the future.

The legal enforcing model, which is more typical of *civil law* countries, emphasizes the guaranteeing function or the protection of biolaw, using a more rigid legal technique, both in the content of the standard and in the definitions required for its interpretation. For the same reason, the legislation tends to be more recharged and exhaustive, leaving little room for the specification by means of regulation or via special authority. The rights that are devoted to people regarding decisions on problematic ethical issues at the beginning and end of life are built on the limits of autonomy, so they operate with a concept of *dignity as constraint* rather than *dignity as empowerment*.

An example of this model was the body of bioethical laws of France of 1994, which were promoted by a permanent national advisory commission on the regulation of bioethical issues (*Comité Consultatif National d'Éthique*, created in 1983). These laws, by the same logic of the model, contemplated a mechanism of revision every five years. In the amendment, this review period was extended to seven years and also included the competence of the *Comité* to organize *état généraux* (conference of citizens elected to represent society in its diversity so that its view was taken into account by the *Comité*). This was done before proceeding with any reform project on bioethical issues (in the field of biology, medicine or health), in such a way that it follows a hierarchical strategy of social consensus in morally controversial issues

in these domains, rather than a strategy of assimilation of public opinion as was the strategy of the *British way.*

In each of the models of biolaw that I have exposed, both in the extreme models as in the intermediate ones, we can identify a way to embody the interface between bioethics and biolaw. Three approaches that I will analyze next emerge here: the one of substitution, the one of confrontation and the one of complementarity. Relevant current conceptions of biolaw can be extracted from them.

4.2 Interface Between Bioethics and Biolaw: Towards a Middle Way Between Convergence and Divergence to Face the Challenges of the 21st Century

The concept of interface expresses the process of differentiation (confrontation or complementation) or undifferentiation (substitution) that has occurred between bioethics and biolaw as normative social systems. In the first phase of bioethics, law was unfailingly integrated within its field of knowledge and practices, but progressively it was reaching a disciplinary autonomy that took the name of biolaw.

A retrospective view of this process allows us to identify many areas where the language and the way of thinking of law were introduced in the nascent discourse of bioethics. This penetration of law focused mainly on two areas: the contribution made in the transition from medical ethics to bioethics and in the introduction of the language of rights in the latter. Law transformed the traditional medical ethics of paternalistic style into a new applied ethics, bioethics, to the extent that it had to account for the new rights of people in the field of clinical relationship and medical research, by integrating concepts such as autonomy, privacy, confidentiality, and other legally relevant interests. On the other hand, law contributed to the disciplinary configuration of bioethics through what was called the rights movement, that is, the use of rights language in the field of health and biomedicine (Sperling 2008), which was recognized in one of the seminal books of bioethics, *Principles of Biomedical Ethics* (Beauchamp and Childress 2013).

In a second phase, when law takes a greater role in society by the growing juridification of bioethical issues through legislation and specific jurisprudence, bioethical and legal doctrines began to consider what the relationship between these *strange bedfellows* is, according to Spielman's metaphor, simultaneously separated and, at the same time, mutually dependent disciplinary fields. In this regard, Spielman (2007) comments:

> Law and bioethics are inherently different social and communicative systems. Each constructs a social reality of its own, communicates different norms and fulfills a different social function. Each has different goals, methods and epistemologies. Each identifies and uses experience, assumptions, values and burden of proof in different ways, yet they are deeply dependent on each other.

With this reflection, I give way to the analysis of the points of convergence and divergence between bioethics and biolaw, which I will systematize in three levels (material, formal and procedural), and then describe, from these levels, three forms of conceiving the interface (substitution, confrontation and complementarity). Each one of them expresses a conception or approach to biolaw.

The interface between bioethics and law can be analyzed in three levels of connection. The first level is the material one, which refers to the way of understanding the relationship between the ethical normative system and the legal normative system, that is, what the common axiological content between bioethics and biolaw is. The second level of connection is formal, which refers to relationships and differences in epistemological and methodological terms. Finally, the third level of connection is the procedural one, which is expressed in the common institutionality between bioethics and biolaw, namely, the relation between bioethics and jurisdictional function, material and normative pluralism of biolaw, and the processes of consensus building in the production and review of biolaw.

A first way to understand the interface between bioethics and biolaw is as substitution, in the sense of a process of legalization of bioethics. As I pointed out earlier, this constitutes an epistemological error, since a normative system like the legal one cannot have as its scope of application another normative system as bioethics. The *Universal Declaration of Bioethics and Human Rights* has validated this approach, since it sets the objective of the instrument "to provide a universal framework of principles and procedures that guide states in the formulation of legislation, policies or other instruments *in the field of Bioethics*" (Italics added). Gros Espiell (2011) reiterates this same mistake in defining biolaw as "the set of rules and principles that legally regulate bioethics". A definition in these terms contradicts what this same author claims about the epistemological statute of biolaw, which, according to him, is not intended to supplant, replace, or displace bioethics.

Clearly, in the substitution approach, a strong connection is established between bioethical principles and norms, and biolegal principles and norms, without taking into account the epistemological difference of each of these normative social systems and establishing a strict correspondence of its axiological content. By criticizing this conception of legalized bioethics, Valdés (2015: 1201) correctly points out that biolaw is:

> An eminently legal approach conceptually separated from bioethics, whose scope of application is law and not morality, for which the product of biolaw is normative and not deliberative. Therefore, although in this sense there is a clear relationship between both disciplines, their meanings, scope and, therefore, their natures, differ, which endows biolaw with identity and epistemological and methodological independence.

This approach may also include the posture of Rendtorff and Kemp (2000) who argue for a transposition of the basic ethical principles they postulate for bioethics (autonomy, dignity, integrity and vulnerability) to biolaw as principles recognized at the constitutional level without raising an epistemic distinction between ethical and legal levels. In this sense, biolaw would consist directly in the application of principles and practices of bioethics with the coercive power of law (Kemp and

Rendtorff 2000: 69). Kemp and Rendtorff place a conception of this type within the humanist tradition and the European legal culture, which is where the personalist model of biolaw rests on.

This direct transposition of bioethics into biolaw can be sustained by a strong methodological connection between legal argumentation and moral argumentation, in the same terms as Beyleveld and Brownsword (2000), for whom the first argument presupposes the second in all cases. For this very reason, the connection at the procedural level tends to be diluted, since the functions of bioethics and biolaw are not well differentiated. To give an example, in the jurisdictional function runs the risk that in the *adjudication processes* the judge confuses the ethical reasons with the legal ones.

Other interpretation of the interface between bioethics and biolaw is what I call the confrontational approach, which denies that there is a necessary connection between the normative content of bioethics and law. The system and legal rules are defined by their formal validity and not by their adequacy to moral contents, so the axiological content is a contingent and not a necessary property of law. Law, in this sense, is incapable of consolidating moral consensus in plural societies. On the other hand, from the methodological point of view, this approach defends the qualitative difference between legal argumentation and the general practical argumentation. A judicial decision does not contain a claim of absolute justification, but only within the framework of a particular legal system, based on either law or a judicial precedent. Therefore, legal argumentation can fall into an inmoral law that, although the judicial decision does not lose its legal character. An approach of this nature is aligned with a libertarian model of biolaw, for which law is an inadequate instrument for regulating decisions that pertain to the sphere of morality.

A middle way between these two approaches is the conception of complementarity between bioethics and biolaw and that can be associated with the permissive biojuridical intervention models. This approach starts from the premise of a necessary material, methodological and procedural connection between ethics and law applied to biomedicine. However, at the same time, recognizes the disciplinary autonomy of both bioethics and biomedicine. The interdisciplinarity and methodological complexity represented by this approach requires a more detailed analysis at each of the connection levels.

At the level of normative material connection, I can distinguish the following aspects. First, adequate procedures for assimilation of extra-juridical scientific-biomedical and bioethical issues by legislative discretion, *rule-making processes*, and judicial, *adjudicatory processes*. Second, the process of intradisciplinary integration of law, that is, of its various branches, for the discussion, analysis and elaboration of legislation. Third, the integration of the processes of shaping of moral consensus in social contexts of axiological and cultural pluralism within the institutional processes of legislative and judicial discretion.

At this level of connection, it is fundamental to take into account that the morally controversial issues that bioethics discusses and analyzes along with scientific questions are part of the social phenomena that law must assimilate as a socially differentiated subsystem. And for this, law has to realistically consider that these disputes,

fueled by needs, desires and very diverse social assessments, are born before and outside the legal world. Therefore, in this sense biolaw fulfills a guarantor function of marginal and complex situations and not the core of socially accepted behaviors.

At the level of the methodological connection, the conception of complementarity takes care of adapting the design and the legal technique to the axiological complexity of moral and scientific phenomena. Thus, it seeks strategies of balance between definitive rules (approximation based on contexts, distinguishing the appropriate qualifications for each fact or process, measuring the weight of defining or not defining), substantive rules (with requirements of necessity, feasibility and systematic compatibility), and procedural ones (oriented, for example, to avoid the judicialization of conflicts in clinical decision-making). At the same time, the recognition of axiological pluralism should be complementary to the integration of material pluralism (independent authorities or technical bodies), normative pluralism (interaction between national jurisdiction and supranational jurisdiction, as has already been experienced with regional human rights courts), and legal pluralism (recognition in the national legislation of normative bodies of different legal traditions, such as indigenous, tribal, religious, among others).

Within this understanding, biolaw acquires its own epistemological status that is not assimilated either to the epistemological nature of bioethics (substitution approach) or to the epistemological statute of traditional law (confrontational approach). First, because it forms a different interdisciplinarity of bioethics, with a methodological scope capable of generating and applying binding norms for new scenarios of biomedicine and biotechnology. Second, because beyond traditional law, it is capable of problematizing classical legal institutions and providing new elements for legal argumentation. Third, because, overcoming the limitations of legal dogmatism operating in isolated branches of law, it is able to identify and elaborate new legal categories and rights, integrating a whole legal system. In this sense, following the concept of Valdés (2015):

> Biolaw is justified and legitimized as a mature and epistemologically independent discipline, since it is capable of identifying new categories of damages and establishing procedural bases for the constitutionalization of fourth generation human rights or biorights.

After reviewing the different approaches to the interface between bioethics and biolaw, it is just necessary to very briefly point out some challenges that, based on the complementarity approach, are still pending for the 21st century biolaw. These challenges are systematized in four dimensions, necessary for the regulation of future technological innovation: (i) Bioethical co-evolution and biolaw; (ii) Regulatory space; (iii) Legal temporality; and, (iv) Legal interoperability.

The relationship between bioethics and biolaw has not only changed the terms of traditional debate on the relationship between ethics and law. However, it has placed the latter relation in a very intense co-evolutionary dynamics, since new biotechnological advances are requiring an ethical, social, political and economic reflection with a prompt legal response through very varied instruments and strategies on a global scale.

That rapid legal response conditions new ethical, social and political reflections, which give a recursive dynamics between ethics and law as never before. The fact that the interface between bioethics and biolaw is increasingly mediated by other sciences and discourses such as biopolitics, bioeconomics, and regulatory sciences, among others, clearly demonstrates that.

Regarding the second challenge, I note that the governance of technological innovation is not exhausted in the production and application of biolaw. Nowadays the regulatory processes for technological innovation are increasingly complex, which is changing the configuration of the space or regulatory environment. The idea of "regulatory space", following Scott (2001), is a metaphor that expresses that the resources pertinent to maintain the regulatory power and the exercise of its capacities are dispersed and fragmented in the society. These resources are not restricted to formal authority, the state derived from legislation or contracts, as it also includes information and organizational capacity, distributed between the State and non-state organizations. In this space, not only regulators and regulators coexist, but also other interested organizations. The relationships between these diverse actors can be characterized by their complexity and their horizontal dynamics of interdependence in negotiation.

A third challenge relates to the temporary adaptation of law for the regulation of technological innovation in society. One problem that technological societies must face is how to stimulate innovation and at the same time regulate it, in a context where perhaps the only certainty for law is the intrinsic risks that innovation entails. According to Ranchordás (2014), an approach to the regulation of technological innovation requires: (i) to accept that legislators do not know the essence of all the problems that need to be regulated; (ii) to look for information and try to adapt their legislative instruments to the nature of the problems; (iii) to experiment with the potential of regulatory solutions; (iv) to extract lessons and incorporate this knowledge into new and better laws; and (v) to recognize legislative errors. Some mechanisms to adapt law to the vertiginous technological changes that have been proposed and implemented are the sunset clauses and the experimental legislation.

A final challenge for the twenty-first century biolaw is related to the need for the development of a transnational or transboundary law, applicable in the area of law and biotechnologies as well as law and convergent technologies (nanotech, cognitive sciences, ICTs), which have an almost immediate global impact. For the development of this cross-border law, we can use the concept of legal interoperability, whose origin comes from the field of information technologies to the right to account for and to legalize intercommunication between different regulatory processes and structures (Santosuosso and Malerba 2014). Legal interoperability addresses the process of making legal rules cooperate across jurisdictions, at different levels within a single state or between two or more states. At the same time, it fosters to adopt different regulatory models: harmonization, standardization, mutual recognition, reciprocity and cooperation (Palfrey and Gasser 2012). In the area of biomedicine and biotechnology, these models are already being used to share biomedical data and to improve governance of research biobanks networks worldwide (Weber 2013).

5 Conclusion

In this chapter, I have argued that the process of co-evolution of the interface between bioethics and biolaw raises, first, a re-actualization of the debate about the relationship between ethics and law in more practical terms, due to the complexity of technological innovation in the era of global society. Secondly, I have argued that the traditional understanding of the relationship between bioethics and biolaw is producing a crisis because of its inability to cope with the simultaneity of ethical debates, as well as to engender legal responses to the challenges of biomedicine and biotechnology, which require new tools to configure a regulatory space for a cross-border regulation.

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