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Editors

Biolaw and Policy in the Twenty-First Century

Building Answers for New Questions

Springer

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This book is dedicated to the memory of Peter Kemp.
Great colleague and good friend.

Foreword

Ethics and law are different. One obvious way of showing that they differ is by pointing to a law that is unethical, such as the laws permitting slavery in the southern states of the USA, or those enforcing racial segregation in South Africa during the apartheid era. Granted, under some conceptions of law, those laws were not valid laws, precisely because they violated fundamental moral principles. This is, however, a conception of law that legal positivists reject, and it is not obvious that they are mistaken about that.

There is a more systematic way in which ethics and law differ, on any conception of law, and even when we are comparing sound ethical judgments and laws that are ethically justifiable. Ethical judgments can be made in very specific situations, in fact in situations that are unique. We can also make ethical judgments in private, I our own minds, without expressing them to anyone else. It can even be right, as the nineteenth-century English utilitarian Henry Sidgwick argued, to do something in secret that it would be wrong to do if it were done openly. Sidgwick's assertion that ethics can be esoteric is controversial, but it does not involve a contradiction. Acts that become widely known may have consequences that are very different from acts that remain secret. That makes it hard for a consequentialist to deny that different moral judgments may apply, depending on whether or not the act can be kept secret (Sidgwick 1907; De Lazari-Radek and Singer 2014).

Law, on the other hand, is inherently public and normally applies to a wide range of situations. For that reason in certain circumstances, it can, surprisingly, be ethically justifiable to break even a good law, the kind of law a country ought to have. One well-known example involves the law against torture, and the "ticking bomb" scenario that philosophers often discuss. In this scenario, a terrorist has planted a nuclear bomb somewhere in the midst of a large city, primed to go off in a few hours. Unless the bomb can be found and defused, millions of innocent people will die, and millions more will suffer horribly from radiation sickness. The terrorist has

been captured, but refuses to say where the bomb is. A psychological profile suggests that torture may induce him to talk. Arguably, in these extraordinary circumstances, the use of torture would be justifiable. Whether or not it would be, however, is clearly a different question from asking whether there should be laws against torture, and whether these laws should permit exceptions. It is at least possible that without an absolute prohibition of torture, it will be used in more frequently occurring circumstances, when it is clearly not justified—as it was used by US military and intelligence personnel in Iraq at Abu Ghraib prison, in 2003. If that is the case, then torture ought to be absolutely prohibited, by law, even if there are conceivable circumstances in which it would be right to torture. In more normal circumstances, those who may be tempted to torture ought to know that they will be breaking the law and risking severe punishment, for then torture is less likely to be used when it is not justifiable.

I offer this example to illustrate a distinction between ethics and law that can shed light on the difference between bioethics and biolaw. Bioethics is the study of ethical issues raised by developments in the biological and health sciences (wider definitions also exist, but this one will do for present purposes). Biolaw can be defined, in a parallel manner, as the study of how law should respond to those same developments in the biological and health sciences that raise the ethical issues that constitute the field of bioethics.

This understanding of bioethics and biolaw as parallel but independent disciplines coheres with Erick Valdes' insistence, in one of his essays in this volume, that biolaw is not parasitical upon bioethics, but has an independent field of study. This field of study will draw upon the social sciences to ascertain the consequences of proposed laws and regulations. Nevertheless, as Valdes (2015) again makes clear, questions about desirable forms of legislation and regulation are, like any questions of public policy, normative questions that cannot be answered by an appeal to facts alone. Ethical judgments must be made about the values to be achieved by the legislation or regulation and about any other ethical constraints, whether absolute or *pro tanto*, that may be applicable.

Bioethics first developed as a field of study in the 1960s, when philosophers, theologians, and lawyers began to take an interest in what had, until then, been considered to be "medical ethics" and thus was left to physicians. Biolaw, as a separate discipline, is even younger. There is therefore still much work to be done in defining the field, setting out the basic principles, and applying it to specific questions, such as genetic selection and genetic modification, the treatment of human embryos and non-human animals, standards for experiments involving human subjects, and so on. There are also useful lessons to be drawn from observing the development of biolaw in different parts of the world.

Certainly, the essays that follow will make valuable contributions to these tasks. Therefore, this pioneering anthology will, by its very existence, help to shape the future of the field it defines and at the same time contribute to the progress of that field.

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Princeton, NJ, USA — Erick Valdés
Santiago, Chile — Juan Alberto Lecaros
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Introduction

Biolegal controversies that arise from revolutionary advances in biotechnology occupy a prominent place on the media. The social and political relevance of these issues finds its roots in complex multifactorial relationships that involve not only science and bioethics, but also law, society, and culture. What methods are morally permissible and legally plausible to carry out biomedical research? Are government institutions capable of creating public policies to regulate and control the development of biomedicine and science? Can polarized positions be reconciled on the limits and scopes of biotechnology and allow a consensus that benefits society as a whole? If legislators avoid these intricate disputes, are courts and judges effectively equipped to competently decide on these issues? Can courts correct the legal gaps and the lack of public policies if legislative action is absent?

Legally, problematic issues of biomedicine continue to be approached from the overly and univocal perspective of traditional law. In this sense, the specificity and absolute novelty of problems raised by biotechnological development require, by their own implications, a specific and original analysis, that is, a new juridical model applied to legal quandaries arising from the strengthening of biomedicine. That new model is called biolaw.

This diagnosis, which indicates the urgency of generating binding deliberative frameworks to legislate and regulate biomedical practices, in order to promote their use with social responsibility and professional excellence, has been assumed as a fundamental fact condition on this book.

Until now, biomedical applications located in the confines of science and its industry have been epistemologically unfathomable to the traditional legal view, whose scrutiny of the events and vicissitudes of genetics is rather a mythical and innocuous effort, which has not even displayed the ability to distinguish with epistemological and methodological solvency, the new nature and scope of biomedical practices.

Therefore, this book opens a new hermeneutical facet to interpret and predict, with an important degree of legal certainty, the consequences derived from biotechnological and biomedical inventiveness, since the interpretative criteria that can be extracted from biolaw have the capacity to identify a more exhaustive set of

impacts and legal scope of these developments. In this way, this volume promotes a better understanding of the incompatibilities between current international legal systems and new technologies that boost biomedical empowerment by addressing an interesting range of issues related to: (i) doctrine and epistemology of biolaw, (ii) biolaw and policy in the world and in Latin America, and (iii) biolaw and its applications on biosciences, health care, and non-human animals.

Biotechnology and biomedicine are developing at a rate that far exceeds the ability to pass laws and policies. In this way, this book is intended to assist regulators, researchers, ethicists, and others by laying the groundwork for biojurisprudence, as well as providing practical recommendations on where biolaw should be in the future. Certainly, improving the value of this work is the fact that it comprises papers from leading international scholars.

Part I, entitled "Foundations of Biolaw," analyzes main epistemological aspects of biolaw from diverse traditions and conceptions. Tom Beauchamp unfolds an analysis of basic universal principles and universal common morality by seeking to show how universal moral principles are connected to human rights, how rules and rights are specified to become detailed and practical for particular moralities, and how these ideas are connected to problems of justification in bioethics and biolaw.

Peter Kemp examines the difficulties in establishing a European policy to foster a law harmonized with the new demands and challenges of biomedical advances, without a general framework of principles that allows Europe to move toward a communitarian regulation. Peter also analyzes the status of that structure and its utility for regulation as well as its contribution to consolidate biolaw as a discipline in Europe.

Jacob Dahl Rendtorff and Peter Kemp discuss the epistemological and practical features of basic ethical principles in European bioethics and biolaw as a result of a relevant project supported by the European Commission between 1995 and 1998. They also show how to reach the conclusion that basic ethical principles cannot be understood as universal, everlasting ideas, or transcendental truths, but they rather function as "reflective guidelines" and important values in European culture.

For his part, Erick Valdés attempts to clarify biolegal scopes of biolaw by defining it as a new juridical model, which can guarantee the identification and recognition of biorights in international legal systems through a constitutional reception of international standards on individual subjective rights. He also identifies, defines, and criticizes three conceptions of biolaw, which show certain insufficiencies to understand, resolve, and regulate novel juridical conflicts arising by virtue of genetic technologies, which remarks the necessity for a new concept of biolaw with the ability to identify other categories of damages caused by biomedical empowerment.

Carlos Romeo Casabona and Sergio Romeo reflect on the little progress in defining biolaw as a legal discipline. They affirm that much has been written about the concept of bioethics and its incardination within applied ethics. However, biolaw has been assumed as a mere terminological update of the classic term "medical law" or "health law," even without distinguishing so well both concepts from each other. The authors state that biolaw does not correspond solely and

exclusively to the set of norms dealing with issues related to life sciences, but it goes further. In this way, they propose biolaw as an autonomous juridical discipline.

Carlo Casonato analyzes the fundamental features of twenty-first century's biolaw. He states that the rapid pace in the progression of life sciences pushes law into one of its most intrinsic significant features: the principle of certainty. As uncertainty in life sciences is common, which is especially problematic in law because it jeopardizes the very essence of equality and non-discrimination, Casonato proposes the idea of an open, updated, and attentive biolaw for twenty-first-century life sciences.

In the last chapter of this part, Juan Alberto Lecaros addresses convergences and divergences between bioethics and biolaw. He affirms that bioethics and biolaw are normative discourses that give reasons for action, whose particularity consists in necessarily interacting with other disciplines and social practices, and especially with life sciences and related technologies. Also, he shows that the relationship between bioethics and biolaw is still an area to be explored, due to complexities of their scope of application, the accelerated pace of biotechnological advances, and the necessary social and cultural adaptation to them in the context of globalization.

In Part II, "Biolaw in the World and in Latin America," several approaches to relevant biojuridical issues in the world and in Latin America are exposed. Certainly, it is not a simple list of scattered topics but a special constellation of theoretical approaches to different issues of biolaw that are currently being investigated in the world and in Latin America. Therefore, this part represents a good sample of the current state of the art of international research in the multi-disciplinary field of biolaw.

Darryl Macer opens this part by raising the fundamental question of whether a common ethical system could be accepted and applied universally, and what consequences this could have for biolaw. His hypothesis is that all human beings are found as members of some society but all accommodate some individualism within a social spot. All societies have ethical norms and some system of ethics and law. Thus, any international ethical and legal approach to help people and systems to make bioethical and biolegal decisions must consider biological, social, and spiritual origins of humanity.

Amedeo Santosuosso tells us the story of his personal involvement in biolaw, having in mind his fascinating and enriching background at the intersection between science, technology, and law. Having spent more than three decades working on the relationship between law and biomedicine, first, and, then, between law and life sciences, and then between law and science and technologies, he concludes that it does not make much sense to create and cultivate discrete fields of law according to specific scientific fields and neither for the area of technology and law.

Camilo Noguera proves that cultural changes influence forms of thought. In fact, any juridical or philosophical or biolegal archetype is irremediably immersed in a sociocultural context, from which it follows that disciplines, in this case biolaw, are daughters of their time. Equally, the ends of law—justice, security, equity, and

common good—are necessarily related to different legal orders and cultural ordering. Therefore, Camilo examines singularities of postmodern consumption, ethics, and bioethics as a useful hermeneutic tool to address the nature of twenty-first-century biojuridical discourse.

On his hand, Eduardo Rueda highlights, from a programmatic way, some tensions against which both the analysis of the current legal order's legitimacy and the development of new publicly acceptable normative proposals have been displayed in terms of biolaw. By tension, he means the presence of immanent explicit contradictions between visions about the scope and limits of constitutional law. He thinks that this review is crucial to understand normative and factual complexities that challenge the field of biolaw in Latin America.

Gabriela Arguedas addresses the problem of hunger and its imbrication with the principle of justice and the doctrine of human rights from the framework of bioethics and biolaw. She states that the persistence of hunger in the contemporary world is a sign of the limited power of the techno-scientific task to solve social problems whose cause is, after all, injustice. The alarming situation of inequality and dispossession in which millions of human beings live in the twenty-first century confronts us with the need to think critically about the dominant economic and political model. Therefore, the patent fragility of the human right to food can serve as a transversal axis in this reflexive process, of which fields of bioethics and biolaw must be active participants.

In the same context of human rights, Aristides Obando affirms that the emergence and praxis of differentiated rights go beyond the scope of formal equality of the liberal citizenship that underlies current Colombian political order. This is in tune with respecting the constitutional mandate to achieve material justice, as a key element to recognize diversities and social inequalities in ethnically plural societies. In this order of ideas, Obando proposes to analyze the emergence and practice of differentiated rights as an expression of material justice within the framework of the ethnic and cultural diversity that Colombian political and juridical orders recognize and protect.

Rodrigo González, David Garcia, Juan Sebastian Barrera, and Andrés Sarmiento carry out an approach to the constitutionalization of biolaw in Colombian legal system. Their main conclusion is that biolaw, as a legal discipline in Colombia, has not made great progress at the legislative level but rather in the constitutional court through the emergence of some jurisprudence based on international comparative law. This, according to the authors, has brought relevant benefits for Colombia in the protection of so-called fourth generation human rights or biorights.

The last chapter of this part, by the Mexican scholar Ingrid Brena, offers a report on the state of the art of biolaw in Mexico. She describes and analyzes certain representative topics of the progress of biolaw in Mexico. In some cases, Ingrid refers constitutional provisions, norms of sanitary, civil and criminal law, which as common denominator, are based on bioethical principles and especially upon those expressed in different documents of international biolaw. Finally, she addresses the interpretation of some laws by courts' judgments, which has expanded perspectives on biomedical matters.

Part III, entitled "Biolaw for the Biosciences, Health Care and Non-human Animals," addresses some important biojuridical topics related to biomedical and bioscientific practices, as well as healthcare issues and applications of biolaw to legal regulation of animal rights.

First, Ilaria Anna Colussi explores the dual-use dilemma, as referred to two areas: the field of nuclear science and technology and the emerging new area of synthetic biology. One important conclusion will be that the freedom of scientific research, which is crucial in this context, has to be protected, but at the same time the other rights and freedoms at stake cannot be "suppressed" or "sacrificed."

On his hand, Daniel Loewe examines some of the articulated criticisms against cognitive enhancement through the use of pharmacological agents as well as some ways of counteracting them. One important conclusion will be that uncertainty about the consequences of cognitive enhancement in health should also be considered in the equation. If there is no damage in its use, there is no reason to restrict access. However, if it causes harm, or it is likely to produce it, this consideration may change.

Laura Victoria Puentes displays a biojuridical analysis of genetic manipulation and human genome matters in the Colombian legal system. She affirms that although Colombian constitutional case law has designed an interesting conceptual platform to guarantee the protection of personal data, it is also true that this is still insufficient to regulate other genetic practices. Laura Victoria concludes by showing the necessity to recategorize concepts of traditional law, which must be rethought, reinterpreted, and redefined to extend epistemological and hermeneutic aspects of other branches of law, such as civil, constitutional, administrative, and criminal law, among others.

In next chapter, Erick Valdés asserts that the unprecedented legal traits that non-therapeutic genetic manipulation of pre-implanted embryos displays require a procedural approach, hitherto unexplored, that in turn demand the redefinition and extension of the legal status of traditional categories of positive law, which reach administrative, criminal, constitutional, and civil law. One of his conclusions is that, far from being established upon the new hermeneutics that biolaw provides, international regulation on this matter is based on traditional positive law; namely, it consists in the simple application of classical categories of law on new problems of biolegal scope.

Marisa Aizenberg addresses the necessity to recognize palliative care as a human right, which means to endow it with two essential characteristics: its enforceability, that is, the punishability of those acts that ignore and/or skip it, and its universality regardless of individual conditions of people. This points out the state as the guarantor not only of the right to health but of the complete state of well-being as recommended by the World Health Organization. Her conclusion is that denying palliative care to a patient, or not contemplating it as a certain and appropriate option in the healthcare system, imputes to the state a particular international responsibility, with the consequent sanctions that could be applied.

In the last chapter, Luis Javier Moreno analyzes the emergence of laws to protect animals. These laws, which have proliferated in recent years in Central and South

America, pursue a common goal: to protect animals from human mistreatment by recognizing their capacity to feel pain and suffering. To meet this purpose, the laws employ a variety of means, ranging from the prohibition and criminalization of behavior, without saying more about the condition of animals, to the visionary chance of recognizing animals as subjects of rights. He concludes that in the current normative context it is no longer possible to argue that animals are mere things or to consider them as mere goods without making differences from other belongings.

Finally, we want to clarify that this book does not represent a strictly epistemological work on biolaw. Certainly, that is one of its main interests, but it also seeks to show the reader a comprehensive overview of the discipline, so we ask ourselves questions inside and outside biolaw by trying to show its main conceptual facets but also its applications to different epistemological areas that until now had only an oblique relation to the discipline. This represents, in our opinion, one of the most remarkable strengths of biolaw. Studying biolaw does not only imply a pure conceptual approach to its nature and meaning, but also challenges us to explore its institutional and political angles, namely to learn about the different ways in which it is deployed in different places of the world. Biolaw requires a multifactorial study. Reducing it to a single form and to a single meaning would be contradictory with its nature and with the spirit of this book. Having said that, we are confident the result is a volume of interesting and connected chapters that help fill a gap in the underdeveloped literature on the subject.

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