Revista Bioética
ISSN: 1983-8042
bioetica@portalmedico.org.br
Conselho Federal de Medicina
Brasil

Schaefer Rivabem, Fernanda
Biodireito: uma disciplina autônoma?
Revista Bioética, vol. 25, núm. 2, 2017, pp. 282-289
Conselho Federal de Medicina
Brasília, Brasil

Biolaw: an autonomous discipline?

Fernanda Schaefer Rivabem

Abstract

The impressive development of biotechnology, especially in the last two decades, has allowed and even required the revision of classic law institutes. The need to study various legal issues arising from technological advances related to medicine and biotechnology, with special reference to the body and human dignity, gave rise to what came to be known as Biolaw. The debate proposed in this paper, based on the literature review, is to analyze if Biolaw can be treated as a new and autonomous branch of law, as a mediator of new conflicts; or if it suffices for the legal system to recognize emerging social relations in light of its traditional branches and deal with them based on purely ethical and legal requirements.

Keywords: Legislation. Bioethics. Biolaw.

Resumo

Biodireito: uma disciplina autônoma?

O impressionante desenvolvimento biotecnológico, sobretudo nas duas últimas décadas, tem propiciado e exigido a revisão de institutos clássicos do direito. A necessidade de se estudar diversas questões jurídicas derivadas dos avanços tecnológicos vinculados à medicina e à biotecnologia, com especial referência ao corpo e à dignidade humana, deu origem ao que se denominou biodireito (do inglês, *biolaw*). O debate proposto neste trabalho, a partir da revisão crítica da literatura, é analisar se o biodireito pode ser tratado como novo e autônomo ramo do direito, intermediador dos novos conflitos; ou se basta ao direito reconhecer relações sociais emergentes à luz de seus ramos tradicionais e tratá-las a partir das exigências puramente bioéticas e jurídicas.

Palavras-chave: Legislação. Bioética. Biodireito.

Resumen

Bioderecho: ¿una disciplina autónoma?

El impresionante desarrollo de la biotecnología, especialmente en las dos últimas décadas, ha posibilitado y exigido una revisión de los establecimientos clásicos de Derecho. La necesidad de estudiar diversas cuestiones jurídicas derivadas de los avances tecnológicos relacionados con la Medicina y la Biotecnología, con especial referencia al cuerpo y a la dignidad humana, dio lugar a lo que se denominó Bioderecho (del inglés, *biolaw*). El debate propuesto en este trabajo, a partir de la revisión crítica de la literatura, es analizar si el Bioderecho puede ser tratado como una nueva y autónoma rama del Derecho, mediador de nuevos conflictos; o, si es suficiente con que el Derecho reconozca las relaciones sociales emergentes a la luz de sus ramas tradicionales y las aborde a partir de las exigencias puramente bioéticas y jurídicas.

Palabras clave: Legislación. Bioética. Bioderecho.

PhD ferschaefer@hotmail.com – Centro Universitário Curitiba (UniCuritiba), Curitiba/PR, Brasil.

Correspondência
Rua Arcésio Correia Lima, 411, Atuba CEP 82630-130. Curitiba/PR, Brasil.

Declara não haver conflito de interesse.

What is the value of words? These questions are not discussed in vain. Thus, in order to answer the questioner, we must direct the mind, after perceiving the signs, to the things they signify.

Saint Augustine [1]

The end of the 20th century and the beginning of the 21st century were marked by issues related to scientific freedom and impressive bioscientific progress, the protection of human life, the pursuit of environmental equilibrium, socialization and the universalization of health, and the recognition of patient autonomy. In addition, ethical and philosophical concern over issues that have long plagued humanity, such as life, reproduction and death, and the incessant search for new moral standards that account for this incipient reality, has increased. It is clear that the law cannot remain still when faced with these new political, economic, social and moral dynamics.

Debates stemming from biotechnological development have also forced a review of classical institutes of law. In order to tackle the new legal issues that have arisen, what is known as "biolaw" has emerged. The analysis contained in this paper aims to identify whether biolaw can be treated as a new and autonomous branch of law and an intermediator of new conflicts, or whether it is enough for the law to recognize emerging social relations in the light of its traditional approaches, and to treat the same through purely moral requirements.

Ethics and law

The relationship between ethics and law has always been close, and therefore understanding (albeit succinctly) the similarities and differences between the two is fundamental to understanding their strong interrelationship, affected by important reciprocal influences. Durand explains that:

ethics (or morals) properly designates a reflection on the set of demands of respect for and promotion of the person. It is a questioning on the goal of a good life, an investigation of universally imposed duties, before it is a set of rules, a systematization of values or principles. It is, above all, of the order of reflection and questioning. Law, in turn - and I mean positive law as opposed to natural law – first designates a set of rules applicable in a given society and sanctioned by public authority [2].

It can be said that ethics - here used as a synonym for morality - has as its object the best possible promotion of the person, while law aims to harmonize social coexistence based on the norms and values that it considers appropriate for the protection of the human person. Ethics corresponds to an ideal to be achieved, while law is concerned with the individual *in concreto*. Ethics is concerned with the interiorization of good behavior (duties of conscience), while law deals with the social effects of the exteriorization of certain behaviors. Ethics requires free adhesion (voluntariness), while law imposes itself as obligatory (coercivity). Ethics has universal intentions, and law is content to represent the society in which it is inserted.

Ethics, as an ideal, requires continuous and sometimes excessive effort; the law requires the minimum of effort for its adhesion as it is defined as the ethical minimum established for a certain social group. Ethics imposes only duties (unilateralism), while the law is marked by bilateralism, imposing legal requirements and conferring rights. Ethics imposes moral sanctions, while for the law the sanction is legal. Ethics is autonomous, because it stems from consciousness; the law is heteronomous, imposed by authority. Ethics has a more restricted field of action than that of law, which can also govern technical and economic issues that may be totally foreign to morality.

Confronted with these points of contact and distance, it can initially be affirmed that bioethics and biolaw cannot be treated as synonyms, despite being intimately linked, as ethics without law loses coercivity and law without ethics loses legitimacy.

Studies proposed by bioethics can also not be confused with those focusing on biolaw. While they may share a common object, different results are sought. While bioethics seeks to ethically normalize complex themes such as the beginning and end of life, law seeks juridical regulation capable of legally protecting the present and future human being in all its dimensions.

The approximation between ethics and law is indissociable if the interdisciplinarity, dialogue and recognition of values and principles necessary for the protection of the human person are to be guaranteed. However, it cannot be denied that their aims are different: the goal of bioethics is not the triumph of particular theses, but the reduction of conflicts in a manner that privileges the coexistence of humanity; biolaw has normative and impositional biases that seek to provide normative solutions to major dilemmas arising from biotechnology.

The relationship between bioethics and law

The need to approximate basic medical and technical knowledge is an essential prerequisite for the appropriate treatment of emerging issues, especially those arising from technosciences.

Bioethics emerged in the second half of the twentieth century due to the significant scientific and technological progress of the time and the major social and political changes that brought about great changes in human relations. It rejected notions that biomedical advances were indisputable, from an ethical point of view, and discussed new research projects in a more critical manner, in a political-social context marked by the development of the notions of autonomy and freedom:

The first generation of bioethicists occupied themselves more with what we might call the ethical problems posed at a micro level, such as the protection of human subjects in research and patient rights, than macro issues such as social justice [3].

However, with the advancement of studies and discussions, macro-level concerns have also emerged and established new ground for bioethical debates. Little by little philosophers have begun to take an interest in the field of biomedical ethics and, from this interest, the development of normative ethics emerged, consubstantiated in what is today called "bioethics". Necessarily interdisciplinary in nature (as is its epistemic basis), it embraces multiple ethical concepts, a range of theories and theoretical paradigms, and numerous methods and methodologies of analysis.

Bioethics is recognized as part of general ethics, though more as applied ethics than true theoretical ethics. According to Casabona, *bioethics is a clear example of an approach to an object of common, multidisciplinary study, where different sciences come together, as well as ethics, with their respective perspectives and own methodologies* [4]. It developed throughout the 20th century as a corollary of biotechnological knowledge, a branch of applied social sciences that seeks to establish a value system to resolve ethical problems arising from biotechnological discoveries and interventions. It has reached the 21st century facing great moral dilemmas, to which it has not yet found universal solutions, and is based on a pluralistic and dialogical rationality, which imposes constant dialogue with the law:

For bioethics, interdisciplinarity provokes a confluence of themes that are notably distanced from each other and are rarely dominated by a single scholar: reflection on the environment, for example, or on the definition of death, or on the consensus given to the medical act, objectively require extremely articulated and differentiated knowledge if they are to be tackled with due seriousness. Could a greater cultural and cognitive commitment on the part of scholars be sufficient to deal with this difficulty? Certainly, yes - indeed, it should be obligatory - but equally it would certainly not be enough to solve all the problems. The experience accumulated in recent decades has shown us that interdisciplinarity creates new and subtle difficulties, creating paradoxicity (...). The crucial point is that authentic interdisciplinarity, if it is truly respected, implies the creation of a new disciplinarity: that is, of a new epistemology [5].

It is here, then, that bioethics identifies emerging issues and suggests ethical solutions. It falls to the law to provide legal solutions to bioethical conflicts, aimed at the protection of the human being in its entirety, establishing a system of principles and values that can be considered as universal and binding. Hence the integration between bioethics and law, based on a common object: an interest in life in its various dimensions, in biomedical sciences and technoscience and their reflexes on the human being. What sets the two apart is the lens through which they analyze their subjects.

Bioethics proposes ethical reflections; the law proposes legal reflections based on the prism of its most important value: the dignity of the human person. On the intimate relationship between law and bioethics, Broekman affirms that *it is important for bioethics that bodies submitted to medicalization are already legalized and vice versa. Medicalization and legalization are fundamental processes that give meaning to the interpretation of the body as a cultural entity. Therefore, they maintain ethics under their power, as is abundantly demonstrated by law and medicine* [6].

Although different in their perspectives, there is no denying that the influences are reciprocal, with the main point of contact being the dignity of the human person. In this sense, Casabona emphasizes that in the *ultimate extreme, bioethics aspires, as a final objective, to contribute to the law (the legislator, in this case) by providing guidance in this area. But the commitment here is greater, as it must try to contribute with a clear and, in principle, univocal criterion, valid for the resolution of each concrete case* [7]. To achieve this, in the author's view,

 http://dx.doi.org/10.1590/1983-80422017252188

the dialectic between bioethics and law must be based on irrevocable premises:

1) reflect on regulatory principles and seek them out;
2) ensure pluralism in the discussion;
3) seek uniformity of criteria, including supranational and international, harmonizing legislation; and
4) legal intervention must have different approaches: legal instrumentation should be prudent and sober, flexible and open to diverse values and situations.

The intimate relationship between bioethics and law is therefore obvious, but the respective normative orders are distinct: *Law, as a pragmatic order of conflict resolution, can be investigated from a dogmatic perspective. The moral, meanwhile, acts in the legal universe as an auxiliary normative order, it provides support for the formulation and application of law, without, however, confusing it. Bioethics, therefore, has relevance to the law, since it is part of zetetic law* [8].

The fact is that, in the new reality presented, legal science cannot be reduced to a merely instrumental, supporting role, dominated by bioethical discussions that insist on placing morality and even religiosity over social and juridical needs. The law is guided by respect for individual freedoms and the promotion of collectivities, by the curbing of abuses against the person, and the protecting and promoting of human life as a presupposition of one's own dignity. Therefore, only legal norms and laws are capable of allowing rational and morally desirable universal choices in spaces considered democratic.

Related disciplines

A discipline is a *coherent set of principles and methods suitable for the analysis of a particular subject* [9]. Bioethics is undoubtedly an autonomous discipline, not to be confused with other disciplines, which may relate to this area. Related disciplines are those with points of contact with law and bioethics, and which may even interact with them, but without allowing confusion between the areas.

Medical law

Medical law or biomedical law, or biotechnology law (health law, health care law), are used in some systems as a synonym of biolaw. Traditional medical law is dedicated to legal aspects related to the practice of medicine and other professions directly related to health. According to Casabona,

medical law in its traditional conception referred to the professional relations of the doctor (and other similar professionals) with the health and sanitation systems, with the patients and users of the health network, public or private, with other professionals who exercise their activities in the field of health and, above all, with the legal responsibilities that could arise from such relations (usually due to imprudence or negligence, resulting from poor professional practice) [10].

At the same time, several authors, especially those of Anglo-Saxon origin, have sought to broaden the scope of medical law in order to integrate other topics, including financial matters related to health. Also according to Casabona, *biomedical law currently comprises the legal implications of the so-called biomedical sciences and biotechnological sciences for human beings and, by extension, for all living matter (animals and plants), although varied positions can be found for the latter* [11].

Biojuridics

A branch of bioethics centered on the legislation applicable to the human being as a biological entity. *Science that has as its object the foundation and pertinence of positive legal norms, of "lege ferenda" and of "lege data", in order to achieve and verify its adequacy to the principles and values of ethics in relation to human life, which is the same as saying, its adequacy to the values of bioethics* [12].

Iusgenética ("*Iusgenetics*")

An area of study that focuses its discussions on the legal implications stemming exclusively from genetics:

Iusgenetics is an indispensable complement in that it encodes the behavior patterns that a community considers acceptable and ensures that these experiments and their subsequent applications are carried out with the necessary precautions, avoiding the induction of an unwanted biological disorder and the abrupt disruption of the rules of social organization [13].

Health law

Health law, according to Brazilian Health Regulatory Agency (Anvisa), *is a set of federal, state or municipal regulations that, in order to eliminate, reduce or prevent health risks or to intervene*

in health problems caused by the environment, regulate the production and circulation of consumer goods that directly or indirectly relate to health, including all their steps and processes, from production to consumption, as well as the control of the provision of services that are directly or indirectly related to health [14].

Although there is also no unanimity regarding the content of this discipline, most doctrine claims to understand it as the study of the health system and organization, focusing on the public health system. It is also interdisciplinary, as its object covers, as a minimum, studies of administrative law, criminal law, constitutional law, social security law, economic law and even environmental law.

Legal medicine

Legal medicine or forensic medicine is the discipline that *serves as an auxiliary instrument for the administration of justice*, [15] where the conjunction of medical, biological and psychic knowledge is intended to serve the law, assisting in the elaboration and interpretation of legal provisions. According to França, *it is not properly speaking a medical specialty, as it applies the knowledge of various branches of medicine to the demands of law.* (...) *It is science because it systematizes its techniques and its methods towards a determined objective, exclusively its own (...). It is the contribution of medicine and technology and other related sciences to the issues of law in the drafting of laws, in the judicial administration and in the consolidation of doctrine* [16].

Medical Deontology

This area deals with ethical norms designed to regulate medical activity, imposing duties and rights on the professional. Therefore the need to understand the term "discipline" is used here not as a set of theories and methods that are based on a single theory, but as a multiplicity of theories that group together to form theoretical paradigms capable of accounting for the plurality of discussions that take place in this thematic unit.

As such, it is argued here that bio-law, although closely linked to bioethics and many other related disciplines, is not subordinate to them, as its object is broader (bioethical-legal fact). It is an autopoietic system [17] that uses knowledge from other sciences in search of the defense of the human being[18], not restricting itself to the insufficient monologism of legal dogmatics.

Epistemological justification of biology as an autonomous discipline

Biolaw, although clearly a discipline typical of juridical dogmatics, which uses its investigative methodology to solve theoretical problems, has its origins marked by the concerns presented by bioethics: *with law also medicalized, bio-law incorporates the principles of bioethics which, in turn, become a source of inspiration for other principles.* [19] It can be said that bio-law is the legal manifestation of bioethics.

The origin of the term "biolaw" in Brazil is neither certain nor smooth. *In Brazil, until a short time ago, it was called bioethics, and the expression "biolaw" emerged from the positivation and incorporation into the legal system of regulations of therapeutic procedures and scientific research, with several legal texts adopting this denomination. Pioneering works have dealt with the subject, such as the article by Dr. Arnold Wald, under the title "From bioethics to biolaw, a first view of Law No. 9,434" and that of Francisco Amaral, entitled "For a legal status of human life and the construction of biolaw"* [20].

Borba and Hossne [21] state that it would be better to use the term "bioethics and law", because the neologism biolaw: 1) lacks a historical tradition like that of bioethics; 2) could lead to the abandonment of the necessary dialogue with bioethics, adopting a purely horizontal approach from the classic branches of law; 3) would entail a strong presence of procedural formalism with the consequent reduction of the ethical dimensions of the proposed problems; 4) would jeopardize the prudent balance between bioethical principles and legal values and principles.

These arguments cannot be supported, however, as the aim is to construct new juridical perspectives on subjects as old as human consciousness itself: life and death, filiation and fertility, health, physical and psychic integrity, and autonomy. It aims to identify new ethical and social values that are necessary to respond to emerging issues presented by medicine, genetics, biochemistry, biophysics, telematics, biology, etc. There is a single perspective: the human being as the recipient and beneficiary of rights and protections arising from the law. It has only one personalistic foundation: the dignity of the human person, understood not only as a moral choice, but especially protected and promoted as a legal value.

 http://dx.doi.org/10.1590/1983-80422017252188

As such, when one thinks of biolaw as an autonomous discipline, one must keep in mind its extent, which can and should encompass related disciplines by virtue of the required interdisciplinarity. To speak of biolaw is to argue that the unilateral perspectives conferred by classical branches of law (civil, criminal, administrative, etc.) are not sufficient to deal with the emerging issues arising from biotechnology. It is to recognize the need to analyze these situations from an integrating horizontal perspective, based on the vulnerability of subjects, but also to recognize the Federal Constitution as the main foundation.

To discuss biolaw is to recognize the intermediary and dialogical commitment of bioethics, but from a juridical perspective which aims to promote not only dialogue between the public and the private, but also to establish an interdisciplinary commitment, seeking the understanding of the human phenomenon in all its complexity.

Inconsistencies in disciplinary practices, in specific university courses and in its own indexer in bibliographic databases [21] are not sufficient to deny to biolaw the possibility of becoming an autonomous discipline.

In truth, although biolaw is currently in a pre-paradigmatic phase, prior to the recognition of new disciplines, its development is incontestable and imminent. While it could be argued that there would be disagreement regarding its epistemological foundations, as there is with bioethics, this has not occurred. The different approaches are consolidated through the constitutional vision and the recognition of the human person as the value and source of the entire legal order, and it is from the guardianship of the person that the theories of the discipline develop.

The fact that biolaw is inter- and multidisciplinary, like bioethics, does not mean it should be granted the undue status of "pre-science." The monistic view of the concept of a discipline is archaic and unrelated to today's new realities. To assume that for biolaw to become an autonomous scientific discipline it should concentrate on methodological monism, an empirical approach, and the same operational norms as the natural sciences, would ignore the fact that other ways of constructing scientific knowledge exist today. [9] The monologism of legal dogmatics Is insufficient to account for the complexity presented by bioethical problems.

The absence of a unifying code or law is also not sufficient to argue that biolaw does not constitute a legal micro-system with its own characteristics, foundations and principles. Post-positivist, bio-law establishes a new juridical order on issues arising from biotechnology and its intervention on human life in its most diverse aspects. Casabona concludes that:

For this consideration of autonomy it is not an obstacle that biomedical law is not, however, the object of independent teaching, nor that its conceptual bases are imported from the traditional fundamental legal disciplines, since it distances and separates itself from them both through the specific object of its study and by its own methodology; as has been indicated, it can consist of an integrated legal approach, without prejudice to taking, as a starting point, an interdisciplinary and multidisciplinary perspective [22].

Therefore, the procedure of biolaw, as a normative order, is dogmatic, with its norms being prescriptive in character. However, its legal norms cannot be closed, but must be open and flexible enough to ensure that norms remain current and efficient in the face of scientific progress. The model proposed by biology is the model of justice - not as an ethical value but as procedural content, taken in a humanistic sense - whose norms contain several important values aimed at the integral protection of the human person and made effective in human rights and fundamental principles that, when in conflict, can only be resolved in the specific case itself.

Regarding this issue, Fabriz stated that *biolaw emerged in the wake of fundamental rights and, is in this sense, inseparable from them. Biolaw contains the moral rights related to the life, dignity and privacy of individuals, representing the passage from ethical discourse to legal order, but cannot represent "a simple legal normalization of principles established by a group of scholars, or even proclaimed by a religious or moral legislator. Biodiversity presupposes the elaboration of an intermediate category, which is made material in human rights, assuring its rational and legitimating foundations"* [23].

Due to the rapidity with which biotechnological novelties present themselves, it is a branch of law that does not intend to have a single answer, but a number of responses that can be constructed from the concrete case, and which are therefore not limited to legal discourse (Positivism). Biodiversity seeks to organize the conduct of each actor in a

biotechnological society, proposing respect and the promotion of values that serve as a base for all humanity (present and future), organizing freedoms and educating to preserve these essential values.

Biodiversity cannot be treated as an alien approach, as a non-scientific space removed from legal dogma. It must establish itself as its own discipline, with its own method, aggregating other disciplines, which are considered traditional but which contribute to its solidity, with the construction of a language capable of accounting for its natural interdisciplinarity. The differentiation between ethics and law, the historical reconstruction of bioethics itself, the secularization and moral pluralism of bioethics, and the identification of the object of biolaw allow us to affirm that it is a new facet of the field of knowledge that imposes its own methodology and foundations, which can confer upon it the status of academic discipline, working towards the desired transdisciplinarity. This raises a criticism of the statement by Garrafa, who stated:

The neologism they are trying to implant, called 'biolaw', is a cripple. If bioethics is already a new discipline and requires a little of each one, and its great strength is its multidisciplinarity, imagine if they bring up biophilosophy; bioeconomics; biomedicine; biobiology; biopsychology? That is not the idea. There is the danger of using this fad - which is French for a change, but it does not mean that France is not working seriously. In countries that are acting seriously in this area - England, for example - the big issue is bioethics and law, bioethics and law. This issue, when reduced, will be compartmentalized, and this was not the initial idea. I appeal to people who want to put the word 'biolaw' on the street to think twice, or thrice. If 'biolaw' means the law working in biotechnology issues, I agree, but if it means the 'biolaw' with respect to bioethics, I disagree strongly and believe that this is a conceptual impurity and a serious methodological and epistemological error[24].

As has been shown previously, dealing with normative legal issues under the mantle of ethics is a misnomer, since the outcomes of the regulations are diverse. Once again: ethics establishes behaviors to which adherence is voluntary, while the law establishes behaviors whose adherence is mandatory, and imposed. So, although there are unquestionable and desirable reciprocal influences, the fact is that the effects of the performance of each are quite different.

To affirm biolaw as a discipline is not to try to compartmentalize knowledge, as the author affirms, but to organize its methods and theories, values and principles, safeguarding its plurality of sources. There is no methodological error, nor is there an epistemological error. The mistake would be to believe that bioethics is sufficient to standardize and organize all the complex issues that arise from biotechnological development, or to consider that a new branch of law cannot develop, safeguarding the dialogical and interdisciplinary method (characteristic of bioethics).

To recognize biolaw as an autonomous branch is not to propose segmenting the discussion, limiting it to narrow spaces. On the contrary, in proposing the construction of a biolaw, we defend the permanence of the dialectic between law and bioethics, preserving the natural elasticity between them. It is not a question of limiting the study of law to questions of life and human existence, but of establishing a legal debate on the legal repercussions of bioethical questions.

Final considerations

Law cannot remain still in the face of new social relations arising from the development of biotechnology, nor can it seek to give new and effective answers based on old and outdated institutes, concepts and categories established by its traditional branches.

In recent years, bioethical debates have intensified, which has made it possible to focus the legal spotlight on important emerging issues. However, a common mistake is wanting to treat bioethical problems as legal problems and conflicts of interest. Bioethics, as its name implies, must be confined to the moral problematization of issues, with the right to discuss these problems legally and juridically. The intimate relationship between bioethics and biolaw is indisputable, but their goals are distant, as the former gives moral answers, whereas the latter must coercively discipline human behavior.

Recognizing regulatory gaps is the first step in building an autonomous biotechnology that is recognized as interdisciplinary, principiological and dynamic enough to efficiently follow the biotechnological innovations that directly affect human beings, and which can at the same time bring benefits or jeopardize present and future generations.

In order to recognize biology as an effectively autonomous discipline, it is necessary to change perspective, that is, to deepen the question

 http://dx.doi.org/10.1590/1983-80422017252188

from an interdisciplinary view, developing its own dogma. For this reason, it is advocated that biolaw is treated as an autonomous branch of law, typically interdisciplinary, with its own principles, object and methodologies, rejecting the argument that prefers to treat the themes under the heading "bioethics and law". With this nomenclature, the necessary interdisciplinarity would not be evident in relation to other sciences nor to the various branches of law.

Referências

1. Santo Agostinho. De magistro. São Paulo: Abril Cultural; 1973.
2. Durand G. Introdução geral à bioética. São Paulo: Loyola; 1999. p. 83.
3. Ferrer JF, Álvarez JC. Para fundamentar a bioética. São Paulo: Loyola; 2005. p. 69.
4. Casabona CMR. O direito biomédico e a bioética. In: Casabona CMR, Queiroz JF, coordenadores. Biotecnologia e suas implicações ético-jurídicas. Belo Horizonte: Del Rey; 2005. p. 13-44.
5. D'Agostino F. Bioética segundo o enfoque da filosofia do direito. São Leopoldo: Unisinos; 2006. p. 13-4.
6. Broekman JM. Bioética con rasgos jurídicos. Madrid: Diles; 1998. p. 15.
7. Casabona CMR. Op. cit. p. 27.
8. Sá MFF, Naves BTO. Manual de biodireito. 3ª ed. Belo Horizonte: Del Rey; 2015. p. 9.
9. Jonsen AR. The birth of bioethics. New York: Oxford University Press; 1998. p. 345.
10. Casabona CMR. Op. cit. p. 14.
11. Casabona CMR. Op. cit. p. 15.
12. Vila-Coro MD. Introducción a la biojurídica. Madrid: Facultad de Derecho de la Universidad Complutense de Madrid; 1995. p. 2.
13. Mateo RM. Iusgenética. In: Cuchillo M, Choy A. Especial medio ambiente. [Internet]. Barcelona: Universidad Pompeu Fabra; [s.d.]. [acesso 5 fev 2016]. p. 7-35. Disponível: http://bit.ly/2pjCLmj
14. Agência Nacional de Vigilância Sanitária. [Internet]. [s.d.]. [acesso 20 out 2015]. Disponível: http://portal.anvisa.gov.br
15. Casabona CMR. Op. cit. p. 21-2.
16. França GV. Medicina legal. 9ª ed. Rio de Janeiro: Guanabara Koogan; 2011. p. 3.
17. Liedke MS. A bioética e o biodireito enquanto sistemas autopoiéticos. Juris. 2009;14:105-17.
18. Cambi EAS. O caráter universal do direito moderno e os desafios fundamentais impostos pelo biodireito. [Internet]. [s.d.]. [acesso 30 jan 2016]. Disponível: http://bit.ly/2ozyHjD
19. Sá MFF, Naves BTO. Op. cit. p. 16.
20. Dantas I. A era da biotecnologia: constituição, bioética e biodireito. [Internet]. [s.d.]. [acesso 20 maio 2015]. Disponível: http://bit.ly/2oIgJfg
21. Borba MN, Hossne WS. Bioética e direito: biodireito? Implicações epistemológicas da bioética nodireito. Bioethikos. 2010;4(3):285-91.
22. Casabona CMR. Op. cit. p. 17.
23. Fabriz DC. Bioética e direitos fundamentais. Belo Horizonte: Mandamentos; 2003. p. 288.
24. Santos MCCL, organizadora. Biodireito: ciência da vida, os novos desafios. São Paulo: Revista dos Tribunais; 2001. p. 120-1.

Recebido: 22.5.2016
Revisado: 15.2.2017
Aprovado: 27.3.2017