Updating Articles

Debate on the relationships between bioethics and law

Maria Casado

Abstract

This text collects and updates the major point of my previous work '*La bioética como soporte al derecho para regular la biotecnología'* (Bioethics as support to Law in order to regulate biotechnology) [1] dealing with the implication between Law and Bioethics, a relationship that I consider as having a intrinsic feature since contributions from both analyses result in reciprocal use when solving problems brought in by biotechnology, in as much both subjects share the same end: respect and promotion of recognized human rights. Bioethics provide tools during decision-making that affect values and in those which are of particular importance: designing and analysis of agendas that should govern action concerning technical intervention of man on his own life, and the means in which it develops and which soon will become Legal norms.

Key words: Human rights. Bioethics. Medical ethics. Education. Human rights education. Public participation. Public policies.

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Approach: bioethics and law

From my standpoint, Bioethics deals in analyzing ethical, legal and social implications of scientific discoveries and biotechnological applications to propose fair agendas to its treatment and, by it, to request from Law at the time of applying and providing effectiveness to its proposals. Since the birth of the new discipline, both go together through crucial topics such as informed consent and patients' rights, the conflicts on origin and ending of life, or the search for agreements in plural contexts. The implication between Law and Bioethics [2] has intrinsic feature, as well as the contribution of the former is fundamental to the later, contribution of bioethical analysis should be considered as of extreme usefulness for public law at the time of clarifying problems rose by biotechnology

as both disciplines share the same goal, *the respect and promotion of recognized human rights*.

Bioethics provides tools at decision-making instances that affect values and for those in which the elaboration process and analysis of agendas that should govern action regarding men's technical intervention over their own lives and the means from which it develops that soon will become legal norms result of particular importance. The design of procedures for decision making in which all stakeholders can participate presupposes a step of crucial importance. However, in order for its work to be effective, it requires that the stated be expressed in norms that not only express objective, but set out how they can be achieved and evaluated, and assure their implementation. Thus, it is mandatory that a close relationship between science, ethics, and law that overcomes the traditional isolation of these disciplines, allowing achieving a commitment in the designing the rules of the game acceptable to the majority of citizens.

The so-called *bioethical problems*, suppose major ethical-legal issues that should be discussed before normative solutions are adopted, over those that, in a democratic and plural society, is necessary to achieve a consensus. A consensus that in issues concerning particularly individual and collective values [3,4] are hard to achieve. The recognition, through it, of plurality of moral options that characterizes current societies constitutes a central feature for bioethics and proves the need to establish a benchmark agreement through which individuals belonging to diverse moral communities can consider themselves connected to a common framework that allows conflict resolution with enough level of agreement. Precisely for providing this common benchmark, Public Law deals by organizing companionship according to a democratic model where problems should be decided by all citizens through sufficiently informed debate and not only by majority sectors and on opacity conditions. The European Conference on National Committees (COMETH) of the European Council to promote implementation of committees in Member States is a good example, as well as a social debate on the ethical issues that derive from medical and biological applications and in public health realm [5].

Law is an ideal mechanism to assure basic values precisely for its general and bonding feature, and for behavioral guidance function performed in society [6]. This is one of the fundamental missions that, in one hand the international instruments of recognition and protection of human rights exert, and constitutions in the other. The former homogenize minimum basic content in a culturally diverse international context, and the later assure fundamental principles and values within the scope of a state since, located at the top of the normative pyramid of each legal ordaining, link the set.

Constitutions used to establish law directories that are considered fundamental such as life, freedom, free development of personality, prohibition of inhuman and degrading treatment, prohibition of discrimination, intimacy [7] and so many others that lead to important bioethical repercussions, such as, for instance, free traffic of the human body, confidentiality, data protection, informed consent, etc. Likewise, constitutions establish the principles of public policies for family protection, of childhood, health, science promotion, etc. All this normative roll [8] within the scope of public law acts as basis for bioethics issues as it frames them, and to a good extent determines them.

In the international context, Unesco and the European Council – as well as the European Union also– set to establish a common law and to harmonize legislation and criteria in the international scope in terms of bioethics. They have designed, in their particular dedication to protect dignity and human rights[9,10], declarations, covenants, resolutions, and diverse agendas. Their major contributions are the 1997 *Human Rights and Biomedicine Covenant*, from the European Council and three declarations from Unesco: the 1998 *Universal Declaration on Human Genome and Human Rights*, the 2003 *International Declaration on Human Genetic Data, and* the *Universal Declaration on Bioethics and Human Rights*[11], of 2005. These instruments have many scopes and character, but the four base themselves in the principles of freedom, equality, security, and mutual respect for the different options, becoming valuable tools of a regulation that requires the broadest scope.

Law shows an unarguable axiological dimension and opens itself to values, among which the *dignity of the individual* appears as their ethical basis and as intrinsic and specific value of human kind, derived from the common condition of all human beings endowed with autonomy, freedom, and rationality. This axiological dimension that certainly shows its progress in the European post-war compared constitutionalism takes, logically, the conception of human dignity as the constitutional principle of contemporary international order (or better still, supranational), which United Nations' texts consecrates, and whose essential core comprise the 1948 Universal Declaration of Human Rights, and Treaties, adopted in 1966, that make up the set called as the "International Human Rights Law"[12].

Therefore, even if there is not a single shared model of life, there is a broad consensus regarding some basic values and, currently, constitutions advocate values and set basic rights and duties, guided to protect human dignity and respect for the rights of others. The bioethical debate constitutes a previous phase of the political

debate and it falls into norms – particularly in those of public law – seeking that regulations that are set out result more appropriate to the scientific and social context, redounding in a higher normative quality. Effectively, in the topics dealt by bioethics, they have immediate reflect in the legal realm, both at legislative and jurisprudential level and from the standpoint of practical interest of those who work in the several fields of biotechnology whose new implications and responsibilities result problematic.

It can be seen that it is precisely this that happens with the analysis of problems derived from the new genetic technologies, the human genome, assisted reproduction, research and experimentation, sexual and reproductive health, abortion, sterilization, euthanasia, transplantations, informatics, data confidentiality, disabilities, psychiatry, aids, drug addiction, ecology, and the relationships between ethics, medicine, law, and economy of health [13,14]. In all these fields arise, frequently, dilemmas of difficult homogeneous solution in plural societies, and sets out the need to find answers framed in respect and promotion of human rights recognized in international instruments.

Ethical and legal norms for biotechnology and biomedicine

The complex relationships between Bioethics and Law are evidenced particularly in those difficult *cases* [15] (such as Ronald Dworkin streamlined the term *hard case* in the theory of Law) that also constitute paradigmatic bioethical problems in which there is not a clear agreement when defining which should be the required behavior. For example, in occasions, determinedascertain decisions on the withdrawal of treatment of vital support or related to acceptability of certain cases of voluntary interruption of pregnancy, frame cases in which judges should decide without a clear norm, either because there is not a specific norm or because several ones concur, and whose regulation is contradictory. The need to complete the legal system by integrating norms from other systems, such as moral, is something particularly complex in the framework of our society, and it raises the issue of place and character of principles, crucial in the philosophical-legal debate [16-20].

Nonetheless, the standpoint that separates law and moral represents for the modern jurist the requirement [21] that it is the sole instrument of coactive control be law. Although it is certain that part of the moral norms is raised to legal norms, it is not acceptable that a few citizens could impose their private moral on others. It is crucial that, in a regimen of law, there is not any other means of social control that could undo the deed of law, as it would happen if moral rules that did not undergo legal ordaining would have been endowed with coactive sanctions similar to those of law. This would mean that the realm of freedom not affected by

law would be invalidated when invaded by rival control instrument, and the institution that administer them (either churches or other organizations, could impose the external coercion outside the limits of law, with which the guarantees of individual freedom would be null and void. Separation between law and moral contributes to the establishment of political freedom, since only a political system that monopolizes coercion in face of the individual can eliminate this type of vague and uncertain situations.

Major portions of moral norms have a legal equivalent, for example, not killing. However, this equivalence does not exist in other topics, for example, in euthanasia or divorce and, although in certain case there may exist coincidence, the perspective is distinct. Law limits itself in requiring external compliance to its rules in as much as they are necessary for companionship, imposing a minimum of ethics without which social life would be impossible. Law should dictate norms that are valid for all, independently of which are their moral opinions. Thus, the ancient conflict between moral duty and legal duty may arise, in which law does not have other solution but to rule on the limits of conscious objection [22].

When dictating norms, which moral options should be changed into positive law? In which way? How should these two normative systems relate to decide which of them has priority in case of collision? Three type of answers have been historically given to these questioning: the preference of moral over law, the precedence of law over moral, and the customized consideration that advocates that under certain cases, preference should be given to moral that, in general, is law that has it. When a society is homogeneous and has a common ethical perception, or religious, it may be possible to speak on priority of moral over law. This was the case of medieval Europe, of an Empire relatively unitarian around the Christian religion, but religious wars that bloodshed Europe were the great rebuttal over the thesis of natural law [23]. The stand that proposed priority of positive law developed as a necessary consequence to this experience.

Currently, it is common to convene that law represents also a minimum moral needed to survival of society, and that this minimum is established in compliance to recognized human rights. Thus, in view of the traditional jusnaturalist thesis in which law has to follow natural moral principles, either rational, theist or cosmological, the governing thesis establishes separation between law and moral, with hues that derive from the requirement of respect to human rights as minimum ethics. In summary, justice of the system relies in the establishment of human rights as individual's guarantee against undue intromissions, and they constitute the legal basis and the inalienable minimum ethics. Previous statement is central to establishing agendas of assumed behavior for all, independently of the foundations that sets them apart.

Biotechnological risk, law, and bioethics

The possibilities that science and technology have currently to manipulate nature led to the questioning of many aspects of technological progress that were accepted previously without discussion. To the generalized requirement of scientific rigor has succeeded the claim of ethical analyses of the consequences of what is done, and inclusively from the same activity, as it can be noted in the Communication on the Principle of Precaution of the European Commission COM (2000) 1 final, presented in February 2, 2000 [24]. The limits to freedom of research – traditionally conceived as an individual right and protected by law as a fundamental right, currently are under questioning.

The acceptability of risk taken, and inclusively its own evolution, is something that depends in large measure in its cultural perception. Certainly, shared values set the degree of assumption or rebuttal of each form of risk in a way that goes beyond education and access to expert knowledge. Effectively, public reception of any policy on risk will depend on normally accepted ideas about justice [25,26]. It is exactly for this reason that results as indispensable to jointly discuss and decide about the model of life that one deems as desirable. This supposes that society is implicated politically in electing the direction of changes since the mere technological imperative [27], understood herein as scientific progress without limitation, today is arguable [28].

The topics that concern collectivity and scientists go beyond individual preference because the issues on social and legislative politics require joint and multidisciplinary answers: theoreticians' of ethics, jurists, medicine professionals, politicians, and each citizen are those who, in a democratic system, have to make the decisions, whose correctness depends, in large measure, on the quality of public discussion that precedes them.

In the other hand, scientists see increasingly threatened the prestige that derived from neutrality that would presuppose knowledge acquisition, since it is evident that distance between discoveries and their applications – between science and technology – is increasingly lower, inclusively on may say that it does not exist since the lines of research are set as function of their applicability. The huge funds that are needed currently for research called as basic derive from financing ways that – independently of their origin – are awarded in function of practical usefulness of the discoveries.

In the other hand, one realizes, in an ambiance of crisis in confidence of scientists and professionals of many realms' activities, a revaluation of ethics by the society and by different professional sectors.

Through it, the movements for accountability, which scientists themselves have been organizing, constitute a manifestation of the huge interest that the demand for moralization of trades and of the society as a whole, raises nowadays. Scientist's ethical commitment has given fruits of enormous relevance, and ethical reflection undertaken by scientists on their own activity constitutes an example for the other professions.

Law introduces a rationalization and certainty factor, and it exerts a legitimacy and control function, but neither international agreements or national laws, by themselves, can provide direct answers to the inquirers that frame technoscientific progress [29,30]. A whole world, not too far away, of science fiction seems to be around the corner and this closeness invites reflection. Since society, public powers, and legal ordaining should adopt decisions without fear and ignorance, it is indispensable to create new ethical and discussion instances as well, in which citizens, and different institutions are involved. This is, for democracy, a way of didactic closeness that allows assuring citizens' participation establishing spaces for reflection and action.

In these circumstances, information and social debate set out as indispensable and previous requirement to the normative work. The rigor and wealth of this discussion depend right away that adopted solutions are in accordance with the values that society deems as relevant and that can be, in its turn, respectful to the minority options. Effectively, there may be *good reasons* in favor of different stand and from this lack of ethical-social agreement often derivers a demand for legislation that grants to law the role to settle discussions on issues, which by not having univocal social answer, reinforce the demand for legislation. It is unquestionable that the legal ordaining has the function of conflict treatment [31] and resolution, but, in the other hand, it is certain that the existence of a norm does not solve definitively an issue: social debate remains and its application can lead to new conflicts. For whom, in public law faces the problems that we are designating as key issues of bioethics hard cases are forced to know not only what the law sets forth in that respect, but which are the existing moral implications and public perception regarding them, that is to count on the assistance of bioethical reflection.

In a plural society– in which by definition there is not one single acceptable way to decide the good lines of behavior – when facing conflicting standpoints, it is necessary to establish what is the ethical-legal benchmark to solve an issue. For it, the relationship between law and bioethics is narrow to the point that I do not consider possible conceiving one without the other [32]. Bioethics and law [33] feed themselves in one and the other, since the former requires from the later, the later should evolve in view of the findings and consensus achieved by means of social dialogue

and the bioethical analysis. Actually, deeds, values, and norms interact among each other, demand and complete one to the other, as the tridimensionalists have set out straight away. The tridimensional theory of Law makes its stronghold in this issue [34].

Repercussions of bioethics work in law

The work carried out by bioethics committee constitutes a first unavoidable example, since they are interdisciplinary instances that have as general goal to analyze the implications of biotechnology applications within the scope of its activity, issuing their opinion – or reports – so they can be of guidance to instances that depend and collaborate in ethical reflection of citizens in general and, consequently, participating in informed social debate. Committees are not decision making agencies and they do not have any democratic legitimacy. They are not elected, except that their members are nominated by those who created them due to their competences or diverse technical criteria; this may introduce major biases in their composition, reverberating in their decisions. Legitimacy of an ethics committee, independently of its type, is achieved when the exercise of its activity is useful and clarifying, and are invested with this special *autoritas* that derives not only from the merit of its members but from the good work of set as well.

Ethics and bioethics committees currently perform an important work, watching over for the subjects implied in techno-science applications, and acting in order to recommend guarantees and protection measures that soon have to establish who has the authority for it: this is to say the legislative power. Committees foster team work, they contribute to form informed opinions, and by achieving interdisciplinary agreement they collaborate in generating needed trust for the development of science and acceptability of its applications, and they watch over for protecting the individual and the recognized human rights [35-37].

In the other hand, the proliferation of ethics committees may lead at the same time to certain neglect of individual responsibility as there may be a trend on delegating personal decisions in a committee, as well as they may lead to a point of ethics reflection becoming institutionalized – or inclusively to become official – [38]. Bioethics committees respond undoubtedly to a new social need and they are a sample of the great collaboration possibilities and the help that bioethics represents for law. The *Universal Declaration on Bioethics and Human* itself lists the entire typology of ethics committees that are convenient to establish in order to facilitate the application of its principles. In the distinct clauses of its Section 19, it lists the Ethics Committees in Clinic Research, the Ethics Committees in Assistance, and the National Bioethics Committees, which Section 22.2 reiterates by designating to States the task to foment the creation of independent, interdisciplinary, and plural ethics committees.

Finally, I will mention the role of other bioethical instances that are not exactly ethics committees but rather scientific-bioethics groups whose work under the form of proposals for informed public debate, and for the normative reform are providing a clear incidence in the evolution of regulation of dealt issues. I refer really to the normative impact of proposals prepared under the Opinion Documents by the Group from the *Observatori de Bioètica i Dret* (Bioethics and Law Observatory) at the University of Barcelona. This research center offers a way to do bioethics based on a flexible, multidisciplinary and laymen conception, marked by respect to recognized human rights. In addition to carry out research and teaching functions, its objective to provide arguments for the social debate that foster autonomy of people in decision making redounding in the construction of a more transparent and democratic society, these documents had a strong normative impact in our country. For more information, please go to the web page *www.bioeticayderecho.ub.es.*

The Collection of Documents of the *Observatori de Bioètica i Dret* on assisted reproduction (available in Catalan, Spanish, and English) provides the opportunity to analyze the repercussions that they had in the scientific-medical, social context, and in the media, as well to undertaking a detailed consideration of their impact in legislation [39]. Such study confirms the impression already produced by the broad echo gotten in scope of the expertise on the new Spanish legislation that took in large part the recommendations from these documents through several normative texts[40-44] and, thus, achieving outstanding results and it has been applied by those that matters most to jurists and bioethics: to affect the normative change in the professional practice and in the social informed debate.

Other documents of the *Observatori de Bioètica i Dret* [39] have stressed the revaluation of citizen's autonomy within sanitary scope and have yielded in major changes in the administration policy regarding several topics dealt by them. For example, this would be the case of the *Document on sexual and reproductive health in adolescence* that changed the agendas over the consideration regarding underage, as well as that dealing on voluntary interruption of pregnancy whose impact in current Spanish law was relevant [45], or the *Document on refusal of blood transfusions by the Witnesses of Jehovah, which contributed to clarify the distinct situation in the daily work in many hospitals* [46]. The *Document on Anticipated Wills* is likewise of particular importance, whose model was in almost identical way adopted in Cataluña and yielded in specific regulations and acceleration in the establishment of autonomous, now state, registry [47].

The event that the work and opinion of a scientific and academic group has had such relevance in changing laws is particularly significant

for the purposes of the thesis that are sustained in this article because it sets straight forward the narrow implications of technical norms related to the legal ones and gives sense to the role of scientific-technical bodies – formal and informal – in elaboration of laws.

This is a new phenomenon in the world of law and increasingly acquires higher importance in bioethics scope, a field in which ethics committees – as technical committees – ant the scientific groups have a remarkable influence on legislation.

Resumen

A vueltas sobre las relaciones entre la bioética y el derecho

Este texto recoge y actualiza los principales puntos de mi anterior trabajo *La bioética como soporte al derecho para regular la biotecnología* [1] , que trata de la implicación entre el Derecho y la Bioética, relación que considero de carácter intrínseco ya que las aportaciones de ambos análisis resultan de utilidad recíproca a la hora de elucidar los problemas suscitados por la biotecnología, puesto que las dos disciplinas comparten una misma finalidad: el respeto y la promoción de los derechos humanos reconocidos. La bioética proporciona herramientas a la hora de la adopción de decisiones que afectan a valores y en las que resulta de especial importancia el proceso de elaboración y el análisis de las pautas que deben regir la acción en lo que se refiere a la intervención técnica del hombre sobre su propia vida y el medio en que la desarrolla, que luego serán elevadas a normas jurídicas.

Palabras-clave: Derechos humanos. Bioética. Ética médica. Educación. Educación en derechos humanos. Participación pública. Políticas públicas.

Resumo

Às voltas com as relações entre a bioética e o direito

Este texto recolhe e atualiza os pontos principais do meu trabalho anterior, *La bioética como soporte al derecho para regular la biotecnología* [1], que trata da implicação entre o Direito e a Bioética, relação que considero como de caráter intrínseco já que as contribuições de ambas análises resultam em utilidade recíproca no momento de solucionar os problemas trazidos pela biotecnologia, haja vista que as duas disciplinas compartilham uma mesma finalidade: o respeito e a promoção dos direitos humanos reconhecidos. A bioética proporciona ferramentas no momento da tomada de decisões que afetam valores e nas que são de importância especial o processo de elaboração e análise das pautas que devem reger a ação no tocante à intervenção técnica do homem sobre a própria vida e o meio no qual se desenvolve, as quais em breve serão elevadas ao nível de normas jurídicas.

Palabras-clave: Derechos humanos. Bioética. Ética médica. Educación. Educación en derechos humanos. Participación pública. Políticas públicas

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