

## Law and the life sciences: which are the main features of this relationship in your country?

### France

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En France, la loi votée par le Parlement a vocation à régir de nombreuses activités, y compris la médecine, la biologie et la bioéthique.

Depuis 1988, il existe une loi relative aux recherches sur la personne humaine. Elle a été modifiée en 2004, puis en 2012, cette dernière réforme n'étant pas encore en vigueur. Elle organise la protection des personnes qui se prêtent à de telles recherches, notamment en soumettant les projets à des comités, qui contrôlent notamment la pertinence du projet et la manière dont l'information et le consentement sont organisés.

En 1994, les premières lois dites de bioéthique ont couvert un très large domaine, englobant les tests génétiques, l'assistance médicale à la procréation et la recherche sur l'embryon, ainsi que les diagnostics avant la naissance, diagnostic prénatal et préimplantatoire, les prélèvements et les greffes de tissus et d'organes. Le législateur s'est appuyé sur le principe cardinal de la dignité de la personne humaine, et ses corollaires, l'anonymat et la gratuité pour installer des garde-fous contre d'éventuelles dérives, limitant par exemple l'accès à l'assistance médicale à la procréation à des couples formés d'un homme et d'une femme ou interdisant la gestation pour autrui. Des réformes successives, en 2004 et en 2011, n'ont pas apporté de changements fondamentaux. Toutefois, la recherche sur l'embryon et les cellules souches embryon-

naires a d'abord fait l'objet d'une interdiction, suivie de dérogations, avant de devenir autorisée sous conditions, sous le contrôle de l'Agence de la biomédecine, établissement public créé en 2004 avec une compétence générale, notamment d'autorisation, de suivi et de contrôle, des activités dépendant du domaine de la bioéthique.

A partir de 2002, le législateur s'est préoccupé plus particulièrement de l'activité de santé, avec la loi du 4 mars sur les droits des malades et l'organisation du système de santé, qui modifie les relations entre les professionnels de santé et les malades, l'indemnisation des personnes victimes d'accidents médicaux, par les professionnels responsables ou par la solidarité nationale, et fait participer les associations à ce que l'on appelle la « démocratie sanitaire ». Une loi de 2005 a complété la loi du 4 mars 2002 dans le domaine de la fin de vie, permettant la prise en compte de la volonté de la personne, directement ou par l'intermédiaire de directives anticipées ou d'une personne de confiance. Les divers scandales, du sang contaminé au Mediator, ont, en outre, donné lieu à de nombreuses lois spéciales permettant l'indemnisation des victimes de ces dommages en série et organisant une meilleure sécurité sanitaire, tant des activités de santé que des médicaments.

Le législateur a organisé, en amont de l'élaboration des lois, toute une série de consultations impliquant des instances diverses. Le Comité consultatif national d'éthique pour les sciences de la vie et de la santé (CCNE), autorité indépendante composée de personnalités d'horizons et de sensibilité diverses, est officiellement chargé de donner son avis sur les problèmes éthiques et les questions de société soulevés par les progrès de la connaissance dans les domaines de la biologie, de la médecine et de la

santé. Depuis 2011, il doit faire organiser, à cette fin, un débat public sous la forme d'états généraux. En pratique, il y a en permanence des discussions en cours sur tous ces sujets, très controversés en France, qui font intervenir non seulement le CCNE mais aussi des organismes parlementaires, comme l'Office national des choix scientifiques et technologiques, le Conseil d'Etat, et nombre d'académies et de sociétés savantes. La société française est traversée par de fortes tensions entre l'attachement au système actuel, où l'Etat joue le rôle de gardien des valeurs et des mouvements de contestation qui revendiquent plus d'autonomie et des choix de vie non conventionnels.

## France

### Stéphanie Hennette Vauchez

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Biolaw (*biodiritto, biodroit...*) certainly has come to existence in France. In fact, France led the way of institutionalizing bioethics when it created one of the first national ethics committee (*Comité Consultatif National d’Ethique*, 1983). It then indulged in legislative regulation: in 1994, 2004, 2011, important bioethics bills were passed that regulated, for instance, the way assisted reproduction or organ transplantation. Against this background, the state of the debate in France presents two main features: it remains unstable, and it is increasingly Europeanized.

First of all, as in many countries, it seems that legal regulation never settles an issue for good – any anything from political to social events may well reopen any given debate. For instance, although it was explicitly outlawed by the 1994 law, surrogacy reemerged in 2013 in the debate over the legalization of same sex marriage. It was ultimately remanded, but will probably reemerge if/when the question of same sex couples’ access to ART comes to the fore, or because of increasing calls for the legal recognition of filiation in the case of children born through gestational surrogacy arrangements (no less than 4 cases are currently pending before the ECtHR), or as the CJEU is confronted with further questions pertaining to the social rights of female workers who are commissioning mothers and apply for leaves equivalent to maternity leaves (CJEU, 18 March 2014, C-167/12 and C-363/12 recently ruled that the maternity leave mentioned by directive 92/85 presupposed pregnancy and birth and did thus not extend to commissioning mothers, and that

such denials of leaves were not discriminatory, neither on the grounds of sex nor disability; however, advocate general Kokott had reached the opposite conclusion...). End-of-life issues also typically reemerge in ever-new forms –thus underlying, each time, the inadequacy of the legal settlement that had previously been reached. Whereas one of the major individual dramas of the past decade had led to an important bill restating the individual’s right to refuse medical treatment (while also allowing, strikingly, a college of physicians to decide to withhold or withdraw treatment for terminally ill incapacitated patients; see Law 2005-370 of 22 April 2005), further dramas showed its inability to provide with guidelines for all situations, thus leading to a precocious assessment of the 2005 law and increased likelihood of new legal interventions (announced by then candidate F. Hollande during the presidential campaign) –especially after the highly tense and polemical 2013 judicial battle over the fate of yet another young man lingering between life and death (see the Chalons-en-Champagne drama that led to the Conseil d’Etat confirming that artificial hydration and nutrition were to be understood as “treatments” that can be discontinued along the procedures crafted by the 2005 law: CE, 14 Feb. 2014, n°375081, 375090, 375091).

A second feature is the Europeanization of the debate. Europeanization towards Strasbourg and the European Court of Human Rights comes as no surprise. Since the early 2000s, the Court has been regularly confronted with questions relating to bioethics and the life sciences; and since then, the trend had only been increasing. But the most interesting feature of the Europeanization of the debate and modes of regulation of life sciences is that the *other* Europe is becoming an important actor. To be sure, the Eu-

European Union has been developing a significant body of legislation over the years: after the lengthy and contentious landmark adoption of the 1998 Patents directive, many other important texts followed suit and one should now count with directives on Blood, Tissue, Clinical Trials, Organs etc. The EU research policy is also of high importance, especially when it is based on the notion that embryonic research shall not benefit from funding (see FP6 and FP7 founding decisions). But of recent, it is mostly judicial interventions that raise important questions.

The 2011 CJEU *Brüstle* decision (CJEU, 18 Oct. 2011, C-34/10) certainly deserves to be mentioned here, as the Luxembourg judges engaged on a highly unpredictable path as they ruled that there should be an “autonomous notion” of the embryo –and gave a rather extensive definition thereof, one that encompasses cloning (see §§35-36). The repercussions of the ruling remain to be assessed. They are expected to be manifold and impact not only the law and science of innovation and research as far as embryonic material is concerned, but also the more general conversation on the legal status of the embryo and many related topics (from prenatal diagnosis to abortion).

Other important judicial contributions of “Europe” to the debate over the life sciences are encapsulated in the worrying trend by which the European Court of Human Rights seems to rely on the EU-inspired freedoms of circulation to mitigate States’ obligations in terms of human rights. In two grand chamber rulings at least (2010, *A, B and C v. Ireland*, §241; and 2011, *S and H v. Austria*, §114), the Strasbourg court has mentioned that although the State legislations that were being challenged before her were extremely restrictive (and in fact, prohibitive; the legislations at stake were those relating to abortion in Ireland and to ART and the

ban on third party gamete donation in Austria), people retained the possibility of circumventing them by going abroad –where arguably abortive and reproductive services are more easily available. In times where all forms of “judicial dialogue” are regularly celebrated, one finds reason to worry about the extent to which this particular reference of the ECtHR’s reference to freedoms of circulation may ultimately undermine human rights.

## Spain

### Ricardo Chueca

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The scientific and technological advances both in therapeutic strategies and research and in experimentation with genetic material are becoming strongly linked and their regulatory framework is progressively increasing; an increase which simultaneously decreases the space for ethics but does not mean the reduction of the bioethical debate.

That emerging relationship is becoming more complex as it not only involves constitutional rights and principles, but also social perceptions that demand responsive policies which are often difficult to articulate given the rights and legal interests involved.

In Spain the main basis of this regulatory framework is the constitutional system of fundamental rights and its guarantees. The rights to life, to physical and moral integrity, to personal and family privacy and to informed self-determination, along with freedom of scientific research, are the fundamental rights of reference. They enjoy the greatest juridical protection, especially because the legislative is constrained by their constitutional definition. This is the case of the doctor-patient relationship (the right to information, to informed consent, to treatment refusal, etc.) and of the other scenarios considered here.

The rapid transposition of the Oviedo Convention into domestic law, both central and regional, has strengthened and developed their legal protection and has facilitated its acceptance as policy guidelines by all the agents involved.

The growing "culture of rights" in the biomedical field is also explained by the opportunities provided by the simultaneous creation in just

two decades of a public, universal and free health system which is associated with the development of the "Autonomic State" and whose quality is linked to the idea of what an advanced Democracy should be.

The first major challenge in shaping the relationship between law and life sciences emerged in the mid-eighties, during the decriminalisation of abortion under certain circumstances and the subsequent Constitutional Court (TC) decision. The TC then affirmed that art. 15 of the Spanish Constitution proclaimed not only a fundamental right to life but also enshrined the value "human life" which imposed the State's positive obligation to protect human life. However, the exact nature and scope of that "value" was obscure due to an argumentation based on a few dramatic statements with almost no legal effect, as the dissenting opinions to STC 53/1985 stressed. That decision established a doctrine later reinforced with minor changes by SSTC 212/1996 and 116/1999, which supported the constitutionality of certain activities mainly relating to gametes and embryos. In sum, STC 53/1985 upheld the constitutionality of the decriminalisation of abortion in certain cases but forced the TC to examine certain aspects of the fundamental right to life the Court probably regretted.

The subsequent development of the existing relationship between law and life sciences has been influenced in the Spanish case by the questions examined by the Constitutional Court, which have increased the negative nature of the fundamental right to life as a mere prohibition with no positive content.

The current legal situation in Spain, with only one exception, has not been constitutionally challenged and it seems apparently excluded

from the political debate. It can be described as follows:

1. Termination of pregnancy: Law 2 /2010, of 3 March, of sexual and reproductive health and the termination of pregnancy. It combines the free choice of women within the first 14 weeks of pregnancy, with the possibility of interrupting pregnancy both within the first 22 weeks for therapeutic reasons or as a consequence of severe fetal abnormalities, and anytime when the fetus suffers from anomalies that are incompatible with life or from an extremely serious and incurable disease.

The current government has opened the legislative process to reform this legal framework and apparently proposes to return to the criminalisation of abortion except under some circumstances.

2. Assisted reproduction: Law 14 /2006 of Assisted Human Reproduction Techniques (LTRHA). The Law prohibits reproductive cloning, regulates new reproductive technologies, surplus pre-embryos and preimplantation diagnosis. It also legally defines the concept of pre-embryo for the purposes of reproductive practices and enables the selection of pre-embryos for therapeutic purposes. Finally, it regulates some of the filiation issues associated with these techniques and prohibits surrogacy.

Problems: the National Donor Registry does not work, the donor compensation rules and the so called “reproductive health tourism”.

3. End of life decisions. Although there are no constitutional limits, some circumstantial constraints arise in the context of medical treatment refusal. Advanced directives are regulated and assisted suicide is criminalised.

There is a growing social and legal debate in this field.

4. Body parts disposal. In the context of the reproductive techniques: detailed regulation of

the anonymous and free donation of gametes and pre-embryos; in the case of therapeutic interventions: diagnostic and therapeutic interventions in the embryo under certain circumstances and, even, embryo creation for therapeutic purposes. In the context of transplants, the Spanish regulation is internationally considered as exemplary and with a high degree of efficiency.

Emerging problem: illegal *inter-vivos* organ “donations” for a price.

5. Scientific Research: Law 14 /2007 on Biomedical Research. It regulates the research on human gametes, embryos, foetuses and stem cells and the storage and use of biological samples for research purposes (Biobanks). Use of gametes and pre-embryos for research purposes. Spanish legislation allows the so called “therapeutic” cloning and permits the activation of oocytes by nuclear transfer, and prohibits the creation of human pre-embryos for experimental purposes only.

## Spain

### Fernando Rey

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Current Biolaw discussion in Spain refers to various classics on the end and the beginning of human life and the appropriate standards of care, but also to new issues arising from the development of medical technology. Among the subjects traditional or classic, we can identify four:

- a) The issue of abortion. In the Spanish system, the current government, the Popular Party, conservative, has approved a bill repealing the existing system of deadlines to abort (combined with the system of indications from a certain period of time), it is proposed return to the previous system indications (rape of mother, serious risk to life and / or health, physical or psychological, of the mother and risks of fetal malformation, but, it seems, that in the latter case, the reform intended to limit the chances of valid abortion). Linked to this issue is also the classic problem of awareness objection of medical personnel.
- b) The issue of the right to live with dignity the process of death itself, a new right (recognized in various Statutes of Autonomy: Catalonia and Andalusia), which includes the right to grant living will and the right to palliative care and refusal of life-sustaining medical treatments.
- c) The issue of informed consent as a new paradigm of the physician / patient relationship, which replaces the old model of medical paternalism. However, problems arise in the practical application of the new model because it often looks more like a protection against subsequent medical personnel requirements and any liability on the part of patients or their families, that a right of patients. In practice, informed consent

is disproportionately reduced the firm increasingly vast and incomprehensible documents.

d) Spain has one of the most advanced legislation in relation to assisted reproduction, but there continue to be problems of some depth. Among others: the establishment of parentage in some cases; the right of children to know who their biological parents on the figure, initially secret, the identity of the donor of biological material in the heterologous fertilization; the fate of the embryos frozen "surplus"; or the question of motherhood by subrogation or rent, which is illegal in Spain, however, is allowed in other states (for example, California), which, in this way, is being introduced in our system, etc. Along with these classics, the current discussion evokes Biolaw new issues that weigh on the limits of biomedical research and bioethics called emerging situations (cloning, obtaining stem cells, synthetic biology, etc.) The Bioethics Committee of Spain ([www.comitedebioetica.es](http://www.comitedebioetica.es)) collects some of them. I will point out only three new items:

- a) Clinical drug trials. It has approved a new regulation that poses new problems such as, for example, exemption from liability for so-called "low-risk trials".
- b) Banks blood and umbilical cord tissue. The Bioethics Committee is suggesting an approach that discourages trade and economic appeal of this case, in favor of a predominantly public and free treatment.
- c) Synthetic biology. This is the focus of future years, no doubt. There are problems here as his character possible source of biosecurity risk; patentability of these new biological products or responsibility of the scientist.

## Spain

### Carlos M. Romeo-Casabona

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The whole Biolaw has experienced an extraordinary development in Spain over the last decades, with regard to legal scholarship, regulatory framework and case-law. The field mostly affected by this expansion is that of Biomedical Law, without prejudice more recently to other sectors of Biolaw, ie, aspects related to non-human living beings (animals, plants, microorganisms, ecosystems, agricultural and livestock production, food and agriculture, etc...) that also attracted intense interest in the legal field.

The interest and attention paid to Biolaw experienced a steady increase, due to the relevance of many of these matters, both for society and for the basic conceptual legal structures themselves. Indeed, not a few of the legal elaborations related to advanced biomedical research involve extreme complexity for legal analysis.

Biolaw as such or Medical Law are not officially taught in Spanish Universities, although they figure occasionally in postgraduate courses (i. e. Masters in Biolaw, Medical Law or Bioethics) or as a short matter in graduate studies in Medical Schools; most curricula, indeed, tended to include Bioethics. This option is partly due to the confusion on the grounds and tasks of (Bio)Law and (Bio)Ethics, and partly to the idea that Bioethics teachers will not necessarily require previous training in the subject (an opinion which, if that is indeed the case, would be misleading).

In any case, it has to be accepted that Biolaw today is an autonomous discipline which is of crucial theoretical and practical importance given its potential effects on society. Nonetheless, a more interdisciplinary approach is needed in

Spain for a better comprehension of the relationship between Biolaw and Life Sciences.

Specific medical law sources in Spain have developed considerably over the years, especially along the last two decades. A relevant number of Laws in Spain address life science issues, being most of them of medical nature: the 1979 Law on the Removal and Transplantation of Organs, the General Health Law of 1986, as examples of the oldest laws, and the Law on Biomedical Research of 2007 as the latest most relevant issue. All of them are still in force.

Other Laws have been updated or are completely new: the 2002 Law on patient's autonomy and on rights and duties related to information and clinical records, the 2006 Law on Techniques of Human Assisted Reproduction (former Law: 1988), the 2006 Law on guarantees and the rational use of medicines (former Law: 1990), the 2010 Law on reproductive health (voluntary interruption of pregnancy), and others.

These issues are taken up further in Royal Decrees, which cover other aspects also such as blood donation, organs and tissues for therapeutic purposes, biobanks and human samples for research purposes, clinical trials. Although still rather scarce in this field, court rulings, implemented in quantity and quality (argumentations), also can provide important points of reference.

As regards non-specific sources, mention should be made first and foremost of the Spanish Constitution of 1978, which sets out fundamental rights and freedoms which may be affected by medical practice: the right to life and to physical and moral integrity (Art. 15), the right to ideological freedom (Art. 16), the right to freedom [of movement] (Art. 17), the right to privacy (Art. 18), freedom of scientific research (Art. 20.1), etc. The Constitution also enshrines the



principle of non-discrimination (Art. 14) and refers to the dignity of the human being and to the free development of personality (Art. 10.1). On the international level, special reference should be made to the human rights Conventions subscribed and ratified by Spain and which, as result, are now part of domestic law (Art. 96 of the Constitution) and are of help in the interpretation of the fundamental rights laid down in the Constitution. Of particular interest in this regard is the Universal Declaration of Human Rights, which is mentioned expressly in the Constitution (Art. 10.2). Along last decades International Law has developed specific legal instruments, binding or not binding, in matters directly related to biomedical activities of which Spain is a part: Council of Europe Convention on Human Rights and Biomedicine (Convention of Oviedo, 1997) and the Additional Protocol on the Prohibition of Cloning Human Beings, UNESCO's Declarations on the Human Genome and Human Rights (1997), on Human Genetic Data (2003), on Bioethics and Human Rights (2005).

EU law is also getting relevance as a source for Biolaw in all member States, even if its role is limited by the principle of subsidiarity governing this area. As a first step the European Charter of Fundamental Rights is a reference frame for human rights involved in biomedical activities.

## Switzerland

### Roberto Andorno

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Switzerland is probably the only country in the world having introduced explicit norms relating to bioethics into its Constitution<sup>22</sup>. This is due to the political structure of the country, which is a Confederation: all matters which are not explicitly delegated to the Federal State belong to the Cantons. In principle, medical issues are within the competence of Cantons. Therefore, in order to habilitate the Parliament to legislate on a particular medical matter, a specific constitutional provision is required.

In 1992 the first bioethical provisions were granted constitutional rank. This took place after a referendum proposed by a popular magazine ("Schweizerischer Beobachter", or "The Swiss Observer"), which collected the number of signatures that are required to submit an issue to popular vote. The project was conceived to prevent "a misuse of reproductive technologies and genetic manipulation in the human species". The government decided to propose an alternative, more precise project, which was submitted to vote in 1992 and accepted by 74% of the population. As a result of this vote, a new article was introduced into the Constitution prohibiting, among other practices, the creation of supernumerary embryos, germ-line interventions, human cloning, surrogate motherhood, and the creation of mixtures between human and non-human reproductive cells and genetic material (chimeras and hybrids). At the same time, the new constitutional provision requires informed consent for conducting genetic tests, and for storing and disclosing their results.

<sup>22</sup> See the Swiss Constitution at: <http://www.admin.ch/org/polit/00083/>.

The new Constitution adopted in 1999 incorporated this norm (current Article 119) as well as other more general principles, such as the respect for human dignity (Art. 7) and the right to health care (Art. 41b). A new article on organ transplantation was also incorporated into the Constitution, which requires the establishment of criteria for a fair allocation of organs and prohibits organ selling (Art. 119a).

An interesting notion that also appeared in the Constitution since 1992 is the concept of "dignity of creature" in the context of genetic engineering in animals and plants. According to Article 120, "the Confederation shall legislate on the use of reproductive and genetic material from animals, plants and other organisms. In doing so, it shall take account of the dignity of living beings as well as the safety of human beings, animals and the environment, and shall protect the genetic diversity of animal and plant species". However, the notion of "dignity of the creature" remains controversial and it is still unclear what it exactly means. It should be noted that the notion of "dignity of animals" is explicitly used by the Law on the protection of animals against cruelty.

Since 2010, a new constitutional provision (Article 118b) sets up the principles relating to biomedical research involving human beings. It provides that legislation on this matter is required in order to protect human dignity and privacy. The principles governing this field are: the requirement of informed consent, the proportionality of risks and benefits, in the case of research on persons unable to consent, it is only allowed with the consent of legal representatives, if findings of equal value cannot be obtained from research involving competent persons, and if the research does not entail more than minimal risks and minimal burden; and finally, research projects should be approved by

an independent ethics committee. This provision puts the Swiss law in conformity with the European Convention on Human Rights and Biomedicine (Oviedo Convention), which had been ratified by Switzerland in 2008. The principles enunciated by Article 118b were developed through a new and very detailed Law on Research Involving Human Beings (2011), which entered into force in January 2014.

Also based on the above mentioned constitutional provisions, other specific laws on bioethical issues have been adopted such as the Law on medically assisted reproduction (1998), the Law on Organ Transplantation (2004), the Law on genetic testing (2004), and the Law on Research Involving Human Beings (2011).

Regarding the use of *advance directives*, a new Article 372 of the Civil Code recognizes the value of such documents. It provides that “the doctor must respect the advance directive of patients, unless they are contrary to the law, or if there are serious doubts as to whether they express their free will, or whether they really reflect their presumed will in the current situation”.

Concerning end of life decisions, active euthanasia (i.e. killing on request) is illegal, although it is treated as a lesser offense than murder or manslaughter. The peculiarity of Switzerland in this field relates to *assisted suicide*, which is permitted and practiced by (non-physician) volunteers working for nonprofit organizations. According to Article 115, entitled “inducement and assistance to commit suicide”: “Every person who, for selfish reasons, incites or assists someone to commit suicide shall be sentenced to imprisonment of up to five years or a fine.” This article is interpreted as meaning that assistance with suicide is not a criminal offense when it is practiced without any self-interested motivation. Nonprofit organizations that sup-

port assisted suicide have taken advantage of provision to develop their activities. Since they do not have, in principle, any selfish motivations for helping someone to commit suicide, their activities are not considered illegal<sup>23</sup>.

<sup>23</sup> See Roberto Andorno, “Non-physician assisted suicide in Switzerland”, *Cambridge Quarterly of Healthcare Ethics*, 2013, 22(3): 246-253.

## Switzerland

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Durante questi ultimi anni, e fino alle ultime settimane di quest'anno, ferve in Svizzera una intensa attività legislativa legata alle aree di ricerca e di attività clinica in medicina. Questo fervore non ha cause legate ad un preteso vuoto giuridico in questi ambiti quanto piuttosto in un movimento generale di passaggio di competenze dai Cantoni, considerati finora come attori principali nell'attività legislativa in campo sanitario, alla Confederazione. Questa centralizzazione a sua volta è diventata necessaria non solo per la globalità dei fenomeni presi in esame (un paziente si ritroverebbe di fronte a due sistemi legislativi diversi a distanza di pochi chilometri) ma anche a causa degli impegni che la Confederazione elvetica ha assunto nei confronti del Consiglio d'Europa, di cui è membra a pieno titolo.

Enumero, senza la pretesa di essere completo, i temi su cui si stanno operando dei processi di revisione più o meno estesi.

La Svizzera si è dotata di una legge ad hoc riguardante la ricerca biomedica sull'essere umano<sup>1</sup>. In questo senso il governo svizzero prevede tra l'altro di ottimizzare ulteriormente, entro il 2015, il sistema di fissazione dei prezzi dei medicinali e di allestire, entro il 2017, un'agenzia *Health Technology Assessment* (HTA) che verifichi le attuali prestazioni mediche e valuti nuove proposte di trattamento innovative. Inoltre, entro il 2016 vuole migliorare la protezione

contro la contraffazione e l'illegalità dei medicinali e ridisciplinare la ricerca sull'essere umano con la legge sulla ricerca umana, che entrerà in vigore all'inizio del 2014, rendendo più snelle e trasparenti le procedure per l'autorizzazione e lo svolgimento di progetti di ricerca. La nuova legge introdurrà facilitazioni anche per gli studi clinici che potranno essere eseguiti in più sedi contemporaneamente.

Da alcuni anni la *medicina dei trapianti* è regolata a livello centrale mediante una legge federale, entrata in vigore nel 2004<sup>2</sup>. A dieci anni di distanza ha preso inizio una prima revisione della legge, attualmente ancora in corso poiché solo una camera del parlamento l'ha approvata. Questa revisione dovrebbe concludersi nell'anno in corso. Questa revisione parziale permetterà ai cittadini degli Stati dell'UE e dell'AELS affiliati a una cassa malati svizzera nonché ai loro familiari che sottostanno a questo stesso obbligo assicurativo, di beneficiare della parità di trattamento, rispetto alle persone domiciliate in Svizzera, in materia di attribuzione di organi destinati al trapianto. Lo stesso vale per i cittadini dell'EU e dell'AELS che hanno diritto a un'assistenza reciproca internazionale in materia di prestazioni durante un soggiorno limitato nel tempo nonché per i cittadini di Paesi terzi ammessi in quanto frontalieri a esercitare un'attività lucrativa in Svizzera. Inoltre devono essere modificate le prescrizioni, la cui esecuzione aveva creato problemi e insicurezze. D'ora in poi l'autorizzazione per un prelievo di organi potrà essere richiesta agli stretti congiunti già dopo la decisione dell'interruzione dei trattamenti che tengono in vita il paziente. Altresì sono disciplinate, nel caso di un donatore incapace di discernimento, le condizioni alle quali si

<sup>1</sup> Cfr. il testo presso:

<http://www.bag.admin.ch/themen/medizin/00701/00702/07558/index.html?lang=it>

<sup>2</sup> Cfr il testo in:

<http://www.admin.ch/opc/it/classified-compilation/20010918/index.html>

possono prendere provvedimenti medici preparatori in vista di un prelievo d'organi. Un altro aspetto concerne la garanzia finanziaria del donatore vivente. Gli assicuratori devono assumersi le spese mediche per il controllo postoperatorio versando una somma forfettaria unica alla Fondazione svizzera competente per l'assistenza ai donatori viventi di organi. La Fondazione impiega le risorse finanziarie ricevute, alle quali d'ora in poi contribuirà anche la Confederazione, per la tenuta del registro per l'assistenza ai donatori viventi di organi.

Un processo legislativo ulteriore concerne gli esami genetici fatti sull'essere umano. La Svizzera si è dotata al riguardo di una legge ad hoc, tra le prime in Europa<sup>3</sup>. Attualmente il governo ha pure istituito una Commissione di esperti per gli esami genetici sull'essere umano (CEEGU), con il compito di fornire una consulenza scientifica e normativa in materia. Tra gli scopi della Commissione rientrano lo sviluppo scientifico e pratico nel campo della genetica umana, la formulazione di raccomandazioni e la segnalazione di problemi e lacune nella legislazione. Attualmente la Commissione ha lanciato una campagna di sensibilizzazione sui problemi sollevati dalla proposta di test genetici in internet.

Dal 2005 è in vigore in Svizzera pure una legge specifica sulla ricerca fatta con cellule staminali embrionali. Essa non ha subito variazioni, salvo attraverso una nuova versione dell'ordinanza di applicazione<sup>4</sup>.

E' attualmente in corso di revisione la legge federale sulla medicina di riproduzione medicalmente assistita. L'attuale divieto in materia di

diagnostica preimpianto (DIP) verrà rimpiazzato con un'autorizzazione sottoposta a severe condizioni quadro. Il governo ha trasmesso il progetto di regolamentazione e il messaggio relativo al Parlamento nel corso del 2013 ed ora il dibattito parlamentare è ancora in corso. Il Comitato nazionale di bioetica, chiamato Commissione nazionale di etica ha pubblicato un lungo rapporto in vista di questo lavoro di revisione. Tale rapporto ha avuto un forte eco mediatico a causa della sua pretesa linea "liberale" e costituisce un tentativo di riflessione globale su questa problematica<sup>5</sup>.

Va evocato infine il fatto che la Svizzera ha firmato e ratificato la Convenzione sulla biomedicina del Consiglio d'Europa (pur emettendo a priori un numero di riserve) ed ha pure aderito a due protocolli addizionali, quello sul divieto di clonazione quello sui trapianti.

Gli studiosi di biodiritto italiani avranno la facilità di seguire tutti questi lavori legislativi poiché tutti i testi sono accessibili in italiano, in quanto l'idioma di Dante è lingua ufficiale a tutti gli effetti nella Confederazione elvetica.

<sup>3</sup> Cfr.

<http://www.bag.admin.ch/themen/medizin/00683/02724/03676/index.html?lang=it>

<sup>4</sup> Cfr.

<http://www.bag.admin.ch/themen/medizin/03301/03361/03410/index.html?lang=it>

<sup>5</sup> Cfr. il testo in lingua italiana:

<http://www.bag.admin.ch/nek-cne/04229/04232/index.html?lang=it>

## United Kingdom

### Roger Brownsword

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In general, the political and popular culture of the United Kingdom is strongly supportive of the life sciences and their commercial exploitation (see, for example, the *Strategy for UK Life Sciences*, which was launched by the Prime Minister in December 2011). Accordingly, when European institutions, situated in a more pluralistic milieu, adopt positions that reflect rather different priorities, this can create serious concern. For example, the recent decision of the CJEU in the *Brüstle* case (Case C-34/10, *Oliver Brüstle v Greenpeace e.V.* (Grand Chamber, 18 October 2011)), ruling against the patentability of innovative stem cell science that relies on materials derived from human embryos that have been necessarily destroyed in the process, was viewed by many United Kingdom intellectual property lawyers as retrograde—not only does the *Brüstle* decision go against the liberal grain of local patent law, it applies the deeply contested notion of human dignity to the protection of human embryos in a way that has little resonance in mainstream British thinking. Similarly, in the United Kingdom research community, there is considerable anxiety about the impact of the draft Regulation on data protection—particularly with regard to the requirement that a participant's consent must refer to a 'specific' research purpose. If the Regulation is finalised in such terms, the fear is that it will undermine the broad consents on which UK Biobank and similar projects rely.

In the United Kingdom, the regulatory environment for research and development in the life sciences comprises a range of 'hard' and 'soft' law instruments. The regulatory aspiration is to

strike an acceptable balance between two potentially competing sets of demands: on the one hand, there is the demand that the risks presented by emerging technologies should be properly assessed and managed so that there is a reasonable response to concerns about human health and safety as well as the integrity of the environment; and, on the other hand, there is the demand that beneficial innovation should not be stifled and that scientific research should be adequately supported. At the 'hard' end of the regulatory range, there are various statutes—some of the more prominent recent examples include the Human Tissue Act 2004 and the Human Fertilisation and Embryology Act 2008—statutory instruments, and judicial precedents. Some of the relevant legislation—such as the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007—implements EU Directives. At the 'soft' end of the range, there are less formal governance regimes such as those that (prior to the HTA) regulated the use of fetuses and fetal tissue for research (the so-called Polkinghorne Guidelines) and that direct the operation of research ethics committees; and the Ethics and Governance Framework that regulates the operation of UK Biobank is a leading example of non-statutory governance.

Although the life sciences are heavily regulated in the United Kingdom, there are still significant points of legal uncertainty. For example, the long-standing view that the person who is the source of removed human tissue does not have proprietary rights in relation to the tissue was seemingly challenged by the Court of Appeal in the *Yearworth* case (*Yearworth v North Bristol NHS Trust* [2009] EWCA Civ 37); and it is a moot point whether a failure by researchers to return incidental findings to an identifiable individual

research participant could be actionable whether as a claim for breach of contract or as a tort (see Carolyn Johnston and Jane Kaye, 'Does the UK Biobank have a Legal Obligation to Feedback Individual Findings to Participants' (2004) 12 *Medical Law Review* 239). There are, moreover, new issues to be addressed by regulators as and when synthetic biology develops beyond its present immature stage (see, e.g., *Synthetic Biology Dialogue*, available at <http://www.bbsrc.ac.uk/web/FILES/Reviews/1006-synthetic-biology-dialogue.pdf>).

Stated summarily, in the United Kingdom, the key feature of the relationship between the law and the life sciences is that the former is geared to support the latter. However, as a member of the larger European community, the United Kingdom is not entirely in control of the regulatory environment, the social licence given to the life sciences being to some extent regional rather than national. Moreover, in the life sciences, things do not stand still and, regional considerations apart, it is a challenge for any national regulator to keep the law properly connected to the latest technologies while, at the same time, supporting beneficial innovation and responding to public concerns about health and safety as well as the dilution of fundamental values (see, generally, Roger Brownsword and Morag Goodwin, *Law and the Technologies of the Twenty-First Century* (Cambridge University Press, 2012)).

## United Kingdom

### Sheila A.M. McLean

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Historically, it can be said that the relationship between the law and the life sciences was at best tenuous and at worst non-existent. The role of the law was primarily to judge technical disputes based, generally, on the lessons learned from precedent; the life sciences, on the contrary, were forward looking, developing and proactive. Particularly beginning in the 20<sup>th</sup> century, this situation began to change. As medicine, in particular, advanced its capacities, so too it began to impinge more closely on the lives of individuals and on the consciousness of communities.

Arguably, the first steps towards a closer (albeit not necessarily non-adversarial) relationship can be traced to the development of human rights dialogue, particularly in the developed world. Recognition that individual integrity – physical or mental – formed a fundamental platform for rights-based claims ensured that interventions in such integrity came to be viewed not solely as a clinical matter but also as one with which individual rights were engaged. Second, the pervasive nature of health care ensured that it became an issue not just for individual patients and clinicians, but also for society as a whole. In particular, in countries with a state-funded health care system, such as the United Kingdom, the availability of health care became of economic as well as therapeutic concern. Enthusiastically or not, legislators and courts became increasingly involved at both a macro and a micro level in resource allocation decisions. Finally, and derivative from the growth of the use of human rights language referred to above, an increasingly alert and in-

formed public became more comfortable in challenging individual or state decisions, as well as demanding the services provided were of a high quality and standard. Adjudication on disputes arising from a perceived failure in these respects inevitably became the province of the law, often through the courts.

The parallel development, from the middle of the 20<sup>th</sup> Century, of bioethics as a discipline exposed further areas of potential controversy, leading to an increased opportunity for conflict. While ethical issues are not strictly the province of the law, over the years courts in particular have increasingly been engaged with such dilemmas. Arguably, therefore, the role of the law in relation to the life sciences has become much closer and at the same time more complex.



## United States

### Charles Baron

*Professor Emeritus, Boston College Law School*

The signature characteristic of law and bioethics in the United States is the process by which principles in the field are preeminently generated, namely, by judicial law making, both substantive and constitutional. Courts at all levels in the fifty states and the various federal jurisdictions participate in the process. Law-making in the United States does not have to wait for action from legislators or administrative bodies. The courts are always open to suits seeking relief in cases raising bioethical issues. In deciding such cases, courts draw upon principles they find primarily in opinions written in earlier decisions – not only those of courts in their own jurisdiction, but also of courts in other jurisdictions whose reasoning they find persuasive. The judges then further refine those principles in applying them to the cases before them. It is this process that has arguably put the United States in the forefront of the development of law related to bioethics. New issues in bioethics quickly create situations in which individuals seek relief from courts whose decisions gradually produce a body of laws governing them.

Thus, in 1964, in the Georgetown Hospital Case, the Washington, D.C., courts were forced to deal with the question of whether a hospital could force a life-saving blood transfusion on a Jehovah's Witness who refused such treatment on religious grounds and, in the process, laid the foundation for a long series of state and federal cases that would eventually establish across America a competent patient's right to refuse life-prolonging treatment on any grounds. In 1980, in *Diamond v. Chakrabarty*, the Supreme Court of the United States (by a 5 to 4 vote) interpreted American law to permit a

microbiologist to obtain patent protection on a life-form – a new bacterium – that he had created. And, in 2001, in *Grimes v. Kennedy Krieger Institute*, the Maryland Supreme Court, faced with a suit for damages arising from lead paint poisoning experiments conducted on children in Baltimore, adopted ethical principles drawn from, among other sources, the Nuremberg Code as part of Maryland common law.

Of course, the legislative and executive branches have made important contributions as well. However, often statutes have essentially only restated and generalized the principles developed by the courts. And when they have come into direct conflict with those principles, the courts have often found ways around them – despite the basic rule that statutes (theoretically representing the will of the people) trump judge-made law. Constitutional principles, both state and federal, trump statutes, and the courts in the United States tend to get the last word interpreting and applying those. The U.S. Supreme Court's 1973 decision in *Roe v. Wade* struck down restrictive state abortion statutes countrywide. Its 1990 decision in *Cruzan* made uniform across the country the right-to-die principles that had been developing in many, if not all, state courts. At times, legislatures have willingly accommodated to these moves. After the Supreme Court of Connecticut, in its 1989 decision in *McConnell v. Beverly State Enterprises*, avoided finding its state's Removal of Life Support Systems Act unconstitutional by giving it a "saving interpretation," the state legislature amended the act to comply. But, in many other circumstances, most famously the struggle that took place from 1990 to 2005 between all three branches of the Florida state government over termination of life support for Terri Schiavo, courts have found themselves placed under fire by political forces responding

to popular fear of incursions upon respect for human life. The continued development of American law regarding bioethics follows a vector primarily driven by the interplay between these forces and the courts.

*Forum*

## Argentina

### Paula Siverino Bavio

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#### Introducción

En la Argentina será evidente, a partir del año 2003, un giro radical en la política de Derechos Humanos y su expresión a través de la reflexión bioética, el cual se hizo patente en su activa participación y liderazgo, junto a Brasil, en los trabajos preparatorios y posterior aprobación de la Declaración Universal de Bioética y Derechos Humanos y en las discusiones por la modificación de la Declaración de Helsinki. En este contexto, el quiebre con la bioética principialista de corte anglosajón a fines de los años noventa motivada fundamentalmente por el repudio al doble estándar ético que pretendía aplicarse en la investigación en seres humanos en países en vías de desarrollo propició el nacimiento de la Escuela Latinoamericana de Bioética, que tiene su base en la Bioética de los Derechos Humanos<sup>1</sup>.

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<sup>1</sup>Cfr. TEALDI, Juan Carlos *Bioética de los Derechos Humanos. Investigaciones médicas y dignidad humana*. UNAM, México, 2008,, SIVERINO BAVIO,

La Bioética de los Derechos Humanos se desarrollará de manera sistemática en la Región a partir de la Carta de Buenos Aires<sup>2</sup>, documento político aprobado el 6 de noviembre de 2004 en el marco de las consultas regionales previas a la aprobación de la Declaración Universal de Derechos Humanos, desde dos premisas básicas: a) el reconocimiento como mínimo indiscutible del respeto a la moral universal de los derechos humanos y la universalidad de la bioética de los derechos humanos basado en el concepto de la dignidad humana; y b) la necesidad de dar cuenta de las relaciones de la racionalidad moral con las racionalidades jurídicas, científicas, tecnológica y estética<sup>3</sup>. Esta posición rescata los problemas éticos vinculados al medio ambiente y la diversidad; la perspectiva de la salud integral entendida como desarrollo de las capacidades humanas esenciales (lucha contra la pobreza, acceso al agua potable, vivienda, educación, erradicación de la violencia, etcétera); la idea de justicia como fundamento esencial en el contexto interpretativo de los derechos humanos y la

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Paula "Una Bioética en clave latinoamericana: Aportes de la Declaración Universal sobre Bioética y Derechos Humanos de UNESCO", *Derecho PUCP* Nro. 63, Fondo Editorial de la Pontificia Universidad Católica del Perú, Lima, 2009, disponible en <http://revistas.pucp.edu.pe/index.php/derechopucp/article/view/2986> (consultada el 15 de febrero de 2014).

<sup>2</sup> Carta de Buenos Aires disponible en <http://www.unesco.org/uy/ci/fileadmin/shs/redbioetica/CartaBuenosAires-RED.pdf> (consultada el 15 de febrero de 2014).

<sup>3</sup> TEALDI Juan Carlos, entrada "Bioética de los Derechos Humanos" en *Diccionario Latinoamericano De Bioética*, TEALDI, Juan Carlos (Director) UNESCO-Universidad Nacional de Colombia, Bogotá, 2008, p.127, p.177.

necesidad de construir una Bioética Latinoamericana<sup>4</sup>.

A continuación una sintética presentación de las principales líneas de trabajo que expresan de manera concreta los postulados de esta Bioética de los Derechos Humanos en la Argentina, que lograron consolidar un andamiaje normativo debido a una clara y sostenida vocación política en este sentido:

### 1. Juzgamiento y condena de delitos de lesa humanidad

En el año 2003 el Poder Legislativo, el Ejecutivo y el Judicial impulsaron fuertemente la condena de los delitos de lesa humanidad cometidos en la última dictadura militar (1976-1982). El presidente Kirchner promovió activamente la reapertura de las causas judiciales; la Corte Suprema de Justicia de la Nación declaró la imprescriptibilidad de los delitos de lesa humanidad<sup>5</sup> y la inconstitucionalidad de las leyes de Obediencia Debida y Punto Final<sup>6</sup> y el Congreso de la República anuló las leyes de impunidad (indultos y leyes de Obediencia Debida y Punto Final<sup>7</sup>). A partir de entonces militares y, actualmente algunos civiles, están o han sido procesados y condenados por secuestros, torturas, homicidio y desaparición forzada de personas, así como por la sustracción, retención, ocultamiento y adulteración de identidad de niños pequeños y

de bebés nacidos en cautiverio<sup>8</sup>. A febrero del 2014 son 110 los nietos recuperados por las Abuelas de Plaza de Mayo<sup>9</sup>, 195 casos están bajo investigación judicial y se estima fueron unos 500 los bebés apropiados, hoy ya adultos.

### 2. Defensa de la diversidad sexual y cese del modelo heteronormativo

La sanción, el 9 de mayo del año 2012, de la Ley de Identidad de Género<sup>10</sup>, aunada a la Ley de Matrimonio igualitario<sup>11</sup> consolida la ruptura total con el modelo heteronormativo vigente en el resto del mundo. La gran diferencia en el caso argentino es el reconocimiento pleno de la identidad trans (su no patologización) y el acceso, bajo el plan de prestaciones médicas obligatorias (de efectores públicos y privados) a las intervenciones quirúrgicas y hormonales, en el caso que la personas trans las solicite, no siendo necesaria la voluntad de realizarse una intervención de reasignación sexual para el reconocimiento de la identidad. Toda persona mayor de dieciocho años (y los menores de edad mediante representación legal) puede solicitar la rectificación registral (mediante una gestión administrativa) de su sexo y su nombre

<sup>8</sup> Mega causa ESMA:

[http://memoria.telam.com.ar/noticia/megacausa-esma-declaran-imputados-por-el-robo-de-bebes\\_n2301](http://memoria.telam.com.ar/noticia/megacausa-esma-declaran-imputados-por-el-robo-de-bebes_n2301);

[http://es.wikipedia.org/wiki/Megacausa\\_ESMA](http://es.wikipedia.org/wiki/Megacausa_ESMA).

<sup>9</sup> <http://www.inforegion.com.ar/noticia/74322/ya-son-110-los-nietos-recuperados-por-abuelas>.

<sup>10</sup> Ley 26.743 sancionada el 9 de mayo de 2012 disponible en

<http://www.infoleg.gov.ar/infolegInternet/anexos/195000-199999/197860/norma.htm> (consultada el 15 de febrero de 2014).

<sup>11</sup> Ley 26.618 sancionada el 15 julio del año 2011 disponible en

<http://www.infoleg.gov.ar/infolegInternet/anexos/165000-169999/169608/norma.htm> (consultada el 15 de febrero de 2014) Esta Ley modifica numerosos artículos del Código Civil.

<sup>4</sup> Una obra estructural que organiza el pensamiento y desarrollo de la Bioética Latinoamericana es el *Diccionario Latinoamericano De Bioética*, TEALDI, Juan Carlos (Director) UNESCO-Universidad Nacional de Colombia, Bogotá, 2008, puede ser consultado en <http://www.unesco.org.uy/shs/fileadmin/templates/shs/archivos/DicoPartel.pdf> (consultado el 15 de febrero 2014).

<sup>5</sup> CSJN (Fallos:327:2312).

<sup>6</sup> CSJN (Fallos: 328:2056).

<sup>7</sup> CSJN (Fallos: 328:2056).

de pila si no coinciden con su identidad autopercibida. Ya la ley de Salud Mental<sup>12</sup> había establecido que en ningún caso podía hacerse un diagnóstico de enfermedad mental sobre la base exclusiva de la elección o la identidad sexual (artículo 3 inciso c). La Ley de Matrimonio Igualitario equiparó, a todos los efectos, el matrimonio entre personas del mismo sexo al matrimonio entre personas heterosexuales modificando numerosos artículos del Código Civil y leyes complementarias.

### 3. Derechos de las mujeres: Salud Sexual y Reproductiva<sup>13</sup>

Argentina se había diferenciado históricamente del resto de Sudamérica por su política pronatalidad habiendo atravesado períodos de prohibición total de venta de anticonceptivos y difusión de planificación familiar desde la década de los años setenta hasta 1985. En el año 2002 se crea el Programa Nacional de Salud Sexual y Procreación Responsable<sup>14</sup>. Tendrá dos modificaciones importantes: el reconocimiento de la anticoncepción quirúrgica voluntaria<sup>15</sup> y de la anticoncepción oral de emergencia<sup>16</sup> como métodos contraceptivos. De vital importancia

será la Ley sobre Educación Sexual Integral sancionada en el año 2006<sup>17</sup>, trabajándose actualmente en lograr su implementación nacional y en los contenidos sobre sexualidades diversas. La Ley Protección Integral contra la Violencia (Ley 26.485)<sup>18</sup> contempla de manera expresa la violencia institucional, ginecológica y obstétrica contra las mujeres, la que muchas veces se observa en la atención post aborto. El aborto está regulado en el Código Penal y es permitido en caso de que corra riesgo la salud o vida de la mujer y en caso de violación. La extensión de la despenalización por violación (antes admitida con reparos sólo para mujeres con capacidades mentales disminuidas) fue establecida por un fallo de la Corte Suprema de la Nación en el año 2012.<sup>19</sup> Allí mismo se dijo que la exigencia de las instituciones de salud públicas de una autorización judicial para realizar un aborto legal configura violencia contra la mujer en términos de la Ley 26.485. Completa el panorama la Ley de 26.862 del año 2013, que garantiza cobertura en el sistema público y privado de salud, a toda persona mayor de edad (independientemente de su estado civil, identidad u orientación sexual) de tratamientos de reproducción asistida<sup>20</sup>.

<sup>12</sup> Ley 26.657, noviembre 2010 disponible en <http://infoleg.gov.ar/infolegInternet/anexos/175000-179999/175977/norma.htm> (consultada el 15 de febrero de 2014).

<sup>13</sup> Para un desarrollo in extenso ver SIVERINO BAVIO, Paula. "Panorama sobre la salud sexual y reproductiva en Argentina" en *Responsabilidad de los médicos*, GARAY, Oscar (Dir) La Ley, 2da. Ed. Buenos Aires, 2014.

<sup>14</sup> Ley 25.673 de Salud Sexual y Procreación Responsable, Dec.Reg. 1282/2003.

<sup>15</sup> Ley 26.130 de octubre del año 2006 disponible en <http://infoleg.mecon.gov.ar/infolegInternet/anexos/115000-119999/119260/norma.htm> (consultada el 20 de febrero de 2014).

<sup>16</sup> Ministerio de Salud de la Nación, Resolución Ministerial 203/07.

<sup>17</sup> Ley 26.150, octubre 2006 disponible en <http://www1.hcdn.gov.ar/dependencias/ceduccion/ley26150.htm> (consultada el 20 de febrero de 2014)

<sup>18</sup> Ley 26.485 sancionada el 11 de marzo de 2009. Ley de protección integral para prevenir, sancionar y erradicar la violencia contra las mujeres en los ámbitos en que desarrollen sus relaciones interpersonales disponible en <http://www.infoleg.gov.ar/infolegInternet/anexos/150000-154999/152155/norma.htm> (consultada el 15 de febrero de 2014).

<sup>19</sup> CSJN "F.AL, s /medidas autosatisfactivas" (F.259 XLVI) sentencia del 13 de marzo del 2012.

<sup>20</sup> Ley 26.862 sancionada el 5 de junio de 2013 disponible en

#### 4. Derechos de las personas en situación de vulnerabilidad

Ha habido un amplio abanico de disposiciones de protección de personas en situación de vulnerabilidad pero, en el contexto de esta breve síntesis, destacamos a nivel normativo: la ya mencionada Ley de Protección Integral de las Mujeres contra la Violencia y la Ley 26.364<sup>21</sup> -y su modificatoria Ley 26.842<sup>22</sup>- de Prevención y Sanción contra la Trata de Personas y Asistencia a sus Víctimas.

No podemos dejar de mencionar la Ley 26.061 de Protección Integral de Niñas, Niños y Adolescentes<sup>23</sup>, que consagra los principios de interés superior de niño y participación del niño en las decisiones sobre temas que lo involucran conforme el principio de desarrollo progresivo, lo cual impacta en la consideración de su competencia frente a las decisiones sobre su cuerpo.

Otra disposición trascendente es la Ley 26.529 sobre Derechos de los Pacientes<sup>24</sup> la cual consagra de manera definitiva el cambio de paradigma del modelo de beneficencia, paternalista, a un modelo de autonomía más propio de un Estado Constitucional de Derecho

<http://www.infoleg.gov.ar/infolegInternet/anexos/215000-219999/216700/norma.htm> (consultada el 15 de febrero de 2014).

<sup>21</sup> Ley 26.364 disponible en

<http://www.infoleg.gov.ar/infolegInternet/anexos/140000-144999/140100/norma.htm> (consultada el 16 de febrero de 2014).

<sup>22</sup> Ley 26.842 disponible en

<http://infoleg.mecon.gov.ar/infolegInternet/anexos/205000-209999/206554/norma.htm> (consultada el 16 de febrero de 2014).

<sup>23</sup> Ley 26.061 disponible en

<http://infoleg.mecon.gov.ar/infolegInternet/anexos/110000-114999/110778/norma.htm> (consultada el 20 de febrero).

<sup>24</sup> Ley 26.529 de Derechos de los Pacientes en Relación con los Profesionales e Instituciones de la Salud, promulgada el 19 de noviembre de 2009.

y su modificatoria, Ley 26.742<sup>25</sup>, llamada de "Muerte Digna", que reconoce de manera explícita la autonomía de los pacientes para decidir sobre cuestiones al final de la vida: ya sea aceptar o rechazar tratamientos médicos incluidos los de soporte vital (comprendiendo hidratación y alimentación), dejar directivas anticipadas de tratamiento y nombrar alguien que lo represente o subrogue en la toma de decisiones médicas.

Las normas mencionadas se han destacado por el amplio debate social que suscitó su propuesta y posterior aprobación.

#### 5. Desarrollos en biotecnologías

La Argentina es uno de los países líderes en la utilización de cultivos genéticamente modificados (GM), con más de 22 millones de hectáreas dedicadas a los cultivos de soja, maíz y algodón que utilizan este tipo de tecnologías<sup>26</sup>. Desde 1991, la Argentina regula las actividades relacionadas con organismos genéticamente modificados (OGM) de uso agropecuario a través de la Comisión Nacional Asesora de Biotecnología Agropecuaria (CONABIA)<sup>27</sup> como instancia de evaluación y consulta, en el ámbito de la Secretaría de Agricultura, Ganadería y Pesca. La CONABIA está constituida por representantes del sector público y privado involucrados en la biotecnología agropecuaria, su el objetivo de esta evaluación es garantizar la bioseguridad del

<sup>25</sup> Ley 26.742 disponible en

<http://www.infoleg.gov.ar/infolegInternet/verNorma.do?id=197859> (consultada el 20 de febrero 2014)

<sup>26</sup> TRIGO, Eduardo. *Quince años de cultivos genéticamente modificados en Argentina*, ArgenBio, Buenos Aires, 2011 disponible en [http://www.argenbio.org/adc/uploads/15\\_anos\\_Estudio\\_de\\_cultivos\\_GM\\_en\\_Argentina.pdf](http://www.argenbio.org/adc/uploads/15_anos_Estudio_de_cultivos_GM_en_Argentina.pdf) (consultado el 15 de marzo de 2014).

<sup>27</sup> CONABIA, resolución 124/91.

agroecosistema. De las numerosas áreas de investigación y desarrollo vale destacar la llamada “Granja Farmacológica”, que tiene por objetivo producir proteínas recombinantes en animales de granja en vez de en biorreactores o fermentadores industriales<sup>28</sup>. Los primeros trabajos de clonación en mamíferos tuvieron lugar alrededor de 1994 en el Instituto de Biología y Medicina Experimental (IByME)<sup>29</sup> y actualmente existe una nutrida agenda de investigación y desarrollo relevante para la innovación en varios sectores tecno-productivos clave, tanto públicos como privados, en la producción ganadera, la producción de drogas biogénicas en el sector farmacéutico y la medicina regenerativa. En la Argentina se han producido terneras clonadas y transgénicas cuya leche contiene insulina (ternera Patagonia<sup>30</sup>), hormona del crecimiento (ternera Pampa y ternero Pampero<sup>31</sup>), leche maternizada (ternera Rosita<sup>32</sup>); así como vacas, cabras, toros y caballos de polo clonados<sup>33</sup>.

<sup>28</sup> *¿Por qué Biotecnología? Animales como fábricas de moléculas*. Cuaderno 47, ArgenBio disponible en <http://www.porquebiotecnologia.com.ar/index.php?action=cuaderno&opt=5&tipo=1&note=47> (consultada el 15 de febrero de 2014).

<sup>29</sup> “La clonación de animales en Argentina y Brasil” noticia del 21 de enero de 2010. Argenpress. Disponible en <http://www.argenpress.info/2010/01/la-clonacion-de-animales-en-argentina-y.html> consultada el 16 de febrero de 2014.

<sup>30</sup> “Crean vacas capaces de producir insulina” noticia del 14 de abril del 2007, Intramed, disponible en <http://www.intramed.net/contenidover.asp?contenidoID=46122> consultada el 16 de febrero de 2014.

<sup>31</sup> “Bio Sidus: Pampero, primer macho transgénico, perpetuador del tambo Farmacéutico” <http://www.premioseikon.com/?bio-sidus-pampero-primero-macho-transgenico-perpetuador-del-tambo-farmacutico&page=ampliada&id=388&s&page=tags> (consultada el 16 de febrero de 2014).

<sup>32</sup> “Rosita produce leche maternizada” Inta informa, noticia del 7 de febrero de 2012 disponible en

Asimismo se ha realizado una fuerte inversión en el desarrollo del Programa Educativo “¿Por qué Biotecnologías?” de ArgenBio - Consejo Argentino para la Información y el Desarrollo de la Biotecnología - que mediante su plataforma web ofrece material para capacitación de docentes, información al público en general y documentos de divulgación científica sobre lo que son las biotecnologías y su impacto social.<sup>34</sup>

#### 6. Apoyo al Desarrollo en Ciencia y Tecnología

En el año 1996 se creó mediante el decreto 1660/96 la Agencia Nacional de Promoción Científica y Tecnológica (ANPCyT)<sup>35</sup>, un organismo nacional dependiente del Ministerio de Ciencia, Tecnología e Innovación Productiva, dedicado a promover el financiamiento de proyectos tendientes a mejorar las condiciones sociales, económicas y culturales en la Argentina. Las líneas de financiamiento cubren una amplia variedad de destinatarios desde científicos dedicados a investigación básica, hasta empresas interesadas en mejorar su competitividad a partir de la innovación

<http://intainforma.inta.gov.ar/?p=11838> (consultada el 16 de febrero de 2014).

<sup>33</sup> “Ñandubay, primer caballo clonado en Argentina” Clarín/Sociedad [http://www.clarin.com/sociedad/Presentaron-Nandubay-caballo-clonado-Argentina\\_0\\_356964378.html](http://www.clarin.com/sociedad/Presentaron-Nandubay-caballo-clonado-Argentina_0_356964378.html) (consultada el 16 de febrero 2014); “Nació Silvina Luna, primera yegua de polo clonada en el país”, <http://www.cronista.com/negocios/-Nacio-Silvina-Luna-la-primera-yegua-de-polo-clonada-en-el-pais-20131219-0010.html> (consultada el 20 de febrero de 2014).

<sup>34</sup> <http://www.porquebiotecnologia.com.ar/index.php?action=acerca&opt=2>.

<sup>35</sup> <http://www.agencia.mincyt.gob.ar/upload/Creacion-de-la-Agencia-Dec1660-96-Poder-Ejecutivo-Nacional.pdf>.

tecnológica<sup>36</sup>. La Agencia, a través de sus cuatro fondos (FONCyT, FONTAR, FONSOFT y FONARSEC) financia proyectos de innovación tecnológica y productiva orientados a diferentes tipos de públicos, entre ellos: emprendedores, becarios, personas físicas, profesionales, investigadores, instituciones y empresas. Asimismo se coordinan programas de transferencia tecnológica de las universidades públicas hacia el medio regional en el que están insertas, teniendo en cuenta los núcleos socio-productivos estratégicos. Dos de los recientes proyectos exitosos fueron: lograr una vacuna contra el cáncer de pulmón<sup>37</sup> así como el desarrollo de un software para la detección de hidrocarburos<sup>38</sup>.

### Colofón

Las relaciones entre las Ciencias y el Derecho pueden ser leídas desde muchas perspectivas, siempre teniendo en consideración que las ciencias biológicas también son tributarias de una historia, sesgos de género y clase, tensiones y relaciones de poder, prejuicios y cuestiones varias. Un error común del Derecho es haber tomado de manera acrítica los postulados o construcciones de la Medicina y la Biología como “neutros” u “objetivos” sin contextualizar y sobre todo, cuestionar desde qué criterios o parámetros se ha producido un determinado conocimiento (por ejemplo aquellos estudios

sobre las “hormonas sexuales” o los “genes sexuales”<sup>39</sup>)

En este sentido, la interrelación dinámica y permanente entre Bioética y Derechos Humanos, inclusiva de la perspectiva de género, ofrece el piso normativo de un moral común (aquella que responda a las exigencias de una sociedad democrática, por ende plural y respetuosa de las diversidades) y herramientas concretas para plantear respuestas a interrogantes complejos en sociedades multiculturales.

<sup>36</sup> <http://www.agencia.mincyt.gob.ar/#>.

<sup>37</sup> “Desarrollo argentino de una vacuna contra la cáncer de pulmón”, <http://www.agencia.mincyt.gob.ar/frontend/agencia/post/1217> (consultada el 24 de febrero de 2014)

<sup>38</sup> “Desarrollo de un software para detección de hidrocarburos”, <http://www.agencia.mincyt.gob.ar/frontend/agencia/post/1255> (consultada el 24 de febrero de 2014).

<sup>39</sup> Ilustra esta posición lo sostenido por FAUSTO-STERLING, Ann. *Sexing the body. Gender politics and the construction of sexuality*, New York, Basic Books, 2000.



## Brazil

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In Brazil, from my standpoint, there are three important questions which influence the relationship between law and life sciences: the religious profile of the population, the composition of the Parliament and the judicialization of politics. These three issues are also intimately related.

According to the latest census, held in 2010, the Brazilian population is composed by 64.6% of catholics and 22.2% of evangelicals. Over the last decades, there has been a considerable growth of evangelical religions, but we are still the largest catholic nation in the world. It is also true that the number of people with no religion has increased. However, 86.8% of Brazilians are Christians. This has a strong impact on the legal debate over matters of life and death.

As a reflex of these populational data, the evangelical representation in the National Congress has grown from 36 representatives in the 2006 legislature, to 73 elect representatives in 2010. The increase of over 100% bolstered their ability to articulate and negotiate their interests in the National Congress. That meant the House of Representatives' Human Rights and Minorities Committee ended up being presided, in 2013, by a pastor from Partido Social Cristão (Christian Social Party), who stood clearly against gay rights.

The composition of Brazilian Congress, in addition to the naturally morose decision process of a democratic parliament and the generosity of the Brazilian Constitution towards the fundamental rights, particularly social rights, have all contributed for the debate on the rights of the

individual to move from the Legislative to the Judicial Branch<sup>1</sup>.

Three frequent situations have been witnessed: a) the minorities cannot find the protection of their rights in the political struggle inside the Parliament, so their demands are judicialized, stimulating the counter-majority function of the Judicial Branch; b) the conservative political forces are defeated in the Parliament and, due to the wide array of those who are legitimately able to submit controversial issues to the Federal Supreme Court (article 103 of the Federal Constitution), the issue is also judicialized; c) a right, even constitutionally granted, is not effectively protected by public policies implemented by the State, so the demands are also taken to the Judicial Branch.

In the field of life sciences, there are in Brazil examples of these three situations.

The Brazilian Penal Code, from 1940, allows the interruption of pregnancy where there is risk to the mother's life, or for pregnancies caused by rape. Nevertheless, in the past decades, there has been no advancement in the discussion in the Parliament over broadening the reach of the abortion decriminalization. Frequent fetal malformation cases used to be taken to the Judicial Branch, seeking permission to interrupt pregnancy. Some judges granted the request, while others had a different interpretation, since the law did not provide for such hypothe-

<sup>1</sup> Obviously, these are not the only factors which have been contributing for the increase of judicialization of politics in Brazil. For a broader view on the issue, among several other works on the topic, refer to: Cittadino, Gisele. "Judicialização da política, constitucionalismo democrático e separação de poderes", in Vianna, Luiz Werneck. *A democracia e os três poderes no Brasil*. Rio de Janeiro: IUPERJ/FAPERJ, 2002, p. 17 a 42; e Vieira, Oscar Vilhena. "Supremocracia", *Revista Direito GV*, São Paulo 4 (2), p. 441-462, jul-dez 2008 (<http://www.scielo.br/pdf/rdgv/v4n2/a05v4n2.pdf>).

sis. This went on until the matter reached the Federal Supreme Court, which, in 2012, by a majority of votes, decided that Brazil – a secular republic which must be neutral towards religions – did not criminalize the interruption of pregnancy for anencephalic fetuses, considering women’s sexual and reproductive freedom, as well as the protection of their health, dignity and self-determination<sup>2</sup>.

In 2005 the Biosafety Law<sup>3</sup> was issued, granting in its article 5, the possibility, for research and therapeutical purposes, of the use of embryo stem cells obtained from in-vitro fertilized human embryos not used in the respective procedure, provided there was compliance with the law<sup>4</sup>. When questioned about the constitutionality of such legal provision, in 2008, the Federal Supreme Court understood that, in such case, there was no violation of the right to life. The use of embryo stem cells in scientific research for therapeutic ends was in compliance to the Federal Constitution, thus not characterizing practice of abortion. Furthermore, the law in such case protected the fundamental right to a

life with dignity, which entails the right to health and family planning<sup>5</sup>.

Finally, over the past decades in Brazil, there has been a great effort in order to safeguard the effectiveness of social rights, particularly the right to health. Such effort, which has as its big strategy the judicialisation of demands related to the supply of medicine, was fruitful. On the other hand, it has generated a series of problems such as, for instance, the imbalance of government budgets and the disorganization of Public Administration, without, paradoxically, contributing to the reduction of social inequalities<sup>6</sup>.

These are important issues, relating law to life sciences in Brazil, but there is much progress to be made in the discussion about this relationship. And a debate which tends to rise in the following years is the one on euthanasia, still in its embryonic stage in Brazil.

<sup>2</sup> Federal Supreme Court – ADPF (Arguição de Descumprimento de Preceito Fundamental) nbr. 54, Rapporteur Minister Marco A. Mello, trial date: 12/Apr/2012

(<http://redir.stf.jus.br/paginadorpub/paginador.jsp?docTP=TP&docID=3707334>).

<sup>3</sup> Law 11,105 of March 24th, 2005: ([http://www.planalto.gov.br/ccivil\\_03/\\_ato2004-2006/2005/lei/l11105.htm](http://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/lei/l11105.htm))

<sup>4</sup> Article 5 reads: “For research and therapy purposes, the use of embryonic stem cells obtained from human embryos produced by in vitro fertilization and not used in the respective procedure shall be allowed under the following conditions: I – they are inviable embryos; or II – they are embryos frozen 3 (three) or more years ago, at the date of the publication of this Law, or if already frozen at the time of the publication of the Law, at the end of 3 (three) years, starting from the date of freezing.”

<sup>5</sup> Federal Supreme Court, ADI (Ação Direta de Inconstitucionalidade) nbr. 3,510, Rapporteur Minister Carlos Ayres Britto, trial date 29/May/2008 (<http://redir.stf.jus.br/paginadorpub/paginador.jsp?docTP=AC&docID=611723>).

<sup>6</sup> On this issue, see, for instance, Dias, Roberto. “O que os juristas e o Judiciário têm a dizer sobre saúde pública”, Sundfeld, Carlos Ari; Rosilho, André. *Direito da regulação e políticas públicas*, São Paulo: Malheiros, 2014, p. 296-313.