Defining Health Law or the *Edgewood syndrome*

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"The study of health law presents a unique opportunity to apply law and legal analysis to an industry that dramatically affects our lives, is undergoing tremendous change, and is filled with challenges that the thoughtful application of law can help us to meet constructively. Few fields of applied law match the richness of health law."

(Annas *et al*. 1990. *xxxi*)

The authors' main purpose is to present ideas on defining Health Law by highlighting the particularities of the field of Health Law as well as of the teaching of this legal branch, hoping to contribute to the maturity and academic recognition of Health Law, not only as a very rich legal field but also as a powerful social instrument in the fulfillment of fundamental human rights. The authors defend that Health Law has several characteristics that distinguish it from traditional branches of law such as its complexity and multidisciplinary nature. The study of Health Law normally covers issues such as access to care, health systems organization, patients' rights, health professionals' rights and duties, strict liability, healthcare contracts between institutions and professionals, medical data protection and confidentiality, informed consent and professional secrecy, crossing different legal fields including administrative, antitrust, constitutional, contract, corporate, criminal, environmental, food and drug, intellectual property, insurance, international and supranational, labor/employment, property, taxation, and tort law. This is one of the reasons why teaching Health Law presents a challenge to the teacher, which will have to find the programs, content and methods appropriate to the profile of recipients which are normally non jurists and the needs of a multidisciplinary curricula.

By describing academic definitions of Health Law as analogous to *Edgewood,* a fiction house which has a different architectural style in each of its walls, the authors try to describe which elements should compose a more comprehensive definition. In this article Biolaw, Bioethics and Human Rights are defined as complements to a definition of Health Law: Biolaw because it is the legal field that treats the social consequences that arise from technological advances in health and life sciences; Bioethics which evolutions normally influence the shape of the legal framework of Health; and, finally Human Rights theory and declarations are outlined as having always been historically linked to medicine and health, being the umbrella that must cover all the issues raised in the area of Health Law.

To complete this brief incursion on the definition on Health Law the authors end by giving note of the complex relations between this field of Law and Public Health. Dealing more specifically on laws adopted by governments

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to provide important health services and regulate industries and individual conduct that affect the health of the populations, this aspect of Health Law requires special attention to avoid an imbalance between public powers and individual freedoms.

The authors conclude that public trust in any health system is essentially sustained by developing health structures which are consistent with essential fundamental rights, such as the universal right to access health care, and that the study of Health Law can contribute with important insights into both health structures and fundamental rights in order to foster a health system that respects the Rule of Law.

Keywords: Health Law; Bioethics; Biolaw; Human Rights; access to health care; Public Health Law.

Introduction

This article presents ideas on defining Health Law from three senior Health Law teachers. Although separated by the Atlantic Ocean these three authors have in common the uncommon experience of teaching Law in a post graduate institution not of law but of public health[1]. Teaching health professionals about law requires becoming "translational" lawyers, who can provide health professionals with significant juridical and legal knowledge and offer relevant subjects in health affairs to keep the teaching content meaningful and alive, all the while remaining sensitive to several interdisciplinary idiosyncrasies, including the often ingrained perspective of their own legal education.

In the next paragraphs the authors will try to highlight not only the particularities of the field of Health Law but also of the teaching of this legal branch. These perspectives, based on many years of experience, will, they hope, contribute to the maturity and academic recognition of Health Law, not only as an autonomous legal field but also as a powerful social instrument in the fulfillment of fundamental human rights, such as the *right to a standard of living adequate for the health and well-being of himself and of his family, including medical care*, which is inscribed in article 25 of the Universal Declaration of Human Rights (United Nations, 1948).

[1] The present paper also testifies to the continuity of the collaboration between the Portuguese ENSP and the Department of Health Law, Bioethics & Human Rights of BUSPH, started in 2004 and already solidified in two books gathering the scientific work developed in the two first "Biennial Seminars in Health Law and Bioethics", which have allowed the possibility to build scientific bridges between North American, Portuguese universities and other European high education institutions and professionals in the fields of Health Law and Bioethics.

Health Law is a legal discipline, but several features distinguish it from traditional branches of law. It cuts across various branches of law (Constitutional Law, Civil Law, Administrative Law, Criminal Law, and Information Law, amongst others) and applies their principles to subjects in quite different branches of knowledge, e.g. Biology, Medicine, Genetics, Philosophy and Ethics. In addition, those who teach outside the typical law school must address the needs of a very different audience, usually consisting of professionals and very rarely by students at the undergraduate level. The characteristics described give the teaching of Health Law a complexity that presents a challenge to the teacher, who has to find the programs and pedagogical methodologies appropriate to the profile of recipients and the needs of multidisciplinary areas.

Although Health Law has been studied and taught in the United States for more than 50 years, it is a more recent addition to academics in Portugal. Only in the last ten years have Portuguese universities begun to include in their *curricula* the study of the legal aspects related to health care and biomedicine. There are still few Portuguese academics in this area and a small number of court decisions, particularly compared with the US, leaving both doctrine and law underdeveloped. A more robust curriculum in Health Law is needed to respond to the needs of Portuguese jurists and the health professionals.

1. Inside the *Edgewood syndrome* or what is Health Law?

> "Law and medicine are separate professions, and attorneys and physicians often see their professions in conflict. There are, however, more similarities than differences between the two professions. And there are areas of mutual concern and overlap that demand the application of both legal and medical knowledge for the good of society. These areas have historically been united under the broader term of *health law*."
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> (Sanbar *et al.* 2004. 3)

Those who attempt to define Health Law often experience what we might call the *Edgewood syndrome*. *Edgewood* was a fictional house described in John Crowley's fantasy novel, *Little, Big* (Crowley, 2006). Built by a fictional architect in 1894, the house pieced together several Victorian architectural styles — Italianate villa, Tudor manor house, neo-classical, country cottage. Yet, these could not be seen simultaneously; an observer could

see only one façade at a time from any vantage point. One of the authors of this article has described academic definitions of Health Law as analogous to viewing *Edgewood* from separate vantage points (Mariner, 2009). Some authors emphasize a specific area of Health Law[2], without discussing or recognizing the whole. For example, some authors identify Health Law with legal problems of the medical profession, health care and the biomedicine developments. This aspect is the more traditional part of the Health Law, composed of the juridical tools (legislation, doctrine, and jurisprudence) that apply mainly to the health care act and settings. This part is sometimes called by other names such as "Medical Law"[3], "Health Care Law" or "Biomedical Law" and is often used for audiences composed of physicians, as was the description quoted supra. Nevertheless, these last terms always evoke a narrower scope than Health Law has come to encompass. The study and teaching of Health Law normally covers issues such as access to care, health systems organization, patients' rights, health professionals' rights and duties, strict liability, healthcare contracts between institutions and professionals, medical data protection and confidentiality, informed consent and professional secrecy (Auby, 1981; Annas *et al.,* 1990, Faria 2007).

A more modern and accurate definition of Health Law attempts to avoid the *Edgewood* syndrome by being more comprehensive. This presents a difficult challenge because of the growing number of legal issues that the field now covers. These include aspects of administrative, antitrust, constitutional, contract, corporate, criminal, environmental, food and drug, intellectual property, insurance, international, labor/employment, property, taxation, and tort law (Mariner, 2009). It is especially challenging for the teacher, who must master all the law that could be relevant to health issues. Acquiring the requisite breadth risks missing the depth of knowledge needed to appreciate and convey fundamental principles of law or important facts about medicine, economics, finance, and administration, for example. But the difficulty of mastering the field does not make mastery any less necessary. Instead, it suggests that the qualifications for teaching the subject should remain rigorous enough to ensure that the field is well understood and well taught.

One solution to the breadth problem is to limit oneself to one aspect of Health Law. This is already common practice not only among professors, but also among practising jurists. Thus, one can subspecialize in one area of Health Law, while simultaneously recognizing that the field of Health Law is much broader.

A different challenge to defining Health Law lays in the content of the jurisprudence that Health Law claims as its own. One of us has argued that "the doctrines and principles grounded in other legal domains have come to apply to health problems with less and less special adaptation to the particular circumstances of the medical profession or the physician-patient relationship. Doctrines look less like unique rules for health than relatively straightforward applications of principles of contract, tort, administrative law, or insurance, for example" (Mariner, 2009). It is somewhat paradoxical that as Health Law became established in the United States as a unique field of law dedicated to health matters, the juridical and legislative doctrines it used became unmoored from the health care context. As Health Law grew from a narrow field of medical jurisprudence to the broader field encompassing professional, financial and civic relationships among patients, government, health providers, and financing institutions, its jurisprudence began to look increasingly like more general principles outside the health context. The doctrine of informed consent, for example, developed because of the needs of patients for information from a physician with specialized knowledge, yet it applies principles of autonomy and self-determination which reserve to the individual the right to make her own decisions, even about medical treatment (Annas, 2004). Scientific advances and changes in the way health care is organized and financed also contributed to the development of Health Law principles (Mariner, 1988). Many laws that had not seemed relevant to the physician-patient relationship have strongly influenced how medicine is practised, as well as access to health care[4].

[2] See generally George J. Annas, Health law at the turn of the century: from White Dwarf to Red Giant (1989) [hereinafter White Dwarf]; M. Gregg Bloche, The invention of health law (2003); Henry T. Greeley, Some thoughts on academic health law (2006); Mark A. Hall, The history and future of health law: an essentialist view (2006) [hereinafter Essentialist View]; Rand E. Rosenblatt, The four ages of health law (2004); S. Sandy Sanbar et al., Legal medicine and health law education. In S. Sandy Sanbar et al., ed. lit., Legal medicine (2007); Walter Wadlington, Some reflections on teaching law and medicine in law school since the '60s (2004).

[3] *E.g.* the Jonathan Montgomery, Health care law (2003) and the French classical Gérard Mémeteau, Cours de droit médical (2003) show very similar contents.

[4] See generally Group Life & Health Insurance Co. v. Royal Drug Co., Inc., 440 U.S. 205 (1979) (applying Sherman Act to Blue Cross); Jefferson Parish Hospital District No. 2 v. Hyde, 466 U.S. 2 (1984) (applying Sherman Act to insurer); Darling v. Charleston Community Memorial Hospital, 33 Ill.2d 326, 211 N.E.2d 253 (1965), cert. denied, 383 U.S. 946 (1966) (applying corporate liability for negligence to hospital).

Nevertheless, it remains important to recognize when and how many of these principles and doctrines are modified to fit the particular circumstances of health problems[5].

2. Biolaw, Bioethics and Human Rights (3 more pieces to the Health Law defining puzzle)

As a complement to a definition of Health Law, it becomes nowadays necessary to mention the more recent term Biolaw[6], as the legal field that treats the social consequences that arise from technological development (Neirinck, 1994). Scientific advances or any revolutionary new technique in peoples' lives have always had strong repercussions in the Law. The industrial revolution led to civil strict liability; the automobile created the concept of mandatory insurance; photography gave forth the right to one's image; the development of the press made it necessary to invent a right to privacy; the use of computers led to data protection laws and to the right to informational self-determination (Faria, 2003).

During the last years recent developments in the areas of Medicine and Biology seem to have created an even greater challenge for Law, challenging some of its traditional fundamental concepts, such as the classical dichotomies between "persons" and "things" (*e.g.* in which category should we place DNA?); women and men (*e.g.* difficulties on the civil status of transsexuals); motherhood (*e.g.* where to place "surrogate" mothers); life and death (*e.g.* today's reanimation devices allow the prolonging of life into states of vegetative life which don't differ much from death and transplantation symbolically continues the "life" of deceased donors) (Faria, 2006).

In a world where science and biomedicine manipulate living creatures and transform them, Biolaw aims at regulating these actions, allowing some and forbidding others, with or without sanctions. This concept is usually linked to Bioethics as we may read in the following Judith Miller's definition in which Biolaw is the taking of agreed upon principles and practices of bioethics into law with the sanctions that law engenders, including legislation on bioethical issues, interpretation of such legislation and case law made by judges (Miller, 2000).

In addition, Biolaw requires its academics to develop a knowledge based not only in legal concepts and theory but also in scientific ones, and sometimes dealing even with hypothetical situations that approach the predictions of science fiction (e.g. nanomedicine, cyborgs, stem cells promises, reproductive cloning) making this new legal territory also the confluence between the real and mere conjecture. This requires from the lawyer who moves in this field the capability to distinguish the true extent of the situations to deal with. We find an example of this statement in the case of reproductive cloning of humans, which, despite having already a normative framework that provides a ban by the international community[7] (Council of Europe, 1998) never took place in practice and therefore no certainty exists regarding its viability.

On top of this, one of the features that involve the typical situations of Biolaw scope of action is that these areas are very touchy and dear to humans, implying a high level of emotion and therefore becoming desirable as instruments of political manipulation, when necessary. In the U.S., many bioethical issues have served to fuel political factions, keep jobs and win or lose elections (Nichols *et al*., 2005). Knowing that, deep down, these situations are inherently a medical and private issue of those who are directly involved, the emotions generated in the society during the course of such conflicts are so strong that political organizations cannot resist trying to pull something out of them. Sometimes, however, a political attitude less skilled in such situations can generate a negative effect with serious repercussions for the party seconded.

A very concrete example of such a situation (2005) in which a Biolaw case led to change the political chess game of a country is the case of Mehmet Yildiz, a boy of 7 years who needed a bone marrow transplant, which was intended could be done by collecting a future Mehmet's brother, conceived through assisted reproduction to allow preimplantation diagnosis (Solbakk, 2005). The difficulties that Norwegian law put to the achievement of this medical procedure in the Mehmet case got the massive interest of the *media,* managing to move the entire community. Under pressure from an independent committee of experts in bioethics and biolaw called to give its opinion, the Norwegian legislation on biotechnology — *Norwegian Act on Biotechnologies* — (Norwegian Parliament, 1994), was modified so that the preimplantation diagnosis was allowed for cases like the Mehmet one. However, the expert committee in

[5] See generally Alberts v. Devine, 395 Mass. 59 (1985) (physician's duty of confidentiality).

[6] The term was first used by the North-American review Bio-Law (1986) and is later used in the title of a French book in 1993 ("De la Bioéthique au Bio-Droit", under the direction of Claire Neirinck (1994). In Portugal the term "Biodireito" is already a well known terminology in the academic field of Health Law.

question, because it decided contrary to the opinion of the minister of health in office, was dismissed following this and replaced by new members. This was clearly condemned by public opinion and contributed to the fall of the political party in question in the next elections. According to the Norwegian bioethicist Helge Jan Solbakk that was part of the committee of experts that was dismissed, in this type of situation there are only two possibilities regarding the political dimension of Biolaw: 1) the "politicization" of the bioethics that feeds it, which would be the end of the neutrality of the same and its consequent scientific corruption or 2) a desirable "ethicization" of biopolitics (Solbakk, 2005).

Some authors complain that there is a growing sense that scientific research, which, in the end, is defined by the quest for truth may be manipulated for political ends (Blackburn, 2004). This manipulation can be triggered by an adulteration of the debate within Biolaw if ethics and impartiality of the legal proceedings are replaced by political or economic interests. It is up to us, lawyers and academics who work in this new area of law to be aware of this and other threats to scientific neutrality, engaging in an activity of knowledge of the situation at hand, in a dispassionate and impartial manner, guided by principles and parameters that favour the primacy of justice, autonomy and equality of human beings (Faria, 2007).

The transformation of Bioethics in Biolaw is, though, not an easy task. Biolaw must first of all be adaptable to the future developments of scientific knowledge that is always evolving and so its norms must be flexible or they risk becoming soon obsolete. And, secondly, it has to reflect the consensus of society and the scientific community or it may create conflicts capable of jeopardizing the applicability of its norms. As a classic example of the difficulties that surround the making of "bio-norms" we can quote the French "*Lois Bioéthiques*" (Lois Bioéthiques, 1994), the first version of which dates from July 1994, but have been preceded by approximately 10 years of public debate including five exhaustive ministerial reports (Braibant, 1988; Lenoir, 1991; Sérusclat, 1992; Bioulac, 1992; Mattei, 1993).

In Portugal the debate over a legal framework for medically assisted reproduction took 20 years as the first steps on the regulation of this subject date from 1986 and only in 2006 the law was approved and published, even if some controversial issues still remain unsolved[7].

For what concerns "Bioethics", although the identification of its genesis may differ amongst the doctrine[8], it is consensual that it started to be considered[9] as a kind of ethics that would include not only our obligations to other human beings but to the biosphere as a whole such as Van Rensselaer Potter coined it in his famed book *Bioethics: bridge to the future* (Potter, 1971). Later in 1988, Potter presented a definition of Bioethics on the cover of another book (*Global Bioethics*) as "Biology combined with diverse humanistic knowledge forging a science that sets a system of medical and environmental priorities for acceptable survival" (Potter, 1988).

The concept evolved and in 1995 the *Encyclopedia of Bioethics* (Jonsen, 1998. 1) defined it as the "systematic study of the moral dimensions — including moral vision, decisions, conduct, and policies — of the life sciences and health care, employing a variety of ethical methodologies in an interdisciplinary setting." Moral dilemmas linked to abortion, suspension of artificially supported life, surrogate motherhood, conception of children for the purpose of bone marrow donation and more recently reproductive cloning and the use of human stem cells in animal embryo are examples of bioethics typical issues.

Nevertheless, it is almost impossible to define which is the exact content of Bioethics (Silva, 2002) its boundaries tending to become wider every day. In this sense the recent UNESCO "Universal Declaration of Bioethics and Human Rights", approved in 19th of October 2005 (UNESCO, 2005) shows how Bioethics has again enlarged its scope almost returning to its primitive "ecological" dimension, assertion that can be testified by the following articles of the mentioned declaration:

- Article 16 ("Protecting Future Generations") mentions that "the impact of life sciences on future generations, including on their genetic constitution, should be given due regard" and;
- Article 17 ("Protection of the Environment, the Biosphere and Biodiversity") states that "due regard is to be given to the interconnection between human beings and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to the respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity."

[7] Such as the controversy on single mothers or homosexual couples rights to medically assisted procreation which are denied in the law (see Lei nº 32/2006).

[8] See for a different perspective G.J. Annas, American Bioethics: crossing human rights and health boundaries (2005).

[9] For the same interpretation see Bioethics : an antology (Kuhse, H.; Singer. P., 2001) 1.

Bioethics is, as already mentioned before, intrinsically linked to Health Law and as such, the evolutions in this field normally influence the shape of the legal framework in all the overlapping areas of these two connecting fields.

Finally, Human Rights theory and declarations have always been historically linked to medicine and health (the 1948 Nuremberg trials and Code), and the introduction of Human Rights side by side with Health Law and Bioethics is based on the idea that "in our increasingly globalized world, human rights will become the umbrella field under which the work done by both American bioethics and American health law will be linked and furthered" (Annas, 2005. *xv*).

Human Rights have also influenced the movements that lead to establish Patients Rights as a fundamental piece of contemporary Health Law (Annas, 2004) and they are also the cornerstone of the 1997 Council of Europe Convention for the protection of Human Rights in Biomedicine, so called *Oviedo Convention* (Council of Europe, 1997) and more recently to the already mentioned 2005 UNESCO Universal Declaration on Bioethics and Human Rights (UNESCO, 2005).

However, the *Oviedo Convention* will always be remembered as the first international normative text to have linked so undoubtedly Human Rights to Health Law[10] and it is therefore never too much to remember its fundamental principles:

- The interests and welfare of the human being shall prevail over the sole interest of society or science (art. 2);
- Equitable access to health care of appropriate quality (art. 3);
- Relevant professional obligations and standards for any intervention in the health field, including research (art. 4);
- Free and informed consent to any intervention in the health field (art. 5);
- The right to respect the private life of the patient in relation to information about his or her health (art. 10);
- Prohibition of any form of discrimination against a person on grounds of his or her genetic heritage (art. 11);
- Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling (art. 12);
- An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants (art. 13);
- Prohibition of selecting sex by medically assisted reproduction (art. 14);
- Scientific research in the field of biology and medicine shall be carried out ensuring the protection of the human being (art. 15);
- Adequate protection of the embryo shall be ensured when the law allows it (art. 16, 1);
- Prohibition of the creation of human embryos for research purposes (art. 16, 2);
- Removal of organs or tissue from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness. Necessary consent must have been given (art. 19,1);
- The human body and its parts shall not, as such, give rise to financial gain (art. 20);
- When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures (art. 21).

These principles are generally reflected in European Health Law and show how the spirit of Human Rights is present in this legal field, which is crucial in an area where the concepts of humanity and human dignity are always at stake.

3. Health Law and Public Health — in search of the perfect match

> "The world is accustomed to thinking of the law as an instrument of justice, but not as an instrument of health (…) It is time that the tools of law be harnessed in the service of global health and global justice."
>
> Blanke; Mitchell, 2002.67

Another aspect of the field of Health Law is public health, which addresses the power of government to prevent illness and injury and provide the infrastructure to promote health on a population basis

[10] In Portugal the Convention is part of the Law by the Presidential Decree (see Decreto do Presidente da República n.º 1/2001).

(Wing *et al*., 2007). Originally identified with preventing disease, public health includes matters of environmental protection, occupational health, and food and water safety, as well as epidemic. This aspect of Health Law focuses more specifically on laws adopted by governments to provide important health services and regulate industries and individual conduct that affect health. Of particular juridical concern in this area are laws that enhance or threaten human rights.

In the United States, after September 11, 2001, federal policy shifted the resources for public health law from essential tasks of providing public education and services to emergency preparedness. One consequence of this shift was a new emphasis on national security, bioterrorism, and personal responsibility (Mariner, Annas e Parmet, 2009). That approach has been criticized by health professionals as distracting from the primary mission of public health and ineffective in preventing harm from natural disasters or pandemic (Schoch-Spana, 2008). Moreover, effective emergency preparedness may depend more on everyday prevention and the availability of appropriate resources and planning than on laws specially designed for emergencies. The linkage of public health with national security has also been criticized by legal scholars, including two of the authors, for distorting fundamental principles of law and human rights. For example, some law proposals in the United States called for increasing government authority to involuntarily detain individuals without evidence of danger and to force them to undergo medical treatment, while reducing official accountability for error (Annas, 2002). Such proposals raise serious questions about whether emergencies can ever justify altering fundamental legal principles and rights. Current concerns about possible new influenza pandemics raise similar questions about the limits of government power and the extent of protections for human rights in Portugal and other countries.

There is a clear relationship between some traditional components of Health Law and the more recent problems of public health and emergency preparedness. Even in an emergency, most people turn first to physicians and hospitals as the most trusted sources of care and advice. Health Law addresses assuring the supply of hospitals, trained health professionals, clean water, food, safe medicines and equipment, and health care safety and quality, including important infection control practices. Access to regular medical care also keeps the population healthier and better able to survive an emergency (USA. Institute of Medicine, 2003a). There is substantial evidence that populations who lack access to care or health insurance coverage have higher risks of disability and death than the general population (USA. Institute of Medicine, 2001). Such disadvantaged groups may not be able to have their illness diagnosed, and if they have a contagious disease, could spread it to others unwittingly (USA. Institute of Medicine, 2003b; Williams, 2007). Moreover, terrorists may have little incentive to attack a healthy population that is able to survive and prosper (USA. Commission for the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, 2008). As several of us have argued, "expanding access to health care to the entire population [...] is the socioeconomic equivalent of vaccination against disease" (Mariner, Annas e Parmet, 2009; Glass e Schoch-Spana, 2002).

Final word

In conclusion, public trust in any health system is essentially sustained by developing health structures which are consistent with essential fundamental rights such as the universal right to access health care. The study of Health Law can contribute with important insights into both health structures and fundamental rights to foster a health system that respects the Rule of Law.

We hope this article has given to its readers the interest or at least the curiosity of reading further on the intricate relations between Law and Health, knowing that the soundness and the fairness of a health system or public health decisions depend on how well Governments manage to use powers within strict respect for fundamental rights and freedoms.

□ References

ANNAS, G. J. — American bioethics : crossing human rights and health boundaries. New York : Oxford University Press, 2005.

ANNAS, G. J. — Bioterrorism, public health, and civil liberties. *New England Journal of Medicine.* 346 : 17 (2002) 1337-1342.

ANNAS, G. J. — Health law at the turn of the century : from White Dwarf to Red Giant. *Connecticut Law Review*. 21 : 3 (1989) 551-569.

ANNAS, G. J. — The rights of patients. 3rd ed. New York : New York University Press, 2004.

ANNAS, G. J. *et al.* — American health law : preface. Philadelphia, Pennsylvania : Little, Brown and Company, 1990.

AUBY, J. M. — Droit de la santé. Paris : PUF, 1981.

BIOULAC, B. — Rapport d'information sur la bioéthique. Paris : Commission des Affaires Culturelles, Familiales et Sociales. Commission des Lois Constitutionnelles, de la Législation et de l'Administration Générale de la République, 1992.

BLACKBURN, E. — Bioethics and the political distortion of biomedical science : perspective. *New England Journal of Medicine*. 350 : 14 (April 1, 2004) 1379-1380.

BLANKE, D.; MITCHELL, W. — Towards health with justice : litigation and public inquiries as tools for tobacco control : report prepared for the Tobacco Free Initiative. Geneva : World Health Organization, 2002. 67.

BLOCHE, M. G. — The invention of health law. *California Law Review*. 91 : 2 (2003) 247-322.

BRAIBANT, G. — Aux sciences de la vie et aux droits de l'homme : de l'éthique au droit : rapport Braibant. [Em linha]. Paris : La Documentation Française, 1988. Rapport au Premier Ministre. [Consult. 15 Março 2009]. Disponível em http://infodoc.inserm.fr/inserm/ethique.nsf/9372385 20af658aec125704b002bded2/5456dc8838db5aadc12570a500515111/$FILE/Introduction.pdf.

COUNCIL OF EUROPE — Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings. Strasbourg : Council of Europe, 1998. [Consult. 30 Outubro 2009]. Disponível em http://conventions.coe.int/Treaty/en/Treaties/Word/168.doc.

COUNCIL OF EUROPE — Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine : Convention on Human Rights and Biomedicine, Oviedo, 4.IV.1997. Strasbourg : Council of Europe, 1997. [Consult. 15 Março 2009]. Disponível em http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm.

CROWLEY, J. — Little, Big. New York : Harper Perennial, 2006.

DECRETO DO PRESIDENTE DA REPÚBLICA n.º 1/2001. D.R. I.ª Série-A. 2 (2001-01-03) — 14 — Ratifica a Convenção para a Protecção dos Direitos do Homem e da Dignidade do Ser Humano face às Aplicações da Biologia e da Medicina: Convenção sobre os Direitos do Homem e a Biomedicina, aberta à assinatura dos Estados membros do Conselho da Europa em Oviedo, em 4 de Abril de 1997, e o Protocolo Adicional Que Proíbe a Clonagem de Seres Humanos, aberto à assinatura dos Estados membros em Paris, em 12 de Janeiro de 1998.

EMERGENCY PREPAREDNESS CONFERENCE, November 5-7 2007, Washington, DC — Vulnerable populations : emergency planning. [Em linha]. Baltimore : Centre for Health and Homeland Security. University of Maryland. McCormick Tribune Foundation, 2007. [Consult. 15 Março 2009]. Disponível em http://www.umaryland.edu/healthsecurity/mtf_conference.

FARIA, P. L, *et al.* — Health law and bioethics : a European perspective. In EUROPHAMILI — The European Management Training Course for Health Services Professionals. Rennes : École Nationale de la Santé Publique, 2003. 69-94.

FARIA, P. L. — 1st Biennial Seminar in Health Law and Bioethics on "The role of health law and bioethics and human rights to promote a safer and healthier world" : an introduction. In FARIA, P. L., ed. lit. — The role of health law and bioethics and human rights to promote a safer and healthier world. Lisboa : FLAD — Fundação Luso-Americana para o Desenvolvimento. ENSP-UNL, 2006. 9-26.

FARIA, P. L., ed. lit. — The role of health law and bioethics and human rights to promote a safer and healthier world. Lisboa : FLAD — Fundação Luso-Americana para o Desenvolvimento. ENSP-UNL, 2006. 9-26.

FARIA, P. L. — Biodireito : nas fronteiras da ciência, da ficção científica e da política. *Sub Judice*. 38 (2007) 9-13.

FARIA, P. L. — Ownership rights in research biobanks : do we need a new kind of "biological property"? In SOLBAKK, J. H.; HOLM, S.; HOFFMANN, B., ed. lit. — The ethics of research biobanking. Dordrecht : Springer, 2009. 263-277.

GLASS, T. A.; SCHOCH-SPANA, M. — Bioterrorism & the people : how to vaccinate a city against panic. *Clinical Infectious Diseases*. 34 : 2 (2002) 217-223.

GREELEY, H. T. — Some thoughts on academic health law. *Wake Forest Law Review*. 41 : 2 (2006) 391-409.

HALL, M. A. — The history and future of health law : an essentialist view. *Wake Forest Law Review*. 41 : 2 (2006) 347-364.

JONSEN, A. R. *et al*., ed. lit. — Source book in bioethics : a documentary history. Washington, DC : Georgetown University Press, 1998.

KUHSE, H.; SINGER, P., ed. lit. — Bioethics : an antology. Oxford : Blackwell Publishers, 2001. (Blackwell Philosophy Anthologies; 9).

LAVIALLE, C. — De la difficulté à legiférer sur le vivant. In NEIRINCK, D. C. ed. lit. — De la bioéthique au bio-droit. Paris : L.G.D.J., 1994.

LEI n.º 32/2006. D.R. I.ª Série. 143. (2006-07-26) 5245-5250 — Procriação medicamente assistida.

LENOIR, N. — Aux frontières de la vie : une éthique biomédicale à la française. Paris : La Documentation Française, 1991. Rapport au Premier Ministre.

LOIS BIOETHIQUES du 29 juillet 1994. 94–654. J.O. (1994--07-30).

MARINER, W. K. — Informed consent in the post-modern era. *Law & Social Inquiry*. 13 : 2 (1988) 385-406.

MARINER, W. K.; ANNAS, G. J.; PARMET, W. E. — Pandemic preparedness : a return to the rule of law. *Drexel Law Review*. 1 (2009) 341-382.

MARINER, W. K. — Toward an architecture of health law. *American Journal of Law & Medicine*. 35 : 1 (2009) 67-87.

MARINER, W. K.; FARIA, P. L., ed. lit. — Law and ethics in rationing access to care in a high-cost global economy. Lisbon : ENSP-UNL. School of Public Health. Boston University, 2008.

MATTEI, J. F. — L'ethique biomedicale. [Em linha]. Paris : Office Parlementaire d'Évaluation des Choix Scientifiques et Technologiques. Publications de l'Assemblée Nationale, 1993. [Consult. 15 Março 2009]. Disponível em http://infodoc.inserm.fr/inserm/ethique.nsf/937238520af658aec125704b002bded2/5456dc8838db5aadc12570a500515111/$FILE/Introduction.pdf.

MÉMETEAU, G. — Cours de droit médical. 2nd edition. Bordeaux : Les Etudes Hospitalières, 2003.

MILLER, J. — Is legislation in Bioethics desirable? : an exploration of aspects of the intersection of Bioethics and Biolaw. In KEMP, P. *et al*., ed. lit. — Bioethics and Biolaw. Vol. I. "Judgment of life". Copenhagen : Rhodos International Science and Art Publishers. Centre for Ethics and Law, 2000.

MONTGOMERY, J. — Health care law. 2nd edition. Oxford : Oxford University Press, 2003.

NATH, U. R. — No health without law. Geneva : WHO, 1986. (WHO Health for All 2000).

NEIRINCK, C., dir. — De la bioéthique au bio-droit. Paris : L.G.D.J., 1994. (Collection Droit et Société).

NEVES, M. C. P. — A fundamentação antropológica da bioética. *Bioética. (Brasília)*. 4 : 1 (1996) 7-16.

NICHOLS, B. *et al.* — Politicians might feel repercussions of Schiavo case. [Em linha]. *USA Today*. (3/31/2005). [Consult. 20 Maio 2009]. Disponível em http://www.usatoday.com/news/nation/2005-03-31-schiavo-politics_x.htm.

NORWEGIAN PARLIAMENT. MINISTRY OF HEALTH AND CARE SERVICES. NORWEGIAN BOARD OF HEALTH SUPERVISION. THE NORWEGIAN BIOTECHNOLOGY ADVISORY BOARD — Norwegian Act on Biotechnologies. Oslo : The Norwegian Biotechnology Advisory Board, 5 August 1994.

POTTER, V. R. — Bioethics : bridge to the future. Englewood Cliffs : Prentice Hall, 1971.

POTTER, V. R. — Global bioethics : building on the Leopold legacy. East Lansing : Michigan State University Press, 1988.

ROSENBLATT, R. E. — The four ages of health law. *Health Matrix*. 14 : 2 (2004) 155-196.

SANBAR, S. S. *et al.* — Legal medicine : historical roots and current status. In SANBAR, S. S. *et al*., ed. lit. — Legal medicine : American College of Legal Medicine textbook. 6th ed. Philadelphia, Pennsylvania : Mosby/Elsevier, 2004. 1-23.

SANBAR, S. S. *et al.* — Legal medicine and health law education. In SANDBAR, S. S. *et al.,* ed. lit. — Legal medicine. Chapter 1. 7th ed. Philadelphia, Pennsylvania : Mosby, 2001. 3-20.

SCHOCH-SPANA, M. — Community resilience for catastrophic health events. *Biosecurity & Bioterrorism : Biodefense Strategy, Practice & Science.* 6 : 2 (2008) 129-130.

SÉRUSCLAT, F. — Sciences de la vie et droits de l'homme : bouleversement sans contrôle ou législation à la française. [Em linha]. Paris : Office Parlementaire d'Évaluation des Choix Scientifiques et Technologiques. Publications de l'Assemblée Nationale, 1992. [Consult. 15 Março 2009]. Disponível em http://infodoc.inserm.fr/inserm/ethique.nsf/9372385 20af658aec125704b002bded2/5456dc8838db5aadc12570a500515111/$FILE/Introduction.pdf.

SILVA, P. M. — Bioética para as ciências naturais : prefácio. In ROSA, H. D., ed. lit. — Bioética para as ciências naturais. Lisboa : FLAD, 2002. 7.

SOLBAKK, J. H. — The bio-politics of extending pre-implantation genetic diagnosis : a Norwegian case story. In JÓNSDÓTTIR, I., ed. lit. — PGD and embryo selection : report from an International Conference on Preimplantation Genetic Diagnosis and Embryo Selection, 2005. 99-104. (TemaNord 2005; 591). [Em linha]. Copenhagen : Nordic Council of Ministers, 2005. [Consult. 15 Março 2009]. Disponível em http://www.norden.org/da/publikationer/publikationer/2005-591/at_download/publicationfile.

UNESCO — Universal Declaration of Bioethics and Human Rights. [Em linha]. Paris : The United Nations Educational, Scientific and Cultural Organization, 19 October 2005. [Consult. 15 Março 2009]. Disponível em http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html.

UNITED NATIONS — The Universal Declaration of Human Rights : article 25. [Em linha]. New York, NY : United Nations, 1948. [Consult. 20 Setembro 2009]. Disponível em http://www.un.org/en/documents/udhr/index.shtml#a25.

USA. COMMISSION FOR THE PREVENTION OF WEAPONS OF MASS DESTRUCTION PROLIFERATION AND TERRORISM — World at risk : report. Washington, DC : Commission for the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, 2008. [Consult. 15 Março 2009]. Disponível em http://www.preventwmd.gov/report/.

USA. INSTITUTE OF MEDICINE — A shared destiny : community effects of uninsurance. Washington, DC : Institute of Medicine, 2003a.

USA. INSTITUTE OF MEDICINE — Coverage matters : insurance and health care. Washington, DC : Institute of Medicine, 2001.

USA. INSTITUTE OF MEDICINE — Hidden costs, value lost : uninsurance in America. Washington, DC : Institute of Medicine, 2003b.

WADLINGTON, W. — Some reflections on teaching law and medicine in law school since the '60s. *Health Matrix*. 14 : 1 (2004) 231-236.

WILLIAMS, V. J. — Fluconomics : preserving our hospital infrastructure during and after a pandemic. *Yale Journal of Health Policy, Law and Ethics*. 7 : 1 (2007) 99-152.

WING, K. R. *et al.* — Public health law. New York : LexisNexis, 2007.

□ Resumo

DEFINIR O DIREITO DA SAÚDE OU O SÍNDROMA DE *EDGEWOOD*

O objectivo principal dos autores é apresentar ideias sobre a definição de Direito da Saúde, destacando as particularidades desta área do direito, bem como do ensino deste ramo jurídico, na esperança de contribuir para a maturidade e para o reconhecimento académico do mesmo, não só como um campo juridicamente muito rico, mas, também, como um poderoso instrumento social no cumprimento dos direitos humanos fundamentais. Os autores defendem que o Direito da Saúde tem diversas características que o distinguem dos ramos tradicionais do direito, como a sua complexidade e natureza multidisciplinar. O estudo do Direito da Saúde abrangendo normalmente questões como o acesso aos cuidados, a organização dos sistemas de saúde, os direitos e deveres dos doentes e dos profissionais de saúde, a responsabilidade civil, os contratos entre instituições de saúde e profissionais, a protecção e a confidencialidade de dados clínicos, o consentimento informado e o sigilo profissional, implica uma abordagem transversal de diferentes áreas legais, incluindo os Direitos contratual, administrativo, *antitrust*, constitucional, empresarial, penal, ambiental, alimentar, farmacêutico, da propriedade intelectual, dos seguros, internacional e supranacional, trabalho, fiscal e penal. Esta é uma das razões pelas quais o ensino do Direito da Saúde representa um desafio para o professor, que terá de encontrar os programas, conteúdos e métodos adequados ao perfil dos destinatários, que são normalmente não juristas e às necessidades de um currículo multidisciplinar.

Ao descrever as várias definições académicas de Direito da Saúde como análogas a *Edgewood*, uma casa de ficção que apresenta um estilo arquitectónico diferente em cada uma de suas paredes, os autores tentam encontrar os elementos que deveriam compor uma definição mais abrangente. No artigo, Biodireito, Bioética e Direitos Humanos são descritos como complementos de uma definição de Direito da Saúde: o Biodireito, dado que é o campo jurídico que trata as consequências sociais que surgem dos avanços tecnológicos na área da saúde e das ciências da vida; a Bioética cujas evoluções influenciam normalmente o quadro jurídico da Saúde; e, por fim, a teoria dos Direitos Humanos e as suas declarações as quais têm estado sempre historicamente ligadas à medicina e à saúde, devendo funcionar como pano de fundo de todas as questões levantadas na área do Direito da Saúde. Para finalizar a sua breve incursão sobre a definição de Direito da Saúde, os autores dão ainda nota das complexas relações entre este último e a Saúde Pública, onde se tratam mais especificamente as leis aprovadas pelos governos para regular os serviços de saúde, as indústrias e as condutas individuais que afectam a saúde das populações, aspecto do Direito da Saúde que requer uma atenção especial para evitar um desequilíbrio entre os poderes públicos e as liberdades individuais.
Os autores concluem afirmando que a confiança do público em qualquer sistema de saúde é, essencialmente, sustentada pelo desenvolvimento de estruturas de saúde que sejam consistentes com o direito constitucional da saúde, tais como o direito universal ao acesso a cuidados de saúde, e que o estudo do Direito da Saúde pode contribuir com elementos importantes para a realização de um sistema de saúde que respeite o Estado de Direito e os Direitos Fundamentais.

Palavras-chave: Direito da Saúde; Bioética; Biodireito; Direitos Humanos; acesso a cuidados de saúde; Direito da Saúde Pública.

INSTRUÇÕES AOS AUTORES

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ARONSSON, G.; GUSTAFSSON, K.; DALLNER, M. — Sick but yet at work : an empirical study of sickness presenteísm. [Em linha] *Journal of Epidemiology and Community Health.* 54 : 7 (2000) 502-509. [Consult. 20 Jan. 2005]. Disponível em http://www.jech.bmjjournals.com/cgi/content/full/54/7/502

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WONCA INTERNATIONAL CLASSIFICATION COMMITTEE — ICPC-2 : international classification of primary care. 2nd ed.. NewYork : Oxford University Press, 1998. ISBN 0-19-262802-X.

ILO — INTERNATIONAL LABOUR ORGANIZATION — SafeWork : Global Program on Safety, Health and the Environment, 2004. [Em linha] [Consult. 20 Jan. 2005]. Disponível em http://www.ilo.org/public/english/protection/safework/mandate.htm

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GJERDING, A. N. — The evolution of the flexible firm: new concepts and a Nordic comparison. [Em linha]. In Conference, Rebild, Denmark, June 9th-12th — National innovation systems, industrial dynamics and innovation policy. Rebild: Danish Research Unit for Industrial Dynamics, 1999. [Consult. 2006-01-12]. Disponível em www.druid.org.

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