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Erick Valdés

Biolaw: Origins, Doctrine and Juridical Applications on the Biosciences

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Introduction

There is no international consensus on biolaw's epistemological scope. Whereas disciplinary reflection on ethical/juridical dilemmas arisen from clinical practices and genetic techniques are turning almost fifty years, such task has been mainly carried out from bioethics and human rights' categories. As a matter of fact, while deliberation on these issues has been profuse, neither bioethics nor human rights' international instruments have been able so far to engender a steady normative universe to address biosciences' juridical quandaries from a legally binding perspective.[1]

I will defend that successfully understanding and ruling biomedical techniques depend on biolaw's epistemological consolidation. However, it is intriguing how the word *biolaw* raises both confusion and distrust. As this emerging field espouses an autonomous disciplinary dimension, different from bioethics, confusion about its meaning is gradually boosting in academic atmospheres. Biolaw is often understood as bioethics, by detracting it from its legal range. This slanderous and reductionist intellection questions biolaw's nature, and it is common not only among non-experts but among scholars, even those who consider to be themselves biojurists.

Readers may not know what biolaw is, or they may believe they do. For that reason, there exist some odds you consider my opening argument an absurd or trivial exaggeration. I myself, eight years ago, would have thought this way if I suddenly came across such statements. However, eight years ago, I did not know what I know now.

Since bioethics broke through, the Council of Europe's law began to be filled with bioethical terms, and the so-called international biolaw's biolaw instruments were justified upon common morality principles already identified and defined by American principlism.[2] Bioethical colonization of European biolaw—first known as a Life Sciences Law—determined the hatching of various conceptions of biolaw,

[1] By virtue of what I could call 'epistemological economy' and since it does not impact the essential meaning of what I seek to mean, I will use the terms "biosciences," "biotechnology," and "biomedicine" indistinctly in this book.

[2] When I refer to "American" bioethics, principlism and so forth, or "American" conception of biolaw, I always mean United States' bioethics and biolaw. As the term "American" in the colloquial and academic use is easily understood as belonging to the United States of America, I have seen no problem to use it that way in my book.

epistemologically divergent to each other, but coinciding on a fundamental point: they all grasped biolaw from bioethics. This obsequious concept of biolaw as depending on bioethics, pointed to understand this new field either as a juridified bioethics, or a traditional law evolving towards biomedical settings, or simply as law supported by bioethical criteria and discourses. Such an orthodox intellection prevented biolaw from being understood as a new branch of law with legally binding force, which has certainly dwindled its epistemological density.

This book is not about bioethics, traditional law, biomedical law, medical law, or law and bioethics. It is not aimed at outlining a comfortable and superficial conception of biolaw, understood as a soft law, that is, as a constellation of not legally binding instruments, principles and recommendations on biomedical practices. Nor it is about medical ethics' codes or legal regulations engendered from categories of traditional law and, therefore, quite inefficient. This is a revolutionary book as it seeks to deconstruct the history of biolaw and its oblique epistemologies, which means not accepting perennial axioms, and not seeing paradigms where only anachronism and anomaly still exist. It is a book aimed at validity, but also at solidity, because the truth of biolaw has never been told before. In that sense, it is also a revealing text.

Therefore, shaping biolaw as an independent and compelling branch of law, with a legally binding scope, will boost the effectiveness of new deliberative models for legal sciences, as well as will utterly reinforce original hermeneutical and epistemological approaches, in tune with the complexity of disturbing legal scenarios created by biomedical sciences' latest applications. No doubt this new conception will demand to address biojuridical quandaries adeptly to avoid muddle and uncertainty. That is what this book is intended to. Otherwise, it would only reach an oblique and also epistemologically ravaging outcome.

I will address the origins of the European biolaw and its connections with American bioethics. I will also analyse different biolaw's epistemologies historically developed both in Europe and in the United States, to finally offer a new conception of biolaw as a new branch of law, by exploring its theoretical and practical atmospheres. More specifically, this book responds to the following detail.

Chapter 1, entitled "The Birth of Biolaw: From American Bioethics to European Biolaw," addresses the origins of biolaw, placing its birth on theoretical and procedural developments of American bioethics, and showing how this field influenced European Law's regulation, jurisprudence and instruments. Historical events that triggered the emergence of American bioethics are analysed, as well as two paradigmatic international texts that identified principles to govern biomedical research with human subjects (The Nuremberg Code and The Belmont Report). The impact of the seminal book *Principles of Biomedical Ethics* and its influence on the emergence of what was later known as "European bioethics and biolaw" are also thoroughly explored.

In Chap. 2, "Traditional Conceptions of Biolaw", different biolaw epistemologies that have arisen so far are perused. Those theories, which I have already identified and defined in previous works, are deepened in this book, by seeking to prove why none of them was able, over twenty years, to understand biolaw as a legally binding branch of law. The reader will see that each of these conceptions has comprehended

biolaw from bioethics, by fostering different sorts of wrong relationships that I will call juridification, complementation, subjection, overlap, substitution, colonization and intersection.

Chapter 3, called "Principles of European Biolaw", addresses the principles of European bioethics and biolaw (autonomy, dignity, integrity and vulnerability). I show why those principles lack normative content and rather point to ontological conditions of the human being, not offering legally binding force whatsoever. Beyond those shortcomings, I examine some interesting and promising aspects of the European proposal, such as trying to assume a principlist format.

In Chap. 4, "Reformulation and Juridification of Biolaw's Principles: A Possible New Framework", I peruse the possibility of building a principlist model of biolaw. In order to do this, I deepen European bioethics and biolaw's principlism, by showing that, at the end of the day, it encompasses, rather, a traditional bioethical model. I also offer an approach that allows the juridification of European biolaw's principles, as well as I assess the (uncertain) possibility of juridifying American bioethics' principles. Finally, I offer a new principlist framework for biolaw, which happens to be more efficient.

Chapter 5, entitled "A New Conception of Biolaw" offers my conception of biolaw that, first, distinguishes it from bioethics and traditional law. Secondly, I discuss what I call "the crisis of biolaw's jurisdiction", meaning the struggle of biolaw for acquiring an institutional dimension. Finally, I justify biolaw as a new legal epistemology, a new deliberative model for legal science, and a new hermeneutical approach in line with current demands and interpellations of biomedical sciences, insofar as it is also a new branch of law that enhances traditional law.

In Chap. 6, "Biolaw and the Biosciences", I discuss some biolegal scopes of controversial biomedical practices and issues. Also, through the study of those developments' potential threatens I prove how it is possible to build new biojuridical models to rule those performs with much more security and efficacy than bioethics and traditional branches of law.

In Chap. 7, "Technology, Nature, Animals and Biolaw", I carry out a philosophical reflection on technology, seeking to clarify the relationship between contemporary technology and law. I will reach a fundamental conclusion: traditional law does not clearly understand its relationship with contemporary technology, so it is not able to engender hermeneutical models able to govern systematic interventions of technology on the natural domain. At the end of the chapter, I scrutinise, in the context of the current reception of technology as an objectifying device of reality, especially built to command it, how nonhuman animals are reified to the extreme.

Finally, I offer fifty conclusions that show, comprehensively, the main earnings of my work.

I have tried not to be tautological in my exposition, so that, practically, on every page, the reader will find a new idea, an original critique or an alternative and competing epistemological proposal regarding those currently existing. When I repeat something, it is to emphasise an idea from another point of view, or to address concepts already analysed, from different theoretical perspectives, but it is never to say the same.

I am not intending to convince anyone that my conception of biolaw is "the end of history". However, I am quite convinced that mine is a more compelling approach to this field, which may mean a less opaque intellection of biolaw, by understanding it as a new branch of law, but also, as a new deliberative model, a new hermeneutical approach and a new epistemology for legal science. However, and as it always happens in these cases, you the reader have the latest word.

Erick Valdés

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About the Author

Erick Valdés is President and Founding Member of the International Network of Biolaw. He has been Visiting Research Professor (2018–2019), University Center for Human Values, Princeton University, USA, and Adjunct Research Scholar at the Kennedy Institute of Ethics, Georgetown University. In addition, he was Resident Professor, Center for Clinical Bioethics, Georgetown University as well as Associate Professor of International Human Rights at The Washington Center for Internships and Academic Seminars, Washington, DC, Adjunct Professor of Bioethics and Theories of Democracy and Human Rights, American University, USA, and Adjunct Professor of Bioethics and Research Ethics, George Mason University, USA. He is the Editor and Co-author of *Biolaw and Policy in the Twenty-First Century: Building Answers for New Questions,* published by Springer in 2019.

Chapter 1
The Birth of Biolaw: From American Bioethics to European Biolaw

Abstract This chapter is focused on the origins of biolaw, placing its birth on theoretical and procedural developments of American bioethics, and showing how this field influenced European Law's regulation, jurisprudence and instruments. Historical events that triggered the emergence of American bioethics are analysed, as well as two paradigmatic international texts identifying principles to govern biomedical research with human subjects (Nuremberg Code and Belmont Report). The impact of the seminal book *Principles of Biomedical Ethics* and its influence on the emergence of what was later known as "European bioethics and biolaw" are also thoroughly explored. Finally, the chapter addresses the birth of European biolaw, which was originally aimed at defining and providing content to ethical principles related to autonomy, dignity, integrity and vulnerability, understood as four important bases for European bioethics and biolaw. Those basic ethical principles could not be understood as universal ideas or eternal truths, but rather, they had the status of "deliberative guidelines" and fundamental values of European culture.

1.1 Inception

The birth of biolaw is not related to a single event, but, rather, it is a multifactorial phenomenon. Certainly, much of its first epistemology was developed in Europe where biolaw gradually acquired a certain procedural consistency and got an incipient disciplinary status. However, and although it is a statement that can be discussed, its conceptual roots, while have some backgrounds in Europe, essentially grew crossing the Atlantic Ocean, namely, in the United States of America. The story is well known, but it has never been linked before to biolaw. It is time to do it.

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1.1.1 The Nuremberg Code

The Nuremberg Trials can be considered an epistemological forebear of international biolaw as well as of the extensive non-legally binding constellation of instruments and provisions of both UNESCO, the Council of Europe and the European Court of Human Rights, aimed at regulating biosciences in Europe. However, they also represent an assemblage of jurisdictional processes that marked seminal criteria for American bioethics. In particular, the Nuremberg Code of Medical Ethics can be considered the first document that identified principles and procedures to govern experimentation with human beings, a scenario that, upon later, the Belmont Report addressed in a paradigmatic way. Therefore, and as the epistemology of American bioethics refined, updated and extended the theoretical and methodological scope of the Nuremberg Code of Medical Ethics, by encouraging the emergence of essential categories for the conceptual configuration of international biolaw, it is tolerable to affirm that the prehistory of biolaw begins in the 1930s.

Earlier, in the mid-1920s, many German physicians, supporters of race hygiene, were accused by the public and medical society of carrying out morally imprecise clinical practices. The use of eugenic prophylaxis was supported by the German government in order to create an Aryan superior race and to exterminate those who did not express harmony with its criteria. The diehards of race hygiene merged with National Socialism to promote the use of biology as a device for achieving ethnic purity, a central concept in Nazi ideology. Doctors were drawn to this dubious conviction and, in 1929, they founded the National League of Socialist Physicians, whose purpose was to purge the German medical community from Jewish Bolshevism. However, the criticisms by important referents of German medicine were profuse and influential.

In response to criticism, the Reich government issued, in Weimar, the *Regulations Concerning New Therapy and Human Experimentation.* The document was based on the obligations to do good (beneficence) and do not harm (nonmaleficence), but, at the same time, it emphasized the legal doctrine of informed consent. Indeed, the guidelines clearly distinguished the difference between therapeutic and non-therapeutic research. They allowed the administration of treatment without consent only in extreme situations, but in the realm of non-therapeutic purposes, any practice or intervention without consent was strictly prohibited.

Thus, the original archetype of the Nuremberg Code emerged in German politics before World War II, specifically in the 1930s, a time when the German Medical Association was considered a progressive and democratic organization, focused on public health. However, Adolf Hitler denied Weimar guidelines. In fact, in 1942, the Nazi party included more than 38,000 German doctors, who helped undertake controversial medical programs like the Sterilization Law.

After World War II, a series of trials were held to make Nazi party's members responsible for a multitude of war crimes. The trials were approved by President Harry Truman on May 2, 1945, and were led by the United States, Great Britain, and the Soviet Union. They began on November 20, 1945 in Nuremberg, Germany, in

what became known as the Nuremberg Trials. In one of the trials, called "The Doctors Trial," German physicians responsible for conducting morally controversial procedures and experiments in concentration camps, in addition to those who participated in more than three million sterilizations of German citizens, were judged.

Many defendants argued that their experiments differed very little from those used before the war and that there was no law differentiating between legal and illegal experiments. This concerned doctors Andrew Ivy and Leo Alexander, who worked with the prosecutors during the trial. In April 1947, Dr. Alexander submitted a memorandum to the United States War Crimes Attorney outlining six points for legitimate medical research.

The Nuremberg Code stated the explicit voluntary consent of patients as a requirement for human experimentation. It was drawn up on August 9, 1947. On August 20, the judges delivered their verdict against Karl Brandt and others 22 people. The verdict reiterated the memorandum's point and, in response to the prosecution's expert medical advisers, increased from the original six points to ten. The ten points became known as the "Nuremberg Code", which includes procedures and rules such as informed consent, absence of coercion, properly formulated scientific experimentation, and beneficence towards subjects of experimentation. The ten points were made explicit in the section "Permissible Medical Experiments", and, in a synoptic version, are as follows:

1. The voluntary consent of the human subject is absolutely essential.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject (Annas and Grodin 1995).

The Nuremberg Code was initially ignored, but it gained much greater importance about twenty years after its writing. As a result, there were major rival claims for its authorship. Some claimed that Harold Sebring, one of the three American judges who presided over the doctors' trial, was the author. In his letter to Maurice H. Pappworth, Andrew Ivy also claimed to be the sole author of the Code. Leo Alexander, approximately thirty years after the trial, claimed sole authorship as well (Gaw 2014). However, after a careful reading of the transcripts, the documents, the antecedents and the final sentences, there is a greater consensus on the authorship was shared indeed, so that the Code has its sources in the trial itself.

Nevertheless, the Nuremberg Code has never been officially accepted as a law by any nation, nor as an official ethical guideline by any association. In fact, the Code's reference to the Hippocratic duty towards the individual patient and the need to provide information was not initially favored by the American Medical Association. The Western world initially received the Nuremberg Code as a "code for barbarians" and not for rational doctors and researchers (Gaw 2014). Furthermore, the final ruling did not specify whether the Code should also apply to cases such as political prisoners, convicted criminals, and healthy volunteers (as is currently the case in human challenge trials to produce a Covid-19 vaccine). Thus, the lack of clarity, the brutality of the tried medical experiments, and the uncompromising language of the Nuremberg Code made people think that it had been created for singularly egregious transgressions.

In spite of the above mentioned, the Nuremberg Code is considered the most important document in the history of clinical research ethics, and it had a massive influence on global human rights. In fact, the Nuremberg Code and the Declaration of Helsinki represent the basis of the *Code of Federal Regulations*, issued by the United States Department of Health and Human Services for the ethical treatment of humans and biological material, and are profusely used by international review boards. Furthermore, the idea of informed consent has been universally accepted and now founds the article 7 of the *International Covenant on Civil and Political Rights.* It also served as the basis for the drafting of the *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, proposed by the World Health Organization.

However, the Nuremberg Code did not gain a conceptual intensity enough to give rise to bioethics or any other relevant epistemology. Something else had to happen in history for the Code to be deepened and endowed with epistemological density. Therefore, American bioethics, a clear theoretical and procedural ancestor of European biolaw and international biolaw, did not hatch because of the single Nuremberg event. Other disturbing happenings had to be debunked.

1.1.2 Tuskegee

The Tuskegee Syphilis Experiment, conducted in hundreds of African-American men, is one of the most controversial and censored investigations on human subjects in the history of American medicine. A true understanding of its implications demands a historical perspective. However, because much of this study was conducted behind closed doors, its details never became fully known and they often are discussed and addressed in reductionist and also emotional terms. However, thanks to the interesting Gregory Pence's work (2004), we can currently access very relevant data and information about the case

As this experiment can be considered one of the most determining milestones for the subsequent disciplinary development of bioethics—which is, in turn, a historical and theoretical precedent of biolaw—it is important that readers find out what really happened. The facts, told in a synoptic way, were as follows.

In 1932, before the purification of penicillin, the treatments for syphilis were as ineffective as dangerous, especially because of their toxicity. In those years, scientific parameters had not yet been developed to accurately determine whether the eventual and unlikely benefits of such treatments could justify to assume the inevitable risks involved. Therefore, medicine lacked relevant knowledge to develop appropriate therapies to control the disease. Physicians and scientists thought then of a possible solution: to explore into the natural progression of syphilis; in other words, to let syphilis spread out in infected patients without applying any treatment. According to that, the patients or rather the subjects of experimentation, should never be medicated.

The same year, the U.S. Public Health Service began a clinical investigation that lasted 40 years and was known worldwide as "The Tuskegee Experiment." The study's goals seemed to be plausible. However, the experimentation itself was very controversial. It consisted in studying the spontaneous evolution of syphilis in 399 African-American men from Tuskegee, in Macon County, Alabama, who were deceived by scientists so that they believed they only had a "bad blood." Most of them suffered from secondary syphilis, which means they were going through a latent or early stage of the disease.

Beyond the ethical reproaches the experiment deserves, it was not a proper research either. Scientific methods were missing while the study was being conducted. Central oversight was never available, nor protocols designed or established to carry out the research were written and, often the 399 subjects' names in the study group were confused or mixed with the healthy subjects' names in the control group.

It is also possible to confirm several inconsistencies in the experiment. Doctors did not keep regular visits to town. In some periods they did not return for years, and visits were not always documented. It is possible to observe a significant gap between 1939 and 1948 where neither activities nor results of the study are documented. The same happens between 1963 and 1970. However, the experiment continued its course. Even when penicillin was approved for mass public use and in 1943 proved to be effective in treating syphilis, the subjects were never medicated.

On July 26, 1972, Jean Heller of the Associated Press debunked the study, prompting its immediate cancellation. However, by then, 28 out of 399 subjects had died of syphilis and another 100 had died of collateral complications. In addition, 19 children had contracted the disease during their gestation period (Jones 1993: 2).

The study's ethical fissures were very relevant and determined the need to identify new deliberative criteria to address moral controversies arising from biomedical research. The subjects were never informed about the true purposes of the study and its possible side effects. In addition, they never knew they had syphilis and, therefore, they always ignored the actual disease's severity. Nobody cared of them, nobody told them the truth, and nobody stopped the study. Those 399 African-American men were simply observed, reified, instrumentalized and used as guinea pigs. And, clearly, they were selected as subjects of experimentation, not only because they had the disease, but also because of their poverty, vulnerability, candour and, above all, because of their skin colour.

Did the scientists obtain conclusive results from the experiment? Of course not. In forty years, the study was unable to identify new information or get more knowledge about the disease than there was when the investigation began.

1.1.3 Willowbrook

From 1947 to 1987, *Willowbrook State School* was a public institution for children with intellectual disabilities, located in Willowbrook, Staten Island, New York. Most of them were orphans or had been abandoned by their parents.

During its first decade of operation, outbreaks of hepatitis, mainly hepatitis A, were common at the school. This involved, between the late fifties and the early seventies, scientists Saul Krugman (New York University) and Robert W. McCollum (Yale University), who conducted a series of controversial medical studies to assess the effects of gamma globulin in the control of the disease. A public protest forced the research interruption as well as other linked medical studies. It was knowing that researchers had used many mentally disabled children to conduct the studies. However, who was, at first, the main critic of the project, New York senator, Seymour R. Thaler, affirmed, later on, that the investigation had been carried out correctly, which pacified the public opinion's outrage.

In fact, both the senator and the scientists were eager to socialize what they called "transcendental research achievements." One of the most important study's outcomes was to achieve a better understanding of the differences between serum hepatitis, which is transmitted by blood transfusions, and infectious hepatitis, which is spread out from person to person, the most common form of catching it, anyway.

However, beyond some proven scientific achievements, the study revealed a sinister background. In an effort to control outbreaks of hepatitis, Willowbrook's medical staff had consulted Saul Krugman about what to do. Krugman discovered

that hepatitis had developed in the ninety percent of the children admitted to Willowbrook shortly after their arrival. Although it was known that hepatitis was caused by a virus, the scientist lacked data about how it broadened, or if it could be prevented, or how many types of viruses were causing the disease. Krugman literally used Willowbrook's children to answer those questions. One of his studies meant the inoculation of the hepatitis virus into sixty mentally impaired children who did not have the disease. The scientist witnessed how their skin and eyes turned yellow and how their livers grew out of control. He saw them to vomit and refuse eating. All children inoculated with the hepatitis virus became ill, some of them very severely. Before that, Krugman reasoned that it was justifiable to inoculate the children with the hepatitis virus because, "most of them would have contracted the disease, anyway." But what he did not compute (or did not want to) is that by injecting the hepatitis virus into healthy children, the odds to get sick increased one hundred percent.

In 1965, Willowbrook was "home" to more than 6,000 children and youth with intellectual disabilities despite having a maximum capacity of 4,000. That year, Senator Robert Kennedy toured the institution, and stated that the boys in the school "lived crowded, in the midst of dirt and filth, with their ragged clothes, and in rooms clearly more uncomfortable than the animals' cages in a zoo," and instructed a series of recommendations to immediately improve the place's conditions.

Although the controversial study of hepatitis had been suspended and the school's reputation was not the best, public opinion was not sure what was really happening indoors. Donna J. Stone, an activist and strong defender of mentally disabled children and victims of child abuse, gained access to the school by posing as a newly graduated social work student. Upon leaving, she shared with the press everything she had witnessed. A series of articles in local newspapers, including *Staten Island Advance* and *Staten Island Register,* described the precarious living conditions at Willowbrook, and the negligent and, often, inhuman treatment to most children.

Shortly after, in early 1972, Geraldo Rivera, then a reporter for WABC-TV in New York, conducted a series of investigations at Willowbrook, discovering deplorable conditions, which included overcrowding, naked and unkempt children moving through the corridors, and filthy sanitary facilities. In addition, Rivera confirmed the worst: several school staff members abused, physically and sexually, the children. The story, titled *Willowbrook: The Last Great Disgrace,* attracted national attention and meant a Peabody Award for Rivera. Currently, Willowbrook's original documentary material remains available for public consultation on Rivera's website and on YouTube.

As a result of overpopulation, inhuman conditions, abuses, rapes, joint to the infamous hepatitis experiment, on March 17, 1972, parents and legal representatives of 5,000 of the children and youth residing at Willowbrook School filed, in federal court, a class action lawsuit against New York State, which would be known as New York ARC v. Rockefeller. In 1975, a consent judgment was signed and the state of New York undertook to substantially improve living conditions at the school. The case's publicity was an important factor to the approval of a federal law in 1980: The Civil Rights Law for Persons with Mental Disabilities.

Previously, in 1974, and already known the devious abuses committed by scientists on their eventual human subjects of experimentation, the Congress of the United States ordered the creation of a commission whose purposes should be to discuss and reflect on the limits of biomedical research, as well as to balance the equation between risks and benefits of research in human subjects, also to provide guidelines and criteria for a fair and equitable selection of subjects of experimentation and, finally, to determine the nature, scope and meaning of the Informed Consent in biomedical research. This commission, which was made up of relevant actors from the American academic world, was called the *National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research,* and is nowadays known all over the world simply as the *National Commission*.

Almost five years later, the *National Commission* would eventually publish the outcomes in a document that quickly became a key reference for bioethics' epistemological development, as well as it increased the accuracy and power of deliberation and decision-making processes. Also, it contributed to the optimization and creation of public policies to regulate experimentation with human subjects. This brief and influential document, known worldwide as *The Belmont Report* (*The Belmont Report: Ethical Principles for Research with Human Subjects*), can be considered, along to the Nuremberg Code, a milestone in the search for criteria to protect human beings in the face of biomedical experimentation. What is new in the Report? It fosters the application of a cluster of "basic ethical principles" whose epistemological and methodological scope, quickly became very workable to explore, understand and solve moral controversies arising in biomedical and clinical fields.

Many of the concepts *The Report* provides, as well as the specific procedures it designs to guarantee compliance with a constellation of well-defined rules and principles that should support any bioscientific research, were received, upon later, by a large part of European Community jurisprudence and European parliamentary law. As over time that reception would detonate the birth of international biolaw, it is pertinent to expose here the most relevant elements of it.

1.2 The Belmont Report

The Belmont Report's main goals (National Commission 2009) were to identify basic ethical principles to guide and rule biomedical research in human beings, and develop procedural guidelines (rules) to ensure that any study is carried out in accordance to those principles.

The document compiled and summarized the *National Commission's* four-years' work, by defining three fundamental principles to protect human subjects from experimentation. Its first goal was to abolish the excessive paternalism, both of scientific practice and medicine, which traditionally did not consider subjects and patients' self-determination as a criterion for carrying out research and treatment. Therefore, *The Report* tried to give pre-eminence to individual autonomy, allowing human subjects

to participate in deliberation and to make decisions on the procedures and treatments that might be applied to them.

Secondly, it was aimed at restoring respect for human dignity, by promoting the maximization of benefits in experimentation, as well as demanding to reduce the potential risks and damages involved.

And third, *The Belmont Report* highlighted the importance of equitable treatment of subjects, granting them the same rights in several important research' stages: (1) Fair methods and procedures to choose them, (2) Equitable distribution of efforts to safeguard dignity, health and life of those involved, and (3) Non-discrimination in research with human subjects, regardless of their origin, race and intellectual, social or economic status.

It is fair to say that *The Report* was the first document in history to identify, articulate and define bioethical principles. Since then, those principles enjoyed a rapid and growing acceptance, not only in the bioethical context but also in the legal one. Both the epistemological scope and the practical application of the principles by far surpassed the disciplinary context they were originally created for. In fact, the *National Commission* itself clarified that the principles were only general guidelines aimed at helping deliberation, enhancing decision-making and moral reasoning, as well as providing criteria for choosing the right courses of action in each case. However, the principles turned into a theoretical framework strong enough to engender more specific rules that eventually would set up procedures to be applied very effectively at a practical level.

Therefore, *The Belmont Report* emphasized the importance of clearly distinguishing between research's nature, its limits and scopes, and possible implications for human subjects' life and safety. The document is divided into three parts: (i) Boundaries between practice and research, (ii) Basic ethical principles and, (iii) Applications.

1.2.1 Boundaries Between Practice and Research

In this part, *The Report* highlights the need to discriminate between biomedical research and therapy. This distinction is not trivial since it determines which steps and activities of research should be thoroughly gaged to protect human subjects. According to *The Report* therapy is an intervention seeking the patient's wellbeing upon good diagnosis and treatment. Research instead aims to prove a hypothesis, reach conclusions and develop deeper and more precise scientific knowledge. Beyond the different role a human being plays in each case (end and means, respectively) *The Report* emphasizes that both purposes must be sought by taking into account people's autonomy, dignity, and integrity, as well as having a high degree of scientific conviction regarding the experimentation's safety and therapy's effectiveness.

1.2.2 Basic Ethical Principles

The expression "Basic Ethical Principles" refers to what we might call fundamental moral milestones of our Western cultural tradition. The principles are the following:

1.2.2.1 Respect for Persons

This principle recognizes people's self-determination. It is, on the one hand, an individual right related to individual's ability to make decisions and proceed accordingly, and on the other, it implies the general duty to respect that capacity. When this faculty is, permanently or temporarily reduced, subjects or patients have the right to be surrogated in their decisions.

1.2.2.2 Beneficence

The Report is emphatic in stating this principle must be understood beyond traditional charity or benevolence. Rather, it epitomises the categorical obligation to promote persons' benefit at every stage of research, and avoid damaging them by all possible means. In this sense, the document defines two general rules as complementary expressions of beneficent actions: (i) do no harm, and (ii) maximize possible benefits and minimize eventual damages. Although this principle is based on the Hippocratic Oath, the *National Commission*'s members showed flexibility in their understanding. Hippocrates conceived the rule of "doing good" deontologically, that is, as an absolute obligation that must be observed even at expenses of a greater general benefit. In other words, the Hippocratic Oath states a person can never be hurt, even if such harm means better goods for others. However, the *National Commission* understood the Oath from a utilitarian key, since it accepts beneficence eventually may/can involve exposing people to risk. Therefore, the big deal here is not the per se harm, but to decide when it is justifiable to seek certain benefits despite damages or eventual detriments caused, and when the benefits, whatever they are, should be ignored because of the critical risks involved.

1.2.2.3 Justice

This principle orders an equitable distribution of research's benefits among the subjects and to avoid risks for the most vulnerable groups. It also seeks to ensure a fair selection of subjects. In this fashion, it is a principle of distributive justice that recognizes five criteria for distribution of benefits and burdens in research: (i) equal share, (ii) need, (iii) effort, (iv) contribution, and (v) merits.

1.2.3 Applications

In this part, *The Report* identifies three fundamental requirements to guarantee principles' respect and compliance.

1.2.3.1 Informed Consent

Procedure defined to meet the principle of respect for persons:

i. *Information*: every person must be fully informed about the possible risks associated with research. This information must be given timely and should include, among others, research's details, procedure's purposes, and the risks involved.
ii. *Comprehension*: any information must be provided in order for the subject to fully understand procedures' nature and scope. Taking into account that intelligence, rationality, maturity and language are different among people, it is crucial to adapt the communication's process to individual capacities.
iii. *Voluntariness:* consent is valid only if it is voluntary. Thereby, a subject must express his/her agreement to get involved without compulsion or unjustified external influence. This rule implies making an accurate distinction between justifiable persuasion and undue coercion.

What is informed consent aimed at? It certainly embodies a conscious, competent and fully informed agreement to engage in research or therapy. However, in the real world its ulterior purpose is obscure. Is informed consent intended to allow subjects or patients to actively participate in medical decisions? Is informed consent aimed at permitting persons to make scientific and clinical decisions exclusively on their own? Are subjects or patients jointly responsible for research and therapy's consequences, whatever they are? Is informed consent's purpose to shield scientists and physicians from eventual legal responsibilities for any harm inflicted on subjects and patients? Is informed consent only seeking to help people understand what treatment or research mean? Is informed consent legally binding?

The Report does not discuss these quandaries and seems to understand informed consent as an untouchable procedural axiom nobody in knows exactly what it is for. As a matter of fact, it is not a mystery that informed consent is applied only partially in most of hospitals and medical centres in the world.

1.2.3.2 Assessment of Risks and Benefits

Procedure created to assure the principle of beneficence's fulfilment. It implies researchers must always balance risks and benefits through a systematic, predictive and utilitarian evaluation. By carrying out this task scientists determine whether studies are properly designed and, therefore, justified. In this fashion, assessment of