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Perspectives of medical law under the auspices of modern biotechnology

Originalbeitrag erschienen in:
Perspectives of Medical Law under the Challenges of Modern Biotechnology*

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1. Introduction

As I am the first foreign speaker to take the floor, I may be allowed to express our full hearted congratulations to the 20th anniversary of the Inter-University Chair in Law and the Human Genome at Bilbao. Since I am connected with its Director Professor Carlos María ROMEO CASABONA in a long friendship, he may remember that, when he first told me about his idea of founding this research center, I was a little bit skeptical whether the time was already ripe for such a juridical genome enterprise. Now, after 20 years of existence you can be very proud of what you and your colleagues and collaborators established. So, most sincere thanks for his visionary courage.

Now, I must confess somehow to stand here with mixed feelings. On the one hand, I feel very honored to have been given the privilege of speaking in this inaugural session. On the other hand, however, I was not assigned a specific topic. So, what to talk about if I should not anticipate what will be dealt with more expertise in detail in later sessions? I think it would be

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* This revised keynote presentation at the XX Conference in Law and the Human Genome (21-22 June 2013 in Bilbao/Spain) is partly based on a contribution to the International Symposium “Medical Law against the Post-Genome Age” (28-29 June in Tokyo/Japan), published in Waseda Proceedings of Comparative Law 11 (2008), pp. 209-226.
worthwhile to look back to the time in which the institution of this 20th anniversary was founded and in what way the discussion on modern biotechnology has changed.

I will do this in four steps. In the first and second, I would like to go back to the findings and resolutions of an international conference on “Criminal law and Modern Bio-medical Techniques” which I had to organize for the Association International de Droit Pénal (AIDP) in the late 80s in Freiburg and Vienna - and thus around the time in which this Basque Chair was established. When re-examining those papers1, I got the impression that most of the general statements and demands made at that time are, at least in principle, still valid. This applies both to the main conflicting interests which arise from modern developments in medicine (II) and to the criteria and methods to be taken into consideration when looking for possible solutions (III). After these more principal remarks, special attention shall be given to interferences with the human genome (IV), with the focus on genetic diagnostics as that has recently become a very hot issue particularly in Germany (V). One of the experiences to be drawn from the relationship between law and modern medicine and biotechnology is its increasing interdisciplinary character. This may allow me to conclude with a plea for medical law as an “integrative” discipline (VI).

2. Benefits and risks of modern medicine and biotechnology – Conflicting interests

Revolutionary progress in modern medicine and biotechnology has produced highly appreciable success in the struggle against diseases and in the improvement of the human wellbeing. At the same time, however, it has also brought undesired side effects and dangers to man and mankind. To solve these new individual and social problems a reappraisal of traditional ethical principles and legal rules was and still is required.

The need is in particular due to the fact that modern medicine with its new methods and applications has developed far from the area of “classical” medical treatment – and this has aroused not only fascination but also considerable anxiety.

This concerns, not the least, the changing role and responsibility of the physician. Traditionally it was considered sufficient for physicians to act according to their conscience and their professional ethics. Nowadays such confidence is not enough. The need for intensified protection of patients and control over medical activity is in particular due to two modern developments:

- In former times a patient used to be treated by an individually known “family doctor” who, based on already existing personal relations, could be trusted upon without much ado. Meanwhile this has fundamentally changed: In modern medicine – especially when exercised in a hospital, though not only there - the patient mostly finds him- or herself exposed to a medical team hardly individually known. Furthermore, treatment is increasingly based on a variety of medical devices and apparatus.

- In addition, due to experimental employment of modern methods of biology and gene technology the medical team is not only composed of genuine physicians but may consist of, if not even be dominated by, scientists who by their very nature understand themselves primarily as researchers more interested in gaining new basic knowledge rather than concerned with the individual well-being of a patient.

As to domains in which new problems and colliding interests are more apparent than in traditional medical therapy, particular attention has to be given to research with human beings (both born and unborn, and most recently including embryonic stem cell production and research), transplantation of organs (both from living and already dead donors), human artificial procreation and reproduction, gene diagnostics and therapy as well as other methods of modern biotechnology.

Regarding the interests which in these areas can collide with each other, the following may be made aware of:

- On the one hand, especially in the field of human experimentation, the protection of the research subject’s self-determination by means of “informed consent” has to be considered as well as the protection of his life and her physical integrity against unjustifiable risks.

In some circumstances, the protection of human dignity against humiliating experiments or the exploitation of particular vulnerability may need special attention.
- Furthermore, modern reproductive medicine not only can lead to ignoring the interests of the prospective child but also to endangering the institutional protection of marriage and family.

- Modern genetic screening and genome analysis can entail discrimination in employment and insurance.

- On the other hand, however, regarding men and women longing for offspring, improvement of their psychic well-being or the aesthetic change of their physical appearance one has to consider their right to the free development of personality (including the right to procreation).

- Furthermore, with regard to freedom of science and research, these rights are not only in the individual interest of the researcher but also in the public interest of further medical progress – as scientific knowledge seems ultimately supposed to serve the prosperity of human beings and mankind.2

3. Criteria and levels of guidelines and regulations

The ambivalent developments in modern medicine and biotechnology are not confined to one country, rather they are of border-crossing character. There may even be an increasing interdependence of conflicting interests among the various countries. Therefore, both to promote equal standards in the treatment of human beings and to avoid discriminatory inequality between medical and biotechnological researchers of different countries, efforts should be made to achieve internationally uniform, or at least harmonized, standards and rules. As far as binding legal regulations appear necessary, these should be introduced on an international level.

➢ In balancing and resolving colliding interests, however, possibly divergent points of view and results have to be taken into consideration due to the influence of different religious, ethical and political convictions based on different social structures and legal cultures.

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➢ To take care of these different interests, differentiated levels and means of principles and rules may be required. These may start from rather “soft” professional guidelines in order to reach or maintain a primarily high ethical-deontological standard; and they may end up with legal regulations which, on their part, might provide diverse enforcement models and sanctioning methods, ranging from administrative-preventive measures to damages schemes of private law or even up to criminal sanctions.

➢ What control mechanism regarding bio-medical procedures will be best appropriate for a country, this can depend also on the ways in which the activities of health care in general and of research personnel in particular are used to be supervised by the ordinary control and sanctioning system of a country. So, while one country may consider it necessary to ensure the protection of patients and test persons by administrative measures or even penal sanctions, the other country may deem it sufficient to provide a regulatory framework in connection with a license authority controlling the activities in the field concerned.

➢ As, to the employment of criminal law as a control mechanism in modern medicine and biotechnology, in particular two cautions must be kept in mind:

- Criminal law, as the harshest and most stigmatizing sanction available in law, can certainly not be the only and all comprehensive device of control in this area. Before this sword is employed to any misconduct of a physician or researcher in the field of modern medicine and biotechnology, more refined instruments of control must first be engaged.

- Thus, as a means of “last resort” (in terms of an “ultima ratio”), the criminalization of medical and research activities is feasible only if the following pre-conditions are fulfilled: first (in German terms of “Strafverdienst”), the values endangered by misconduct must be so high and the blameworthiness of the endangering activity so grave as to be worthy of criminal protection; second, on the basis of a cost-efficiency comparison of different instruments, the employment of criminal punishment must prove as necessary (“Strafbedürftigkeit”) and, third, appear as a suitable means to reach the aspired effect (“Straftauglichkeit”).

After these rather general remarks of colliding interests in modern biotechnology and some strategies of how to solve them, in two more
special steps I would like to focus on interferences with the human genome: beginning with a review on former demands (IV) and continued with a report on the increasing public attention which in particular genetic diagnostics is recently finding in Germany (V).

4. Interferences with the human genotype: genome analysis and therapy

About 30 or 40 years ago when the public at large became finally aware of modern bio-medical techniques at all, primarily it had been questions of experimental therapy and research, organ transplants, in-vitro-fertilisation and other kinds of artificial human reproduction, and, as a sort of a necessary means or unavoidable by-product, embryo research and consumption, that dominated public and political debates. This is not to say that these issues are already out of question; but since meanwhile most countries promulgated more or less soft or restrictive regulations, these issues—maybe with the exception of stem cell research—have lost public attention, thus mainly left to lawyers and professional organizations.

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Somehow contrary to this primarily very high and then steadily decreasing interest in artificial reproduction, issues of the human genome are finding increasing public and political attention. This is not to say that 30 years ago the human genome was not yet on the public agenda. But at that time, not the least due to the scientific-biological complexity of these technologies, genome analysis and therapy as well as other interferences with the human genotype may have been discussed in professional circles rather than in public debates.

Nevertheless it may be interesting to remember what about 25 years ago had been recommended by the aforementioned international conference of the AIDP. Though recognizing the tremendous scientific progress reached in the analysis of the human genome with prospects of improved genetic diagnostics and therapy, considerable dangers going along with it must not be ignored. To keep them under control, certain regulations are wanted. These have been the main suggestions and demands at that time.

In principle, the inviolability of genetic inheritance against artificial intervention should be protected by law. (In this regard one may wonder whether this demand is already set satisfactorily accomplished).

- Special regulation is, in particular, necessary to protect the individual against non-therapeutical application of those techniques.

- Regulation may as well be needed to preserve public health interests. This especially concerns the protection of the environment against pollution possibly caused by biotechnological experiments.

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5 See supra note 1.

The use of prenatal genetic diagnosis should be limited to the suspicion of genetic diseases which appear to be particularly dangerous for the further pre- and postnatal development of the embryo.

- In particular, it was pronounced that employing prenatal screening to determine the embryo’s gender for the purpose of an abortion that is not justified by medical reasons has to be rejected as well as medical advice on the basis of prenatal diagnosis should be restricted to dangers threatening the health of the expected child.

- A further concern at the time was that the required consent of a pregnant woman to prenatal screening must not be made dependent on her willingness to a later abortion of the damaged child.

With regard to epidemiological tests on genetic damage, genetic diagnostics including the documentation related to the individual may, if at all, only be used if the test has a clear medical aim and the collected genetic information is sufficiently safeguarded from misuse.

- Prior to including a person in such tests, it has to have consented after having been comprehensively informed.

- The same applies for all further collection, storage or use of genetic information.

In order to guarantee data privacy and to prohibit wrongful discrimination, as in particular in employment and insurance on the basis of genetic screening or analysis, special legal protection was demanded and should, if not otherwise efficiently secured, be supported by penal sanctions.

Regarding gene transfer two techniques were to be distinguished:

- As concerns gene transfer in somatic cells for therapeutic purposes, there was no reason for any restriction so long as the rules provided for medical treatment are adhered to.

- Gene transfer to human germ line cells for other than therapeutic purposes appear unacceptable without exception. This technique was at least to be forbidden until the reliability and the safety of the germ line therapy have not been proven by prior somatic cell therapy and animal tests.
Cloning experiments on human beings have been found unacceptable and may be even prohibited by criminal law.

Experiments aimed at developing hybrids and chimera creatures by means of core fusion of human germ cells with those of animals were declared hardly reconcilable with human dignity. They should not be permitted and, if not otherwise to be prevented, sanctioned by means of criminal law.

5. Present debates in Germany on genetic diagnostics

Out of these various interferences with the human genotype, already discussed about 25 years ago, genetic diagnostics have gained increasing public attention, at any rate so in Germany. This extraordinary consideration is in particular evidenced by the fact that the German Ethics Council installed and selected by the Federal Parliament meanwhile submitted two comprehensive memoranda: one on pre-implantation diagnostics in 2011 and an even more comprehensive one on “The Future of Genetic Diagnostics - from Research to Clinical Application” – so its full title in english – just recently published at the end of April 2013. As it won’t surprise, none of these memoranda was passed without dissenting votes, although certain recommendations found clear majorities. As these statements reflect propositions and convictions of a mixed group of 26 politically independent members of different professional background, such as physicians scientists, philosophers, lawyers and social workers, and as their observations and recommendations are worldwide probably the most recent ones), it may be worthwhile to present some of their findings.

As to the overall development of genetic diagnostics the German Ethics Council observes three main trends:

- The increasing ability of exploring the entire genome of human beings.

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9 Cf. **Deutscher Ethikrat**, Genetischen Diagnostik, supra note 8, at 112 ss., 170 s.
- The exploitation of this knowledge with growing relevance for health, disease and the conduct of life.

- And with decreasing costs the quicker and broader availability of these techniques even for the professionals and, as a side-effect, a greater accessibility for abuse.

➤ These observations lead the Ethics Council to the following recommendations, thereby distinguishing between genetic diagnostics in general, prenatal diagnostics (PND), and pre-implantation diagnostics (abbreviated as PID in German and PGD in English).

(i) As to genetic diagnostics in general\(^\text{10}\), the recommendations begin with some more professional advises, such as to counteract against a one-sided genetic-biologic understanding of disease, to care for a quality based information of the public on the available genetic tests and their relevance, and to shape medical education in a way that physicians learn on what point they should refer a patient to a specialist.

- These general recommendations continue with improving informed consent by not simply relying on information, but acquiring a personal dialogue between the physician and his patient, particularly so with regard to the outcome of a genetic test.

- In face of the steadily growing mass and detailedness of genetic data, unless explicitly asked for by the patient, the physician should inform her not on every detail, but on types of possible results, such as certain groups of diseases, their gravity, the possible treatment, and is the probability and time of the outbreak of a disease.

- In case of non-competent persons, the exploration of data should be strictly limited to the individual diseases concerned.

- Regarding minors, the majority of the Council recommended that genetic explorations should only be admissible if necessary for the individual welfare of the person concerned.

- An own right of the physician to inform relatives of a genetic disease

\(^{10}\text{Deutscher Ethikrat, Genetische Diagnostik, supra note 8, at 172 ss.}\)
of the patient was objected to by the Council.

- Genetic diagnostics for non-medical purposes though possibly generating medically relevant results, as in case of an entire genome sequencing, this should be subjected to special information and consent and regulated by law.

- Penal sanctions should be provided for the performance of, or participation in, genetic techniques of another person without the required informed consent, as well as for false statements regarding the identity of the person the data come from.

(ii) The second set of recommendations is in particular devoted to prenatal genetic diagnostics (PND)\(^{11}\).

- Starting point is the observation that the increasing variety of diagnostic methods and the interpretation of the results require a particular high degree of genetic counseling: When coming to the decision not to perform a genetic test or to limit it to certain informations, that should be considered a responsible option.

- In these terms, the preparedness of parents to carry out a potentially handicapped child should be assured of social appreciation and advised to easier access to adequate public support.

- In order to avoid overreactions, the majority of the Council wants to have the performance of prenatal diagnostics restricted to the assumption of an heightened risk of a genetically conditioned defect.

- On the same line no information should be given on non--disease related genetic data of the unborn fetus nor on potential dispositions without relevance for the health of the child. In other words: these are precautions against prenatal diagnostic abuse in terms of positive eugenics.

- Regarding these restrictions on gaining and transmitting genetic information, however, a dissenting minority of almost 1/3 of the members of the Council voted against making it harder for the pregnant

\(^{11}\) Deutscher Ethikrat, Genetische Diagnostik, supra note 8, at 178 ss.
woman to gain knowledge of data which she considers essential for coming to a responsible decision.

- With similar pro and contra, the majority of the Council voted for introducing the obligatory counseling of the pregnant woman regarding potential genetic impairments, as it is prescribed for getting an abortion.

(iii) To reach unanimous decisions is even more difficult when it comes to the third area the German Ethics Council was asked for advice: the *pre-implementation genetic diagnostics (PGD)* for finding out whether an in vitro fertilized egg should be implanted or abandoned for reason of some genetic risk. This device is particularly controversial since it regularly entails the destruction of the diagnosed embryo.

One of the factual reasons why the German Ethics Council had to deal with this PGD already in a memorandum of 2011 was a decision of the German Federal Supreme Court on 6 July 2010: Contrary to the widespread opinion that the destruction of an embryo by PGD would not be reconcilable with the German Embryo Protection Act of 1990, the Federal Supreme Court stated that this technique is not covered by this statute. As this situation of a legal lacuna without any public control was widely considered unbearable, the Ethics Council was asked for advice.

When exploring the international scene, it turned out that within Europe mainly three different legal approaches exist. The largest group of countries, beside Portugal and Luxembourg including most East-European states, so far do not have a national legislation on this issue at all. A small group of countries, such as Austria, Italy and Switzerland, in principle forbid the application of PGD. The third part of European countries would allow the application of PGD within a certain legal frame, such as Belgium, France, Great Britain and Sweden.

Somehow similar to the diversity in Europe, the German Ethics Council was deeply divided in its decision, thus not even coming to a clear majority and therefore submitting two contrary alternatives: one for the legal pro-

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13 For details cf. DEUTSCHER ETHIKRAT, *Praimplantationsdiagnostik*, supra note 7, at 69 ss.
hibition of PGD\textsuperscript{14}, and the other one favoring its limited permission, bound by various restrictive conditions.\textsuperscript{15}

To make a long story short, after hot public debates the Federal Parliament finally followed the more permissive direction by inserting a new section 3a in the German Embryo Protection Act:

- In principle, this new provision does not only forbid, but even penalize the genetic exploration of the cell of an embryo in vitro prior to its intrauterine transfer.

- Yet, such diagnostics may be justified in two cases:
  - one when, based on the genetic disposition of the woman or the man or of both, a high risk of a grave genetic disease exists for the offspring,
  - second, if PGD is performed for determining a grave impairment of the embryo which with high probability may lead to a lethal miscarriage.

- In both of these justifications, however, the performance of PID requires various formal duties, such as
  - informed consent with regard to the medical, psychological and social consequences of the genetic diagnostics the woman is asking for,
  - the approval of an interdisciplinary examining commission on certain licensed centers for PGD,
  - the performance of PGD by a specially qualified physician,
  - and, in addition, various registration requirements.

- Regarding the practice of PGD, however, its limited permission in Germany will remain law on paper as long as necessary administrative by-laws are missing as it is still the case.

\textsuperscript{14} \textsc{Deutscher Ethikrat}, \textit{Präimplantationsdiagnostik}, supra note 7, at 111 ss.

\textsuperscript{15} \textsc{Deutscher Ethikrat}, \textit{Präimplantationsdiagnostik}, supra note 7, at 80 ss.
Anyway, since this new law already found criticism from divergent angles, it will probably not be the end of the German PGD story. A major objection is its inconsistency with our abortion law: because abortion, and thus the destruction of an unborn child, can be justified on much broader conditions than the destruction of an early embryo by means of PGD.16

In order to bring this hardly convincing difference in a feasible line, there is already a new proposal on the public table: presented by the ambitious draft of a comprehensive “Act on Reproductive Medicine”, most recently submitted by a private working group of law professors, mainly from the universities of Augsburg and München17.

6. Plea for Medical Law as an “integrative” discipline

After these special remarks on various issues of modern medicine and biotechnology I may be allowed to conclude with some more general considerations regarding the status of medical law as an interdisciplinary discipline. When looking back to the different branches of law which are touched upon by the various phenomena of modern reproductive medicine and genome biotechnology, it turns out that there remains almost no legal discipline that is not involved in the evaluation and regulation in this area: starting with constitutional law regarding human dignity and the rights to life, physical and hereditary integrity on the one hand and freedom of research on the other, going on with private damage and family law, dealing with administrative, labor and insurance issues, and quite frequently ending up with professional-deontological measures and even penal sanctions.

So far, in most countries, if not all over the world, each of these various legal disciplines is dealt with by different scholars and experts: medical-legal issues of constitutional nature will be addressed by colleagues whose main academic turf is in constitutional law, issues of private law are handled by family and torts lawyers, questions of criminalization are taken care of by criminal law people and so forth. Under such conditions, so-called “medical

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law” is, in fact, not yet a genuine discipline of its own but rather a puzzle of legal segments each of which approaches legal questions in medicine from a traditional field of law. Thus, representatives of medical law whose main field is in one of the “classical” disciplines of private, public or criminal law et cetera, will usually recognize part of the problems at stake only and therefore lack the ability of overlooking and understanding the entire medical issue in a comprehensive manner. This means that traditional medical law is merely a “sectorial” composition of partitions taken from various legal fields.

What is, thus, still lacking and all the more needed is a discipline exercised by a person who is less a specialist in one of these various legal branches, but rather a central combiner of the various sectorial knowledge derived from the special legal branches and integrated into a comprehensive picture. This, however, can hardly be expected from a scholar whose central standing is in private, criminal or any other special branch of law, thus, approaching medical issues from his periphery. It rather requires scholars and institutes which, centered in the middle and, from medical perspective, focusing on relevant parts of the various legal branches, try to select and integrate what is required from law in its entirety by the development of medicine.

This is, in short, what I have in mind when I am pleading for a change from traditional “sectorial” to an “integrative” medical law, as described in more detail elsewhere\(^\text{18}\). Regarding the Cátedra Interuniversitaria de Derecho y Genoma Humano at Bilbao the 20th anniversary of which we are happy here to celebrate, I am glad and grateful to say that in my view it is on the right way.