Internationalization of Bioethics: The Search for Common Norms of Bioethics in The EU and The Council of Europe

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Abstract: In this article, the development of bioethics in one of the most scientifically developed regions of the world - Europe- is discussed with reference to the enactments in the Council of Europe and the European Union. An international effort for the creation of ethical and methodological regulations in the medical arena has started in Europe. These efforts were primarily that of the Council of Europe with the Convention of Human Rights and Biomedicine and regulations by the European Union. This study examines the internationalization of bioethics and the national aspects of norm building and decision-making in Europe that covers the political parties, the different stances taken in public debates, evolution of norms and regulations involved in the process and the policies. The questions of the transformation of classical understanding of the state in Europe and the evolution of bioethical norms are also addressed in this study.

The article dwells upon the task of analyzing the attempts for common norms of bioethics in the EU and the Council of Europe in four parts. The *first* part discusses the formal aspects laying down the principles of bioethics in the domain of the Council of Europe and mainly focuses the Convention on Human Rights and Biomedicine. The *second* part moves the discussion to the European Union and generally outlines the attempts by the EU regarding bioethics and the rules of conduct upon the layer initiated by the Council of Europe. The *third* part draws out the future prospects in genetics and biotechnology and makes an assessment of the general trends. The *fourth* part makes a conclusion with a summary of the main points which were discussed through out the article.

Keywords: Bioethics, European Union, Council of Europe, Biotechnology, Human Rights

Introduction

In 'Rappacini's Daughter', Nathaniel Hawthorne, the famous 19th century American writer, tells the story of a scientist with the name Rappacini and his daughter who

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live in a big house with a huge botanic garden which is situated in an isolated estate from the social community. Dr. Rappacini, his daughter and few servants live alone in this big house without any interaction with other people. The garden, which has a wide variety of plants, flowers and trees, is notorious for its richness yet nobody other than the household is allowed to enter the garden. Dr. Rappacini, spending much of his time in his research laboratory alone, is suspected of making weird scientific experiments. Another weirdness of the scientist is that he does not allow anyone even the servants to get into physical contact with his daughter. Nobody is allowed to touch Rappacini's daughter. One day a young man sees the scientist's beautiful daughter behind the walls of the garden when she was wandering and falls in love with her. Although the girl tries to keep away from the young man due to the ban of his father, the man cannot refrain from her and gets involved with the daughter. However, the man dies in consequence of touching her as it surfaces that the daughter had a poisonous complexion due the experiments done by Dr. Rappacini on his daughter, which, of course, was an undesired consequence of the experimentation. The basic idea that Hawthorne pursues in this story is that the scientific intervention in nature might violate the natural order and hence disrupt the harmony. Furthermore, in result of this scientific exploitation, the mankind suffers from this obscure relationship, too. This fear and hesitancy toward the scientific and technological development is the subject of not only of literary fiction but also of politics.

Today, mankind, although not faces an immediate risk of 'dying' due to its intervention in the natural biological order or the nature itself but is still in the dilemma of the 'nature' versus 'culture' with a desire for scientific and technological progress on the one hand and the fear of change and irrevocability related to this interference on the other. The states and private corporations make huge investments in scientific research but at the same time, they try to control the undesired consequences of this dilemma by developing an ethics of the relationship of science with the individual and the society. To put differently, there is a search for rules of conduct for 'not dying' when 'touching the daughter'. This is also a reality evidenced by genetics studying death and seeking scientific explanations for mortality in genetic codes that order proteins to shut off life energy within the cells. Bioethics, the interdisciplinary study of problems created by medical values and progress (Olweny, 1994), surfaces as the triumph of this grand nature/culture dilemma in biological and medical sciences.

Scientific research on humans and its outcome involve a triangular categorical relationship between the individual, the society and the state. By a liberal view, this relationship underlines the individual rights, the common good and the regulatory sovereign as well as the conflicts that may arise between them. The modern state intervenes as the ultimate authority of regulation and specifically on bioethics it has the role of the definer of the boundaries, conductor of policies and guarantor of the legitimacy, accountability and the rules. This is more of a character of developed countries where research and development efforts in science and technology and therefore concerns over bioethics are greater than developing countries where there is not sufficient control for regulation if any kind exists.

It is argued that negotiating on economic concerns where material interests are at stake in the international arena is relatively easier, takes shorter period of time and ends with more concrete results than negotiating ethical concerns. Within the specificity of bioethics, it is emphasized that bioethics is a sphere where international cooperation and collective agreement can hardly be achieved. Rather, the modern state arises as the supreme authority and regulator on the bioethical issues instead of agents of international system such as international organizations and institutions. Contrary to the arguments that claim for the obsoleteness of the classical formation and power of the modern state (Hoffman, 1966), in this article it is suggested that liberal intergovernmental perspective which sets forth the liveliness of the state but with a different formation (Moravcsik, 1991; 1993) provides a valid explanation to the enduring bioethical discussions in Europe. Under the pressure of globalization, the modern state became more reflexive to the societies (Beck, 1997). Societies' general characteristics, beliefs, values, socio-economic structure, interest groups, religious affiliation, demographic nature plus historical background is at the core of the development of bioethics and reflexivity of the state contributes more to the its capacity of codifying ethical standards.

In this article, the development of bioethics in one of the most scientifically developed regions of the world - Europe- will be discussed with reference to the negotiations in the Council of Europe and European Union. An international effort for the creation of ethical and methodological regulations in the medical arena has started in Europe. These efforts were primarily that of the Council of Europe with the Convention of Human Rights and Biomedicine and regulations by the European Union. This study examines the internationalization of bioethics and the national aspects of norm building and decision-making in Europe, the parties, the different stances taken in the discussions, evolution of norms and regulations involved in the process and the policies. The questions of the transformation of classical understanding of the state in Europe and the evolution of bioethical norms are also addressed in this study.

The article dwells upon the task of analyzing the attempts for common norms of bioethics in the EU and the Council of Europe in four parts. The *first* part discusses the formal aspects laying down the principles of bioethics in the domain of the Council of Europe and mainly focuses the Convention on Human Rights and Biomedicine. The *second* part moves the discussion to the European Union and gener-

ally outlines the attempts by the EU regarding bioethics and the rules of conduct upon the layer initiated by the Council of Europe. The *third* part draws out the future prospects in genetics and biotechnology and makes an assessment of the general trends. The *fourth* part makes a conclusion with a summary of the main points which were discussed through out the article.

The Council of Europe and the Convention on Human Rights and Biomedicine

By 1980s, the borders in medicine and health care started to become questionable due to mobilization of the health services, patients and medical knowledge in Europe. The patients, doctors and researchers migrated from restrictive laws at home to liberal nations abroad. Additionally, the developments in medical science with its malpractices and ambiguities as reflected in the increase in the number of the cases held by the European Court of Human Rights made the need for a Convention in Europe explicit (Wachter, 1997; Rogers, 1992b). This conjecture of rapid and revolutionary changes in medicine as well as the inadequacy of the existing declarations of human rights has evolved for the need of building common norms and principles (Wachter, 1997).

The Council of Europe called for a pan-European convention on bioethics and respect for human rights in biomedical research by way of harmonizing national regulations of the member states in 1981 (Wachter, 1997). The aims were to eliminate the abusive use of science and technology, to protect human dignity and the psychic as well as physical integrity of the human being and to promote the interests and welfare of the individuals before the interests of the society (Wachter, 1997). In 1982 the Parliamentary Assembly started to discuss the possibility of a European agreement on legitimate applications of biological sciences to align domestic regulations and harmonize them at an international level (Wachter, 1997; Watson, 1997; Rogers, 1994b). However, bioethics was one of the issues on which the European Countries could not reach international consensus easily and speedily but within a long process of discussion, negotiation and compromise.

In the period of 1980-1990, the Council of Europe accepted many resolutions and recommendations on bioethical concerns of genetic engineering, research on embryos and prenatal testing. In 1987, the recommendation for joint action by all members and observer states was called for the development of common legal instrument in the European Convention on Biomedicine and Human Technology. The Council of Europe had formed an advisory group, which was turned into the Steering Committee on Bioethics (CDBI) based in Strasbourg in 1990. This Committee performing under the general committee of Science and Technology, started to work

on the draft of the Convention. In July 1994, the draft Convention has been released for public debate provoking hot debates among professionals and civic and governmental circles.

The supporters of the draft, which in principle had left further restrictions to national legislations, suggested that the Convention was satisfactory in its assessment of the common practices (Rogers, 1996d; Rogers, 1996e). Embryos until 14 days of age were argued to be permissible as objects of study under in-vitro conditions. The implementation of the 14-day rule for embryo research already applied in Denmark and UK was favored to be the norm for the Convention when national law allows research on embryos (Rogers, 1993a; Rogers, 1996f). Research in-vivo conditions, in other words on pregnant women, were and are still out of question.

On the other hand, the critics directed against the draft centered itself on the vague expressions were included in the draft. Upon the attempt to harmonize national laws, the draft was accused of having directionless impartiality when searching for the common denominator for international consensus (Wachter, 1997). Furthermore, the term bioethics, claimed to give the impression that the convention was exclusively an ethical convention and not a binding legal document (Wachter, 1997). Another point of criticism was directed against the legalization of the necessary medical intervention beneficial for the patient when appropriate consent could not be obtained, liberalization of research on human embryo in-vitro conditions, ambiguity of the limitations of genetic screening and use of genetic information although under limited circumstances (Wachter, 1997).

Germany, the major opponent to the Convention, directed the most severe critics against the Convention. Germany as the most unsatisfied party in the discussions demanded the Convention to be more restrictive and less ambiguous in wording. The German resistance stems partly from the fact that the bioethics convention became a political issue in the campaigns of the elections in 1994. All the political parties in Germany promised they would reject the draft of the Convention on the grounds that it did not go far enough (Wachter, 1997). The Convention, which was planned for signature in 1992, was constantly delayed due to disagreement on common standards. Upon dispute in the Parliamentary Assembly, twenty amendments were proposed in the draft and the vote was postponed mainly due to Germany's opposition (Wachter, 1997). The public discussion in Germany took very long, complicated and problematic process and it was much more heated than other national debates (Wachter, 1997). The public debate in Germany seemed to have been focused on the term 'incapacitated' of which the German translation is very difficult but only with 'handicapped of both physical and mental' (Wachter, 1997; Rogers, 1994a). Some of the non-governmental groups like 'International Initiative against the Planned Bioethics Convention' and the 'European Bioethics Network' interpreted the word as 'mentally ill, handicapped, old, drug addicts, chronic alcoholics, etc.' and claimed the draft to be racist. The Diaonisches Werk (German Evangelical Church) and the Roman Catholic Church also supported the groups who were against the Convention by arguing that it would enable the abuse of the research subject (Wachter, 1997). In 1994 the Justice Minister of Germany declared that on the issue of bioethics, any regulation against national legislation is strictly opposed and invasion of the human body can only be permissible under rigid legal and ethical restrictions (Wachter, 1997; Rogers, 1999).

The debates in the Bundestag in 1995 and 1996 also showed the sensitivity felt towards the scientific experiments during the Nazi period (Wewetzer, 1999). In the 1930s, the Nazis initiated the program of eugenics, which was the means of justification of the extermination of Jews, the handicapped and the gypsies. In the name of creating the master race, human guinea pigs were used in the biological experiments. Regarding these experiences of the past, the genetic sciences have never find a fruitful environment to develop in Germany and produced moral sensitivity on issues of bioethics, incapacitated people, consent and genetic engineering (Wewetzer, 1999). This is why Germany feels itself responsible in the field of bioethics. The majority of the Bundestag agreed on the international necessity of a Convention on bioethics but also claimed that the principle of common denominator was not sufficient on this very critical issue and more decisive and restrictive points such as genetic interventions and tests, embryo research, privacy protection and control mechanisms of the implementation of the convention were needed (Wewetzer, 1999). The German Delegation at CDBI rejected the articles of the draft like the transplantation of regenerative organs such as bone marrow and necessary medical intervention to incapacitated people and called for tighter regulations for the use of human embryos in research and special provisions on the handicapped people. Germany's stance can be summarized as demanding for more restrictive rules with less ambiguous expression in the text of the Convention (Wewetzer, 1999).

Although the Parliamentary Assembly of the Council of Europe has postponed the draft of the Convention of Bioethics several times due to critics mainly directed by Germany, CDBI in 1996 completed the final form of Convention on Human Rights and Bioethics that the Parliamentary Assembly approved. The general tendency in the Assembly was that bioethical matters were so complex and philosophical that they could not be held separately from other social concerns but there was the urgent need for a limited international regulation (Wachter, 1997). International agreements had to focus on basic issues rather than on details that would impinge on regulatory necessities to attain efficiency and speediness (Rogers, 1996f). Stricter

regulations were left to national legislations. The Convention guaranteed that signatory states would be able to maintain standards of protection higher than those offered in the Convention (Rogers, 1996f). Another use of the Convention was that it served as an instrument of guidance for ethical rules in Eastern and Central European states that had legal vacuum on bioethics after the disappearance of disciplines imposed by the authoritarian regimes (Rogers, 1993b; Blasszauer, 1990; Wachter, 1997; Rogers, 1996f).

In the Committee of Ministers, Germany and Poland rejected the Convention. The attempts of the CDBI like replacing the 'incapacitated' in the wording with 'people not able to give consent' did not satisfy Germany claiming that the draft contradicted the German Constitution. Poland's opposition mainly rested on Catholic religious criticisms against the permission to genetic engineering. Belgium abstained from voting because it was holding domestic discussions on the bill of human experimentation; therefore, it did not want any influence on its national legislation. Still, in November 1996, the Committee of Ministers approved the Convention on Human Rights and Biomedicine. 22 members of the Council of Europe signed the Convention in 1997 and most of them sent the Convention to national ratification. The Convention was ratified first by Greece, San Marino, Slovakia, Slovenia and Denmark. The Convention came into force and attained binding character in 1/1/2000. This convention is the first internationally binding document on medical ethics, research and genetics (Wachter, 1997). Other binding conventions on related subjects are 'Convention for the Protection of Human Rights and Fundamental Freedoms' and 'Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data'.

The Convention on Human Rights and Biomedicine has one preamble and 38 articles. In the previous drafts, the terms like 'persons', 'individual' and 'human being' were used but in the final format the subject term 'everyone' is used. In general, the Convention protects the patient rather than the researcher. Basic premise of the Convention is to set forth the interests of the human beings before the interests of the society which can only be overridden in certain circumstances like concerns of public safety, reducing crimes, protection of public health or for the protection of rights and freedoms of others. The Convention provides legal sanctions and compensation for people who are damaged after any medical treatment or research. The Convention emphasized the importance of equitable access to health care, ethical guidelines of research, tissue and organ transplantation, rules for disposal of human body parts, patients rights to know and not to know, the genetic testing possible only for health purposes, descent determination and evidence in official procedure for crime detection, ban of the commercialization of the human body and discrimination

on genetic heritage. The Convention allows genetic engineering for 'preventive, diagnostic, therapeutic purposes' without any modification in the genome of the descendants. It bans creation of embryos for research purposes. The Convention declares that 'where the law allows research on embryos and in vitro fertilization, it shall ensure adequate protection of the embryo.' Where such embryo research is allowed nationally, the embryo research must be limited to embryos that are not more than 14 days old. The experiments on humans can only be done if no other experiment can be done on other living organisms and if the benefits of the experiment are more than its costs. The consent of the patient should be taken. Intervention into incapacitated people is possible if the intervention is beneficial to the subject. Any transplantation of tissue/organ from the incapacitated is restricted unless the transplantation is for the benefit of the incapacitated person's siblings. The issue of consent mentioned in the Convention is historically important because it is the first international agreement where self-determination is accepted as a principle. It is also the defeat for the principle of inviolability of physical integrity.

The Convention was prepared by the principle of common denominator and contained the core of the fundamentals of bioethics. The national laws and regulations were harmonized in a way that the text would encompass the very fundamentals of the international bioethics (Wachter, 1997). However, the principle of common denominator and the distraction of the national laws into a supranational law get criticism on the basis that the result of the harmony and the decision of what the common denominator was incompatible with the national laws (Wachter, 1997). This also explains why the discussion on bioethical norms has not achieved a full consensus. For example, Germany voiced its criticisms by stating that the German national laws were stricter than the Convention. UK, on the other hand, claimed that the Convention rules were very rigid according to national law and they restricted scientific research and development. The supporters of the Convention claimed that the text enclosed the basic, minimal principles and the member states could enact stricter national laws if they were unsatisfied (Rogers, 1996e, Rogers, 1996f; Abbott 1996a). These rules were the lowest common denominator. They also argued that issues of ethics should be separated from issues of safety (Nature, 1997). These hot debates during the preparation of the Convention showed that to reach a consensus on ethical matters were hard to achieve yet the process could have been shortened by negotiating on mutually agreeable issues and delaying more controversial subjects to further protocols of the Convention (Rogers, 1996f). In 1997, the Council of Europe announced the protocol for the prohibition of cloning human beings. The Convention stated that '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 the descendants' (Rogers, 1997b). Since there was no mention of the term 'cloning' explicitly, there arose the need for a more explicit protocol after the technological developments in cloning such as the success of the cloned sheep named Dolly (Rogers, 1997b). Germany was again annoyed by these discussions and demanded for absolute ban of any kind of cloning (Rogers, 1997b).

The European Union and Bioethics

Advances in medical science and increasing cross border opportunities offered by the evolving European Union brought new issues to the agenda such as cross-passing national rules and demands by in-vitro tourism where patients travel from conservative rules on in-vitro fertilization to liberal law countries (Watson, 1994). Many biotech medical products are available in the European market. Consequently, free movement of people and goods across international frontiers and the ability to offer service to nationals of another member state necessitated regulation on health matters.

Among the European countries, the first national bioethics committee has been established in France. In 1992, in total nine countries, Denmark, Finland, Italy, Luxembourg, Malta, Netherlands, Norway, France and Portugal had these committees. In addition to national bodies, an international body as a regulatory center was suggested (Rogers, 1992b; Rogers, 1996a). However, it was realized that beyond the existence of bioethics committees, the bioethical codes of regulation in the countries were too divergent to be harmonized and policy similarities were minimal (Rogers, 1992b; Watson, 1994; Dickenson, 1999).

The European Parliament discussed the draft of the Convention of Human Rights and Biomedicine before its adoption by the Council of Europe whether the European Union members should sign the Convention or not. The Legal Affairs Committee proposed the draft to voting in the European Parliament and the Convention was rejected. The Committee approved a position paper instead, requesting a long list of amendments to the draft of the Convention of the Council of Europe. The European Parliament also issued a resolution that restricted human embryo research and freezing, in-vitro fertilization and prohibited discrimination in employment and insurance on grounds of genetic testing and on other tests assumed to predict behavioral features (Rogers, 1996c). This resolution was decided in the closing session of the monthly plenary and was passed speedily without deep discussions. The resolution was the success of the Christian Democrats allying with the Greens reflecting the good old German opposition. Further actions targeting bioethical consensus was out of the scope of the European Union (Watson, 1994; Rogers, 1996c).

The Council of Europe and European Parliament were of different opinions on bioethics (Watson, 1994). The European Parliament was in search for the definition of what might be ethically permissible in the economy of biotechnology in parallel lines of the free trade mentality (Rogers, 1992c). An ethical issue was seen worthy of elaboration or resolution if and only if that ethical issue was considered vital for free trade purposes (Rogers, 1992c). The Council of Europe, however, laid down rules from the viewpoint of human rights (Watson, 1994). In other words, the European Union had a more market orientation towards bioethics whereas Council of Europe focused more on humanitarian aspects.

A common policy on medical ethics had not been established for the European Union despite growing economic and political integration. The European Commission does not want to get involved in ethical matters because national practices differ a lot (Watson, 1994; Holm, 1992). Legislations on genetics, organ donation, embryo research, abortion and in-vitro fertilization are different in each country, which in a way reflect the cultural diversity between member states (Holm, 1992). For example, use of animal placenta is allowed as the raw material of certain cosmetics in some countries where as in others even research on embryos in-vitro conditions are restricted (Clark, 1995). The member states also have different rules for sustaining confidentiality in health. However, as economic and political integration gets deeper, the legislation and policies regarding bioethics become more problematic (Holm, 1992).

Although bioethical questions fall outside the scope of the Treaty of Rome, in the founding treaty of the EU, they are only considerable when they are related to consumer protection or other market related issues (Holm, 1992). Yet, the European Commission requiring all grant applications for research in the life sciences to be morally acceptable show that ethics in research was not totally disregarded (Rogers, 1996d). The Standing Committee of Doctors also pushes for a common regulation (Rogers, 1996d). European Society for Philosophy of Medicine, the European Association for Bio-industries and Health Care and European Association of Centers of Medical Ethics are other pressure and interest groups in the field (Holm, 1992).

The case of biotechnological patenting is an example for the prioritization of the economic concerns and market forces by the European Union. The European Union attempted to legislate biotechnology-patenting directive but it was rejected several times in the European Parliament due to ethical concerns (Rogers, 1995b; Rogers, 1992a). The European Directive on the Patenting of Biotechnological Inventions was criticized with the logic that patenting genes could pave the path for legalizing the commercialization of the human body (Roger, 1995b; Abbott, 1996a). In result, European Union could not reach an agreement on patenting of biotechnology that

harmonizes legislation across Europe. The European Commission continued to work on the resolution and institutionalization of the patenting in the European Union and after extensive consultation process and consequent modification of the patenting text, it was accepted in the European Parliament in 1996.

Approval of the directive by the Council of Ministers required a simple majority vote as was the voting required for free market issues. Therefore it took until 1998 that the EU has adopted 98/44/EC European Union Directive on Legal Protection of Biotechnological Invention and concluded that a gene could be patented by its discoverer if it could be proved that it was beneficial for a specific industrial application. It would not be possible to patent the human body or part of a human body. It would also be impossible to patent the simple knowledge of the structure of a complete or partial gene sequence without identifying its function. A patent would have to meet the primary requirements of novelty, inventive step and industrial application (Abbott, 1996a). The Directive has one article about ethical dimension of the biological studies that enforces European members that no patent would be available to those inventions of ethically unacceptable. The patent right excluded the possibility of any patenting of the human body but accepted other similar patenting in the field of life sciences such as plant and animal lives.

The Directive created its opponents and defenders as it happened with the Convention of the Council of Europe. The animal right activists campaigned against this directive. Netherlands opposed this directive on the basis of permitting the violation of animal rights. Scientists, on the other hand, claimed that if the directive excluded any patenting on living systems, then the scientific development and competitive power of Europe versus other developed countries would diminish.

The Directive for biotechnological development is insufficient because it lacks agreed standards on bioethics. The case of Edinburg patenting crisis is an example of this (Nau, 1994b). When a university in UK has gotten the patent of isolation, selection and propagation of transgenic stem cells through the European Patent Office, a great deliberation started. The European Patent Office located in Munich is the main authority on patenting and there are no other institutions that control the Office except the European Court of Justice upon appeal. The patent, in a way legalizing the study on human embryos, was found to be unethical by the European Parliament, European Commission and the Science and Technology Committee of the Council of Europe. The legal criticism against the patent rested on the claim that the patent by its nature was against the 1998 European Union Directive on Legal Protection of Biological Invention and 1997 International Convention on Human Rights and Biomedicine. The Directive rules that no patents would be available to inventions that are not ethically unacceptable. The International Convention on Human Rights and

Biomedicine, which is relatively more specific than the Directive in describing what is 'unethical', restricts any research in-vitro conditions on human embryos over 14 days of age. United Kingdom, although accused of pursuing its own research interests and therefore economic interests in a developing area of science, defended the argument that at the present stage, human embryos were subject to research with regard to infertility and contraception so why not for the investigation of diseases. The discussion on the research on the human embryo was followed by a similar discussion on cloning (Rogers, 1997a; Rogers, 1997b; Rogers and Ashraf, 2000). Some countries like Germany absolutely rejected the idea of clone and clone technology whereas others like United Kingdom and France favored the idea because organ transplantation would solve the problem of decrease in organ donors (Rogers, 1997a; Rogers, 1999).

United Kingdom is the most liberal Union member with regards to national legislation on bioethics. The bioethics in UK seems to be in parallel lines with the USA, which permit scientific researching on human body parts abstracted after therapeutic surgeries without consent of the patients whom the parts belonged to (Marshall, 1999). Even, in the USA, doctors advertise spare parts after surgery on the internet for research purposes (Fine, 1998; Clark, 1995). After the tissue or the organ is abstracted from the body, it is assumed that the person previously having the bodily part had lost its legal connection to that bodily part. However, UK differs from the USA by prohibiting the commercial use of the human body parts (Marshall, 1999). UK policies also require that volunteer donors should be well informed, should provide their informed consent, and should not be paid beyond expenses in return for their donation. The Nuffield Council, the supreme advisory body to the government in England, declared in 1995 that patients should not have any property rights over any tissue removed from them nor should hospitals profit from the sale or use of such tissue (Clark, 1995; Dyer, 1995).

The Nuffield Council on Bioethics established in 1991 receives funding from the Medical Research Council, the Nuffield Foundation and the Welcome Trust and works as an advisory body to the Department of Health that reviews the ethical framework and prepares national guidelines. The declarations of the Nuffield Council are liberal to the extent that they do not commercialize the human body (Clark, 1995; Pappas, 1994). It advocates for the liberalization of research for scientific purposes. Other existing channels of ethical approval in United Kingdom are local ethics committees, the Genetic Manipulation Advisory Group and British Transplantation Committee Ethics Division.

There were certain cases that caused great debate in United Kingdom such as xenotransplantation, artificial reproduction of post-menopausal women and infertile women getting pregnant by embryo/egg transplantation from dead women. On the issue of xenotransplantation, the Nuffield Council decided that the use of pig organs for transplantation was permissible. Yet, it also pointed to the need of controlling the problems that may arise from the rejection of transplanted organs by the host body and risks of transferring infectious diseases between species (Dillne, 1996; Ramsay, 1996). Pigs are one of the species that genetic structure is very similar to humans and furthermore, due to their reproduction speed, they are easily available. The problems that may arise after the transplantation of organs adopted from the pigs could be overcome by seeding the human genetic material onto the pig genome which would result in the creation of transgenetically mutated pigs. It is argued that xenotransplantation offers potential benefits under the scarce resources for organ transplantation (Dillne, 1996; Ramsay, 1996). It is thought that if eating animals is allowed for pleasures of appetite, it is logical and acceptable to allow their use for transplantation (Dillne, 1996).

The number of infertile women in United Kingdom is great and the research on reproduction is generally accepted because it meets the demand for knowledge on causes of miscarriage and abnormalities (Nau, 1994b). Yet these transactions needed bioethical regulation. Research on human embryos was regulated in 1990 by the Human Fertilization and Embryology Act, which prohibited propagation of an intact embryo beyond 14 days. Research projects on stem cells can be conducted under a research license issued by the Human Fertilization and Embryology Authority.

Another controversial issue was about genetic information. In 1997, the Association of British Insurers had issued a policy statement that those applicants for life cover should declare known genetic results (Rogers and Ramsay, 1997). However, after discussions on this statement the policy was limited to mortgage. The mortgage below 150,000 dollars would not need any genetic testing result until 1999 but for the amounts above 150,000 dollars would require a genetic testing that excludes the probability of sickness due to genetic reasons (Rogers and Ramsay, 1997).

France is another member state with liberal bioethics and a permanent biomedical agency – INSERM (Moreno, 1996; Nau, 1994a). The French Parliament adopted three laws on bioethics in 1994 after 10 years of medical, scientific, philosophical and political debate of which the two years spent in parliamentary discussion. Generally the public is against post-menopausal pregnancy due to the resulting of the age gap between the mother and the child (Nau, 1994b). The Catholic Church was against medically assisted conception. Scientists, on the other hand, were against restrictions on scientific research (Nau, 1992).

The first law acknowledges the integrity of the human body and dignity, respect for human life, genetic finger printing permissible only for medical reasons and scientific research conducted only by legal, medical and scientific institutions (Nau, 1994b). It also prohibits the patenting of human body parts and knowledge of its genetic structure. The second law regulates donation. It precludes that for donation, consent of the donor and the donor anonymity are to be provided. 'Man and woman forming the couple must be living, of reproductive age, married or living together for at least 10 years and consenting in advance to embryo transfer or insemination' (Rogers, 1997d; Nau, 1994a). Experiments on embryos are permitted for medical purposes under consent but post-menopausal pregnancies are forbidden. The law had to be changed in 1999 and therefore France changed it according to Council of Europe's protocol to the Convention that makes any research on embryo in-vitro conditions possible until the first 14 days of the fertilization. The third law regulates methodology of health research. The rule of medical confidentiality has been accepted as a general rule but the permission for the transmission of an individual's medical data for research in epidemiology, genetics and biostatistics opened the path for genetic studies further (Nau, 1994a).

France is of the idea that economic integration requires a balancing ethical structure and therefore it took the lead in enhancing legislation on bioethics in Europe (Rogers, 1994c; 1992b). France proposed the establishment of a pan-European bioethics body in 1994 similar to its national ethics committee but the idea was rejected with the argument that national ethics were different among countries and finding the common ethical principle would be preferable instead of importing from one of the member states (Rogers, 1994c; Holm, 1992). In order to investigate the common ethical grounds, some of the countries suggested forming a non-governmental body unlike the Steering Committee, which is intergovernmental (Rogers, 1994c; Rogers, 1996a).

Italy has National Committee for Bioethics (NCB) as a consulting body to the government founded in 1990 similar to the Nuffield Council of United Kingdom (Keates, 1992; Cattorini, 1994). The case of 'orphaned in advance' led to an interesting debate in Italy in 1990s. An Italian woman who died in a car accident had her egg transplanted and fertilized in her sister's womb. The sister gave birth to the genetic child of the deceased woman. This event led to debates in the National Bioethics Committee that resulted in some of the members resigning or some others to be dismissed from the Committee. Although some of the scientists named the event as 'orphaned in advance', the Catholic authorities struggled against any legalization of such a case. In result, artificial reproduction was not legally regulated and the existing law of 1994 only allowed simple in-vitro fertilization for married couples without any surplus of embryos. Although many bills were proposed, liberals and conservatives could not have reach an agreement (Cattorini, 1994). The decision-making procedure in CNB was unanimity and this hindered any conclusion for an

agreement because the committee members had different opinions on bioethical concerns. The main difference lied in the perception on embryos- some of the members viewed human embryo as a person from the moment of conception but some others argue that the embryos were not humans until 14 days after fertilization (Cattorini, 1994). The latter view was justified by the Convention on Human Rights and Biomedicine.

Although national debates on bioethics involve many pressure/interest groups, the citizens of the European Union in general feel poorly informed but are willing to learn about biotechnology according to 2004 Eurobarometer survey. Although the use of genetic tests to detect inherited diseases, to clean pollution and to develop genetically modified bacteria to produce medicine or vaccines is found morally acceptable, applications like cloning human cells or tissues to help a patient do not receive the same support. In addition, the public optimism about the potential benefits of biotechnology and genetic engineering has declined since surveys in 1993 and 1991. People are least supportive in countries such as Germany that have a greater public knowledge of the issues and basic science. Enthusiasm is higher in countries with less developed industries like Portugal and Spain. This can be interpreted as the level of involvement in nature by way of genetics increases, the fear of disrupting the nature increases.

Future Prospects in Genetics and Biotechnology

By the 21st century, we witness rapid and path breaking changes in health and medicine: pharmaceutical companies are internationally organized; market for drugs, insurance and medical technology has extended beyond domestic borders; patients going abroad for medical services increased; certain illnesses and viruses like HIV travel worldwide; medical research and cooperation contain international partners; telemedicine (health services via internet like the sale of human eggs on commercial web sites) and internet pharmacies started to take their places in global communication and international trade. These trends are not only illustrative of new innovations and advancements in human health but also of risks and malpractices such as the sale of human organs and commercialization of the human body (Wachter, 1997; Jost, 2000).

In this process of globalization, the national governments aim, by way of their health policies, the protection of their population from illnesses, malicious service, defective drugs and devices and the introduction of new safe methods of therapy and their availability to masses (Jost, 2000). At the national level, these attempts symbolize the desire for harmonizing the globalization process with the internal policies.

Yet, the nation states still feel the tension of designing health policies according to prolific scientific and technological developments that are external to them. This is, in some respect, impotency because the bureaucratic organization of the state cannot compete with the speedy changes and volatile mobilization taking place in health and medicine sector. For example, the drug viagra, which is used for sexual aims, was very quick to surpass national borders and to create a black market of its own before the national regulatory bodies of the state allowed its use. In a different case, in countries where abortion is legally prohibited, clients travel to countries with more liberal laws of abortion. The inability of the state to cope quickly and effectively with the impacts of the global medicine puts off the plea for sovereignty as the increase in the number of trials for violation of human rights in medicine shows (Jost, 2000). These trials are rooted in many internationally binding conventions such as 'Revised Declaration of Helsinki on Research Involving Human Subjects' (Jost, 2000). Under the pressure of globalization and the convergence of the borders, the sovereignty of the state is not divorced from its content and affectivity but a reformulation of the co-existential contract is at stake by way of developing shared norms and values of scientific conduct.

After the 2000s, in German media, the opinions that call for the liberalization of research on genetics and embryo research have started to be vocalized (Miller, 2000). Due to mass protest against a biochemical company, the Company Bayer has decided to plant new investments in biotechnology to USA where relatively more liberal laws are at stake. This took 1,300 new jobs away from Germany (Miller, 2000). The sensitivity toward biotechnology and medical ethics in a way delayed scientific research for years and scientists and investments migrated to ethically more liberal countries. Interestingly, attitudes toward genetics start to change at the state level and developed countries like Germany came to a point of not being able to resist this newly growing biotechnology and realized the interest rooted in the competitiveness in this sector (Rogers, 1996c). Germany has spent 1.2 billion DEM to support human genome project studies at German Universities (Miller, 2000). This trend is valid for other members of the European Union. Total investment on biotechnology in 1999 has increased by 53 % by 579 million euros when compared to 1998 investment figures (Miller, 2000). The shares of biotechnological companies are in an increasing trend in German, French and Italian stock markets. In United Kingdom, the most developed country on biotechnology in Europe, has 560 biotechnological companies and most of the new patents in this sector are obtained by the United Kingdom (Miller, 2000). The French Government has allocated 260 million USD to biotechnology in 1999 (Miller, 2000). Netherlands and Sweden also have biotechnological companies that work on protein codes. Some of the European based pharmaceutical companies face unusual number of expiring patents and they start to invest in life science companies for the innovation of new drugs. These developments show that biotechnology, as an economic sector, is one of the most profitable sectors in the future European market. The development of bioethics and the establishment of common standards will take place greater in the future discussions within the European Union. In other words, as economic concerns become materialized with scientific achievements in genetics and biotechnology, the European Union states will need to develop binding sets of rules and norms that obviously will require fierce discussion and negotiation. It is also predicted that scientific progress equipped with market forces would not keep bioethics silent yet at the same time would not wait for bioethics to surpass.

Conclusion

The general framework of human rights that is considered to be an essential norm and constituting value of the European Union does not provide adequate prescriptions for bioethics and rights of the individual vis-à-vis science, society and state. The emergence of bioethics is a necessary tool in the conduct of modern science and state-society relations. As societies get more complex and advanced in medical sciences and technologies, in a positive correlation, the discussion on bioethics flourishes, deepens and widens.

The argument that consensus among the European Union governments had been difficult in the field of high politics (i.e. foreign and security policies) but had been easier in the field of low politics (i.e. economic and technical issues), does not explain what had happened in the arena of bioethics. This argument, by rejecting the natural outcome of spillover from low to high politics, attributes national interests to be vested in high politics and transnational interests to be influential in low politics. On the bioethics discussions and negotiations, it can be claimed that such a conclusion is hard to reach. Bioethics, which can be considered a technical matter belonging to the sphere of low politics did not follow the path of smooth negotiation and what's more, consensus was not easily achieved. The realist presumptions such as 'the states are guided by national interests' also do not provide satisfactory explanations to the evolution of bioethics and the transformation of the state apparatus in redefining its sovereignty and legitimacy. There are other actors besides states that are actively involved in bioethics and scientific research. There is a constant bargaining going on internally within states by pressure groups and externally among states in institutional settings and European wide non-governmental organizations. In sum, neither the neo-functionalist paradigm in the theories on European integration that presumes spillover in a cooperative and interdependent international system nor the realist paradigm that rests on the primacy of the state interest and the states' decision making totality fit to the discussion of bioethics.

The liberal intergovernmental perspective that makes the internal mechanisms of decision making and international bargaining processes visible to the integration theories gives a more satisfactory explanation of why common ethical policy is as difficult as common foreign policy. The European Union has not come to the point of acting on its own as a regulatory mechanism. The national interests of the states motivate the states for developing an external policy but other factors like the historical experiences of the states (such as Germany regretting the experience of eugenic), the population characteristics (such as the great number of infertile women in United Kingdom), the welfare values (such as sensitivity toward incapacitated persons), market forces (such as the proliferation of biotechnological companies in United Kingdom and France and the position taken by the insurance companies in United Kingdom) and the effect of religious values (felt more vigorously in Italy, Ireland and Poland – Catholic countries) also play important roles in the codification of bioethics. The liberal intergovernmental paradigm, furthermore, shows that the consensus on bioethics is not only internationally but also internally is not easy to achieve due to different positions at the national level between different actors and social groups with different interests and world views. The nation states in this conjecture do not act on their own behalf but in an understanding of reflexive government re-establish their sovereignty by defining the boundaries of bioethics and directing its evolution legally. In other words, the transparency of the borders and the globalization processes reaffirm construction of the dominancy of states with claims over the protection of national public health policies and national interests in the discipline of bioethics. Globalization is an important aspect in the evolution of bioethics.

Democracy is a method of decision-making and deliberation, consultation, persuasion and discussion are important device in this process. The procedure for becoming informed is as vital as the voting mechanism in deciding the 'common good' communicatively. In light of the discussions of on Europe-wide deliberative politics, it can be claimed that although bioethics had shown that despite lack of consensus on bioethics, the procedure of deliberation among social groups and among states in Europe have strengthened democracy and the legitimacy of the decisions.

Eurobarometer shows that most of the Europeans feel themselves not sufficiently informed on biotechnology. This implies that more deliberation and communication is needed for the development of bioethics. The different parties- the insurance companies, the biotechnology companies, the investors, professional organizations, universities, patient organizations, rights defenders (human rights, animal rights),

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environmentalists, feminists, churches, political parties and associations should have a say in the deliberative politics and contribute to democratic decision-making processes.

Biyoetiğin Uluslararasılaşması: AB ve Avrupa Konseyi'nde Ortak Biyoetik Kuralları Arayışı

Özet: Bu çalışmada dünyanın bilimsel olarak en gelişmiş bölgelerinden birisi olan Avrupa'da biyoetiğin gelişmesi Avrupa Birliği ve Avrupa Konseyi'nde yapılan çalışmalar ışığında tartışılmaktadır. Tıp alanında etiksel ve yöntemsel düzenlemeler Avrupa'da bir süredir ele alınmaktadır. Özellikle Avrupa Konseyi'nin İnsan Hakları ve Biyoetik Sözleşmesi ve Avrupa Birliği'nin ilgili yönetmelikleri alandaki önemli belgelerdir. Bu makalede biyoetiğin uluslararasılaşması ele alınmakta fakat bununla birlikte bu uluslararası düzlemin alt yapısını oluşturan ulusal mekanizmalara ve karar verme yöntemlerine de değinilmektedir. Ulusal düzlemde kural koyuculuğun siyasal partileri ve kamusal alandaki tartışmaları kapsayan incelemesinde mercek altına alınan kuralların ve düzenlemelerin evrimsel gelişimidir. Biyoetik kurallarının evrimi Avrupa'daki klasik devlet anlayısının değişimi ve dönüşümüne dair önemli ipuçları da sunmaktadır.

Makale Avrupa Birliği ve Avrupa Konseyi'ndeki ortak biyoetik kuralları arayışlarını dört alt başlık halinde analiz etmektedir. Birinci kısımda Avrupa Konseyi tek başına ele alınmakta ve İnsan Hakları ve Biyoetik Sözleşmesi özelinde ortaya çıkan temel biyoetik prensipler değerlendirilmektedir. İkinci kısım, tartışmayı Avrupa Birliği'ne taşımakta ve Avrupa Konseyi'nin belirlediği biyoetiğin yöntemsel sınırlandırmalarının üzerine inşa edilmeye çalışılan mevzuatı tartışmaktadır. Üçüncü kısım genetik ve biyoteknoloji alanlarında genel eğilimleri ortaya koymakta ve geleceğe dair öngörüleri değerlendirmektedir. Dördüncü ve son kısımda makalenin içeriği özetlenmekte ve değinilen ana noktalar kısaca hatırlatılmaktadır.

Anahtar Kelimeler: Biyoetik, Avrupa Birliği, Avrupa Konseyi, Biyoteknoloji, İnsan Hakları

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