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Source / Izvornik: **Jahr : Europski časopis za bioetiku, 2011, 2, 385 - 394**

**Journal article, Published version**

**Rad u časopisu, Objavljena verzija rada (izdavačev PDF)**

Permanent link / Trajna poveznica: <https://um.nsk.hr/um:nbn:hr:184:799511>

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Download date / Datum preuzimanja: **2024-09-26**



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## European bioethics institutionalisation in theory and practice

### ABSTRACT

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The starting point of this paper is the role the institutions as social facts, have in modern (European) society, as well as the exploring of the meaning and purpose of the institutionalisation process. Institutionalisation is seen as the process understood as establishing different normative and organisational institutions.

Our interest is also concentrated upon following the line of (European) bioethics. Since V. R. Potter used this term in 1970/71 for the first time, bioethics has rapidly *conquered* various levels of the American society, becoming well known and even better present in a series of institutions. At the same time, almost contrary to the American example and experience, European continent has for a long time been resistant to the term of bioethics, as well as to the very idea of such discipline. Until recently, European orientation and devotion to the traditional terms (medical ethics, biomedical ethics, physician's deontology, etc.) and the misconception of (American) bioethics, have been main reasons for the lack of or poor bioethical institutionalisation in European countries and the Union.

Being discovered in 1997 and promoted since 2007, the work of Fritz Jahr has been spreading new lights onto the originality and authenticity of bioethical ideas in Europe, offering remarks regarding the Bioethical Imperative and institutions, as well as possibilities of European bioethical institutionalisation.

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## Introduction

Presented at the first international conference devoted to Fritz Jahr and European bioethics (Croatia, Rijeka/Opatija, 11-12, March 2011), the major part of this paper brings out the results of the research undertaken for the purposes of doctoral thesis entitled *Theoretical strongholds, achievements, and perspectives of bioethics institutionalisation in European Union*<sup>1</sup>.

Orientation towards the European issues in bioethics stresses not only the new trends in the history of bioethics (with emphasis on Fritz Jahr's work), but also opens new chapters in research of bioethics itself. Although bioethics today represents one of the most prominent part of scientific community and almost unique phenomena of different discipline collaboration, research on bioethics usually omits the sociological perspective. Previous attempts of strengthening chains between social sciences and bioethics (De Vries 1998, 2004, 2006, 2007) often remain at using social sciences methods in bioethical research, lacking the possibility of deeper sociological research of bioethics. Going back to the sociological foundations brings out the institutions as facts and products of social reality, as well as points of social stability and creators of new trends. In this sense, understanding the phenomena of bioethical institutions and process of institutionalisation is an important part of undertaking research on bioethics. Exploring the specific characteristics of bioethical institutionalisation in Europe, calls for well known position in theory of institution (Arnold Gehlen), but also for new (bioethical) perspectives regarding institutions (Fritz Jahr).

Due to preliminary results of the project 06.05/17 "*Fritz Jahr and European Roots of Bioethics: Establishing the International Network of Scholars*", EUROBIONETHICS) financed by the Croatian Science Foundation<sup>2</sup>, this paper brings out Jahr's position on institution as a possible contribution to European bioethics institutionalisation process.

## Institution - from social fact to institutionalisation process

Although mostly present in every day life and conversation, there is still no universal definition of the term, meaning and purpose of institution. Going beyond narrowed terminological explanations, in terms of *institute, establishment, association, founda-*

<sup>1</sup> Under the mentorship of professors Ante Čović and Nada Gosić this doctoral thesis was prepared and defended on 12 November 2010 at Faculty of Humanities and Social Sciences, University of Zagreb.

<sup>2</sup> See Introduction.

tions or rule, law, decree, regulation etc.<sup>3</sup>, few sociological founders offer much broader explications<sup>4</sup>. According to Emile Durkheim (1858-1917), the precondition of forming and existence of institution is society's own entity, existence of social life, above pure sum of its individuals<sup>5</sup>. Being new *sui generis* category, society gains new potential: creating its own (social) forms - institutions. In this sense, institutions are facts of society or, even more, social facts, realisation of social collectivity independent of individual wishes, having their own collective existence<sup>6</sup>. Such position still omits other important postulate of Durkheim sociology, the one regarding the role of institutions: "Social fact is any kind of agency having outwarded coercive measure toward individuals."<sup>7</sup> In this sense, compulsion and force are not the essence of social facts, but exterior trait to be recognised and generally accepted by individuals.

Modern definitions of institution even more emphasise their enduring character and society stabilization role: according to Jonathan Turner, institution is "... a complex of position, roles, norms and values lodged in particular types of social structure and organising relatively stable patterns of human activities with respect to fundamental problem in producing life-sustaining resources, in reproducing individuals, and in sustaining viable societal structures within a given environment."<sup>8</sup>, Anthony Giddens claims that "Institutions by definition are the most enduring features of social life."<sup>9</sup> while Jon Elster adds that "Institutions are mechanisms imposing rules and protecting society from decay (as long as there is something protecting institutions from decay)."<sup>10</sup>

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<sup>3</sup> Iva Rinčić, "Teorija institucija Arnolda Gehlena: prilog istraživanju bioetičkih institucija/Arnold Gehlen's Theory of Institutions: A Contribution to the Analysis of Bioethics Institutions", *Filozofska istraživanja* 117-118 (1-2/2010), p. 150., according to Bratoljub Klaić, *Rječnik stranih riječi/Foreign words dictionary*, Nakladni zavod Matice Hrvatske, Zagreb 1986, p. 596.

<sup>4</sup> According to Stanford Encyclopedia of Philosophy, contemporary sociologists even today accept narrow definition of institutions "... to refer to complex social forms that reproduce themselves such as governments, the family, human language, universities, hospitals, business corporations, legal system." (Social Institutions, *Stanford Encyclopedia of Philosophy*, <http://plato.stanford.edu/entries/social-institutions>, 13 June, 2011).

<sup>5</sup> Emile Durkheim, *Pravila sociološke metode/The Rules of Sociological Method*, Naklada Jesenski i Turk, Hrvatsko sociološko društvo, Zagreb 1999, p. 12.

<sup>6</sup> E. Durkheim, *Pravila sociološke metode/The Rules of Sociological Method*, p. 19.

<sup>7</sup> Rade Kalanj, "Predgovor hrvatskom izdanju: Emile Durkheim i metodološko utemeljenje sociologije/Preface to the Croatian translation: Emile Durkheim and methodological foundation of sociology", in: Emile Durkheim, *Pravila sociološke metode*, Naklada Jesenski i Turk, Hrvatsko sociološko društvo, Zagreb 1999, p. VIII. (translation I. R.).

<sup>8</sup> Jonathan Turner, *The Institutional Order*, Longman, London 1997, p. 6.

<sup>9</sup> Anthony Giddens, *The Constitution of Society: Outline of the Theory of Structuration*, Polity Press, Cambridge 1984, p. 3.

<sup>10</sup> Jon Elster, *Uvod u društvene znanosti – Matice i vijci za objašnjavanje složenih društvenih pojava/Nuts and bolts for the Social Sciences*, Naklada Jesenski i Turk, Hrvatsko sociološko društvo, Zagreb 2000, p. 175. (translation I. R.).

It is obvious that we here stand at the position of holistic – including structuralist-functional account, stressing the inter-relationship of institutions themselves (structure), as well as their function in broader society<sup>11</sup>. Seen in this way, institutions have their own structure, organisation and universally known procedures of maintaining, but their mutual connection with other parts of society is also not a question. Without being well incorporated and accepted by the individuals outside institution, institutions lose their own stability and (in the long run) reasons of existence.

In conclusion, here are several notes on process of making institutions – institutionalisation. Although the crucial moment of creating institution is the one when earlier agreed and accepted *contract*<sup>12</sup> acquire institutional form, broader view of understanding institution impose not only pure act or signature, but complete process, period of time in which all needed elements become institutionalised. Even the dynamics of institutions itself, would be more understandable if we accepted institutionalisation as a variable, not a constant or nominal category, points Peters<sup>13</sup>.

## Bioethical institutionalisation in the United States

It is always difficult to be precise in pinpointing the beginning of historical period, cultural movement or, even more, academic discipline. It is the same with bioethics. Although today we know that the first mention of bioethics is the one by a German protestant theologian Fritz Jahr (1895-1953)<sup>14</sup>, still a lot has to be done in exploring the foundation of bioethics. In the meantime, several decades later, new history of bioethics is on stage.

<sup>11</sup> "Functionalist theories in the social sciences seek to describe, to understand and in most cases to explain the orderliness and stability of entire social system. In so far as they treat individuals, the treatment comes after and emerges from analysis of the system as a whole. Functionalist theories move from understanding of the whole to an understanding of a part of that whole, whereas individualism proceeds in the opposite direction." (Barry Barnes, *The Elements of Social Theory*, Princeton University Press, Princeton, N.J. 1995., p. 37., according to Social Institutions, *Stanford Encyclopedia of Philosophy*, <http://plato.stanford.edu/entries/social-institutions>, 13 June, 2011).

<sup>12</sup> In here mentioned meaning, *contracts* are what John Searle calls *conventions*. In his "theory of institutional factors", social facts have their own ontological status, reality in a material world. Money, property or points in premium are not important just for the reason of their material characteristics, but because of the agreement of society upon their other function or value. Institutional facts are the issue of conventional formation (Patrick Pharo, *Sociologija moralna/The Sociology of Moral*, Masmedia, Zagreb 2008., p. 69.).

<sup>13</sup> Guy Peters, Institutional Theory: Problems and Prospects, *Political Science Series* (69/2000), p. 13.

<sup>14</sup> Fritz Jahr, "Bio-Ethik. Eine Umschau über die ethischen Beziehungen des Menschen zu Tier und Pflanz", *Kosmos. Handweiser für Naturfreunde* 24 (1/1927), p. 2-4.

In the last few years lot of work had been done in exploring the American development of bioethics<sup>15</sup>, but no universal answer has been offered. Despite different and opposite explanations, there is no disagreement upon the fact that important element of bioethical development and success was institutionalisation in different parts of social life<sup>16</sup>.

Coming out from the ruts of other American 1960s social movements (women, minorities, peace movement, children, patients...) in the 1970/71, the works of V. R. Potter (1911-2001), plea for institutionalisation of *bioethical* ideas were even earlier a part of Potter's interests. Potter has found the motion for introducing institutional university unit (Future Department) in the works of Margaret Mead (1957), but his permanent interest in providing more humanistic context for modern men culminated in the early 1960s<sup>17</sup>. In 1961 he participated in organisation of Interdisciplinary Seminar for the Future of Men (for university teachers), then at the American Academy of Arts and Sciences' conference, and in the year 1962 at the University of South Dakota he held the lecture *Bridge to the Future. The Concept of Human Progress*. By the same year, Committee for Interdisciplinary Research of Future of the Man has become an official unit of his affiliation (University Wisconsin – Madison)<sup>18</sup>.

1960s traces of bioethics hide one even more important institutional reference of future bioethical development – establishing the first (1962-1967) Ethical Committee in Seattle (Washington State), "... trying to set up ethical standard for the distribution of a scarce medical technology to dying patients (Renal Dialysis)." <sup>19</sup> Estab-

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<sup>15</sup> Tristram H. Engelhardt, *The Foundations of Bioethics*, University Press, New York 1986., Waren Thomas Reich, "The word 'bioethics': its birth and the legacies of those who shaped its meaning", *Kennedy Institute of Ethics Journal* (4/1994), p. 319-336., Albert Jonsen, *The Birth of Bioethics*, Oxford University Press, Oxford 1998., Diego Gracia, "History of medical ethics", in: Henk A. M. J. ten Have and Bert Gordijn (ed.), *Bioethics in European Perspective*, Kluwer, Dordrecht 2001., p. 17-50., Tristram H. Engelhardt, "Introduction: Bioethics as a Global Phenomenon", in: John F. Peppin and Mark J. Cherry (ed.), *Regional Perspectives in Bioethics*, Taylor & Francis Group, London – New York 2008., p. XIII-XXI.

<sup>16</sup> According to Fagot-Largeault, bioethical institutionalisation is one of the stages in development of bioethics (Anne Fagot-Largeault, "L'Émergence de la bioéthique", *Revue philosophique de la France et de l'étranger* 129 (3/2004), p. 345-348.).

<sup>17</sup> Even before this period there were many books *announcing the arrival of bioethical era* (Rachel Carson, *Under the Sea Wind*, Oxford University Press, New York 1941, Aldo Leopold, *A Sand County Almanac*, Oxford University Press, New York 1949, Rachel Carson, *The Sea Around Us*, Oxford University Press, New York 1951, Norman J. Berrill, *Man's Emerging Minds: Man's Progress through Time – Trees, Ice, Flood, Atoms and Universe*, Dodd, Mead and Co. New York 1955, Rachel Carson, *At the Edge of the Sea*, Houghton Mifflin Company, Boston 1955, Rachel Carson, *Silent Spring*, Houghton Mifflin Company, Boston 1962).

<sup>18</sup> Van R. Potter, *Bioetika – most prema budućnosti/Bioethics - Bridge to the Future*, Katedra za društvene znanosti Medicinskog fakulteta Sveučilišta u Rijeci, Hrvatsko društvo za kliničku bioetiku, Hrvatsko bioetičko društvo, Međunarodno udruženje za kliničku bioetiku (ISCB), Rijeka 2007, p. 24.

<sup>19</sup> James F. Drane, *A Liberal Catholic Bioethics*, Münster, LIT Verlag 2010, p. 35.

lishing new form of institutionalised decision making in medicine<sup>20</sup> (interdisciplinary ethics committee vs. physician's paternalism) for some authors represent real birth of bioethics and the moment when the development of later bioethical institutionalisation, sensibility and scientific – professional discussion can be traced later<sup>21</sup>.

Important turning point in many ways in American bioethics are the occasions of establishing scientific institutes and centres. First among them, Institute of Society, Ethics and the Life Sciences (today's Hastings Center, New York), originates from March 1969, owing emergence to Daniel Callahan i Willard Gaylord. As before Potter's work the term and definition of bioethics were unknown in American society, founders decided that the mission of the Center would be "... to address fundamental ethical issues in the areas of health, medicine, and the environment as they affect individuals, communities, and societies."<sup>22</sup>

Bioethical centre situated in the capital of the USA is even more important due to the vision of Andrè Hellegers and Sagent and Eunice Kennedy Shriver. During 1967 the Kennedy Foundation and Harvard Divinity School had already cosponsored international conference on abortion, "... to which both European and North American scholars were invited. In October 1971, within months of the Kennedy Institute's opening, the Foundation sponsored an international conference with the theme 'Choices on Our Conscience.' Speakers from Europe joined their North American colleagues in exploring some of the major issues of that time."<sup>23</sup>. Despite controversies regarding the genesis of the term and name of the Institute (according to Engelhardt it is still not clear whether Hellegers and Shriver *de novo* invented the term or re-applied the one already coined by V. R. Potter), the Kennedy Institute of Ethics "successfully applied a name to a social phenomenon that by the end of 20th

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<sup>20</sup> Crucial role in American birth of bioethics was the tendency of institutionalisation concrete ethical deliberation, assisted by advance of medicine after the Second World War and resumption of normative ethics (Milenko Perović, "Etičke granice bioetike/Ethical limits of bioethics", *ARHE* VI (12/2009), p. 11.). "In the mid-1960s, it became clear that most of medical ethics was really medical morality – a set of assertions and moral precepts without a formal groundwork of ethical justification or argumentation. While many of these moral precepts might be valid, without a justifiable ethical foundation they could easily be challenged, denied, or compromised. This is indeed what happened when medical moral were subjected to critical philosophical inquiry in the early 1970s." (Edmund D. Pellegrino, "From Medical Ethics to a Moral Philosophy of a Profession", in: Jennifer K. Walter and Eran P. Klein (ed.), *The story of bioethics: from seminal work to contemporary explorations*, Georgetown University Press, Washington, D.C. 2003, p. 4-5.).

<sup>21</sup> Ivana Zagorac and Hrvoje Jurić "Bioetika u Hrvatskoj/Bioethics in Croatia", *Filozofska istraživanja* 28 (11/2008), p. 602.

<sup>22</sup> Web page of The Hasting Center points out that it has been "... a non-partisan research institution dedicated to bioethics and public interest since 1969" (<http://www.thehastingscenter.org/About/Default.aspx>, 19 August, 2011).

<sup>23</sup> LeRoy Walters, "The Birth and Youth of the Kennedy Institute of Ethics", in: Jennifer K. Walter and Eran P. Klein (ed.), *The story of bioethics: from seminal work to contemporary explorations*, Georgetown University Press, Washington, D.C. 2003, p. 215-216.

century had transformed the moral context within which medical and science policy were framed. ... The result was a cultural turning point: the establishment of a socially recognized body of moral experts in authority to give moral direction regarding moral decision-making and conduct in health care and the biomedical sciences."<sup>24</sup>

In the year 1987 American Hospital Association published a description of 77 bioethical organisations in USA; since than, such number tripled<sup>25</sup>.

In the field of government involment of regulating biomedical practice and scientific research, much has been done in the United States since Second World War, but still with questionable success. Different attempts (Beecher, 1967) were constantly reminding American public sphere on misconduct of scientific practice or even more, unsatisfied ethical standards in health care.

Even before the establishing of first hospital ethics committees in 1960s, American government in the year 1953 proposed Group Consideration for Clinical Reserach Procedures Deviating from Accepted Medical Practice or Involving Unusual Hazards to be used within newly open NIH reserach hospital (Bethesda, Maryland)<sup>26</sup>. In the 1960s U.S. Public Health Service started to establish permanent ethical standards for research practice, and during 1970s formed the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Reserch. Beside 125 recommedations for improving the protection of human rights and welfare of human subjects, this Commission published the Belmont Report, identifying basic ethical principles (respect for person, beneficence, justice)<sup>27</sup>.

The first public national body to shape bioethics policy in the U.S. was created by the Congress in 1974 and was under the Dept. of Health, Education and Welfare (now known as the Dept. of Health and Human Services), followed by:

[1974-1978] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

[1978-1983] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research

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<sup>24</sup> Such statements are not easy to give, but it is precisely Hellegers's and Shriver's use the term of bioethics in a meaning of biomedical ethics (in a name of new founded university centre) reason of such trend in USA later on (Tristram H. Engelhardt, "Introduction: Bioethics as a Global Phenomenon", p. XV).

<sup>25</sup> F. Drane, *A Liberal Catholic Bioethics*, p. 41.

<sup>26</sup> Robert J. Levine, "Research Ethics Committees", in: Warren T. Reich (ed.), *Encyclopedia of Bioethics*, Rev. ed., Simon & Schuster Macmillan, New York 1995, p. 2266., according to Mortimer B., Lipsett, John C. Fletcher and Marian Secundy, Research Rewiew at NIH, *Hastings Center Report* 9 (1/1979), p. 18-21.

<sup>27</sup> F. Drane, *A Liberal Catholic Bioethics*, p. 39.



[1988-1990] Biomedical Ethical Advisory Committee

[1994-1995] Advisory Committee on Human Radiation Experiments

[1996-2001] National Bioethics Advisory Commission (NBAC)

[2001-2009] President's Council on Bioethics (PCBE)

[2009 - ] Presidential Commission for the Study of Bioethical Issues (Executive Order 13521, November 24, 2009.).

By the end of XX century, despite the time delay, bioethical institutionalisation has achieved international character<sup>28</sup>.

## From the Unites States to "Federation of States"<sup>29</sup>

Being discovered in 1997 and promoted since 2007, the work of Fritz Jahr has been spreading new lights onto the originality and authenticity of bioethical ideas in Europe, so to get more broader view of bioethics in Europe it is necessary to take a look back.

Compared to American history of bioethical development and bioethical institutionalisation, European bioethical episode easily looks too modest and far behind. There are at least several reasons that could try to explain such situation. Probably the first one, but also the most important (and at the same time improperly omitted from discussion) is the *category error*. Namely, speaking of *American* and *European* is not the same, and it is important to add, will never be. The essence of European is hard to define by itself (is it a myth?, is it a territory of a continent?, way of living?, tradition?, new political and administrative system – EU?), and even more in relation to other. Different historical and political foundations could perhaps be left behind when we try to make economical anaylsis or when emphasising the importance (and bravement of tradition but are crucial when we compare the characters of the American or European in cultural or social issues. While in the United States only 10 years have passed between independece of ex-colonias and accepting new federal Constituton (1787) accomplishing a new political unity, in today's modern

<sup>28</sup> Tristram H. Engelhardt, Anna Smiths Iltis and Fabrice Jotterand, Bioethics: Institutionalization of, eLS -*Encyclopedia of Life Sciences* (<http://www.els.net>, 22 January, 2009).

<sup>29</sup> "The concept of a 'Federation of States' (seemingly an oxymoron) has recently been unearthed to this end. Its great merit is to recall that federalism is not reducible to the formation of a federal state. Understood in a wider sense, federalism defines modes of relation between political entities based on peaceful cooperation and legal arbitration." (Paul Magnette, *What is the European Union?: Nature and Prospects*, Palgrave Macmillian Hampshire 2005., p. 5., according to Olivier Beaud, *La souveraineté de l'Etat, le pouvoir constituant et le Traité de Maastricht*, *Revue française de Droit administratif* 9 (1/1993), p. 1045-1068.).

Europe the case is quite different and can hardly be viewed from the same position. Today's European countries, members of the European Union, have first gone through several centuries of their independence, developing strong political systems, sense of national sovereignty and highly organised bureaucracy, then have gone through the catastrophe and fear of world wars and finally decided to merge themselves from 1951 onwards. In this manner, it is not odd that European federalism case is difficult to be discussed or comprehended in traditional terms<sup>30</sup>.

Terminological reasons are not far from previous ones. Being European, as already mentioned, could originate from specific European country, Europe as a continent, Council of Europe (or some other pan-european organisation), finally, from a Union (or Federation) of European states. Nevertheless, any process on the above mentioned level (including institutionalisation) is not isolated, and can hardly be comprehended without taking into consideration strong influences on other social movements and contrary.

Other reason is probably the one that for a long time, Europe has been resistant to American influences and imports: seeing bioethics until 1997 as an "original American product"<sup>31</sup> strongly influenced by law and practical ethics principles, and having own terms (medical ethics, biomedical ethics...) the acceptance of American version of bioethics in Europe was evidently slowed down.

## **Achievements of bioethical institutionalisation in Europe<sup>32</sup>**

"Bioethics – it is everything that Europe is about: sharing common values while respecting European cultural diversity; promoting research and innovation while ensuring respect for these values, providing honest and understandable information to the public about ongoing research not only to generate confidence in new technologies but also to allow public participation in adequate research policy choices in the safety, regulatory and ethical domain."<sup>33</sup> Written several years ago and dedicated to the bio-

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<sup>30</sup> "Between the cooperation of existing nations and the breaking of a new one there is no middle ground. A federation that succeeds becomes a nation; one that fails leads to secession; half way attempts like supranational functionalism must either snowball or roll back." (Stanley Hoffman, *Obstinate or Obsolete? The Fate of Nation State and the Case of Western Europe*, *Daedalus* 95 (3/1966), p. 909-910.).

<sup>31</sup> Ivan Šegota, *Nova medicinska etika (bioetika): priručnik/New medical ethics (bioethics) - a hand-book*, Katedra za društvene znanosti, Medicinski fakultet Sveučilišta u Rijeci, Rijeka 1994, p. 33.

<sup>32</sup> It is, of course, impossible to claim this is a comprehensive review of bioethical institutions in Europe. There are many journals, projects, publications, schools and concepts in different countries developing bioethics in European way.

<sup>33</sup> Noëlle Lenoir, *Biotechnology, Bioethics and Law: Europe's 21st Century Challenge*, *The Modern Law Review* 69 (1/2006), p. 1.

ethics and Europe, this statement could easily be different, especially regarding European experience with constitution treaty and new epoch after the Treaty of Lisbon.

It was not always easy for bioethics in Europe, but it would also be wrong to say that nothing has changed in the last few decades. Taking into consideration the reforms Europe has started in the mentioned period (and are still ongoing), bioethics was not always at the top of European priorities.

In the field of bioethical centres and institutes the leadership belongs to South-European countries<sup>34</sup> (Spain - Institut *Borja de Bioetica*, 1976; France – Center for medical ethics, 1984; Italy – Center for bioethics, 1985; Germany – Center for medical ethics and Academy for ethics in medicine, 1986; Belgium - Center for bio-medical ethics and law, 1986; Croatia – Center for bioethic, 1986 etc), but today bioethical centres are spread all over Europe<sup>35</sup>.

France was also the first European country to establish a national ethics committee: National advisory ethics committee for the life sciences and health (Comité Consultatif National d'Ethique pour les sciences de la vie et de la santé) in the year 1983. The French model of permanent and pluridisciplinary national institution served as a reference to many other countries<sup>36</sup>.

Following the political trends of strengthening the union of European countries, other social phenomena occurred, like establishing bioethical institution at the level of new European community. In July 1988 the European Commission had set up a working group Predictive Medicine Working Party, since 1989 known as Study Group on Ethical, Social and Legal Aspects of the human genome analysis programme (ELSA)<sup>37</sup>. By the end of 1991 the European Group of Advisers on the

<sup>34</sup> One of the possible future research issues could examine whether the catholic Church is the one responsible for such influences and trends. Let us not forget the influences that American theologians had had in establishing Kennedy Institute of Ethics.

<sup>35</sup> According to Lafond, the first phase of bioethical politics in Europe started in a period of professional self-regulation after the Second World War. Professional standards of that period were the first step toward "... the beginning of institutionalization on hospital level, along with a reassertion of the need to protect individuals. Local committees emerged in most Western countries, charged with the task of verifying research protocols and ensuring that the consent of people undergoing experiments had been obtained. However, this trend was neither systematic nor really organized. Most of the time it was simply a matter of collegial decision-making and avoiding the sometimes painful isolation of those who have to decide for others (generally members of medical profession)." (François D. Lafond, "Towards a European bioethics policy? Institutional structuring and political responses", in: Monica Steffen (ed.), *Health governance in Europe: issues, challenges and theories*, Routledge, New York 2005, p. 155-156.).

<sup>36</sup> Ibid., p. 157.

The most prominent achievement of these bodies was the collaboration of political authorities, scientific community and public (Arthur Rogers and Denis Durand de Bousinges, *Bioethics in Europe*, Council of Europe Press, Strasbourg 1995., p. 183.).

<sup>37</sup> This Group was officially recognized at the informal meeting of the Ministers of Research of twelve member states and representatives of Commission in Kronberg (Germany), March 1990. At the same meeting, another

Ethical Implications of Biotechnology was established by Commission to identify ethical questions regarding biotechnology development, to evaluate ethical activities within the Community and to identify impacts to broader society. In 1998, this body was replaced by a European Group on Ethics in Science and New Technologies, (EGE), active in different mandates today.

Beside the European Commission, the Parliament also became involved in bioethical issues from 1984 (it was following the rumours concerning the trafficking in fetuses and their possible misuse, as a consequence of law absence). The Parliament has used its new competences in research (contained in Single European Act, 1987), in the occasion of the adoption of the research programme "Analysis of the Human Genome" (1989-1991). "Since then, and in line with US model, all community research programmes have devoted a small share of their budget to studies to the ethical, social and legal consequences of research on the human genome."<sup>38</sup>

Considering the tradition Council of Europe has had in human right protection (European Convention for the Protection of Human Rights and Fundamental Freedoms, 1950), since late 1970s this institution has started to deal with bioethical questions, setting up resolutions and recommendations and being involved in "third-generation human rights".<sup>39</sup> The need for new bioethical institution within Council of Europe culminated in the year 1983 with Ad Hoc Committee on Genetics Experts (1985 this body was transformed into the Ad Hoc Committee of Experts on Bioethics; 1992 into the Steering Committee on Bioethics, CDBI). The main role of CDBI was identifying priorities, with special emphasis on the possibility of preparing and adopting common European *bioethical convention*.

Not only by its name<sup>40</sup>, this document was for the several following years point of interest of European structures. After years of negotiating and lobbying, the final version of the document Convention on Human Rights and Biomedicine, CETS No.: 164. has been signed in Oviedo on 4 April 1997 by 22 of 40 members, and

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working group was organized - for the research on the human embryo (HER). (F. Lafond, "Towards a European bioethics policy? Institutional structuring and political responses", p. 166.).

<sup>38</sup> Ibid., p. 164-165., according to European Commission (1998) *Ethical, Legal and Social Aspects of the Life Sciences and Technologies Programmes of Framework Programme IV*, Catalogue of Contracts, Oopec, Luxembourg 1999.

Despite the fact that Parliament played (only) a motivation role, the power of Commission was also limited. "In the absence of the competences clearly established by the treaties, the European Union's interventions was marginal, reactive and gradual." (Ibid., p. 163.).

<sup>39</sup> Ibid., p. 159.

<sup>40</sup> The suggestion *bioethical convention* was later an issue of great pressure and critics, for the reason the document (as a kind of normative institution) can only be an instrument of law, not of bioethics (Jan K. M. Gevers, *De Bio-Ethiek Conventie: kanttekeningen bij een ontwerpverdrag van de Raad van Europa*, *Tijdschrift voor Gezondheidsrecht* (8/1994), p. 456.).

came into force on 1 December 1999 after six countries (Denmark, Spain, Greece, San Marino, Slovakia, Slovenia) had initially ratified it<sup>41</sup>. Since then, four more Additional Protocols<sup>42</sup> were adopted, with no possibility to be signed and ratified without the main document<sup>43</sup>.

## Theoretical approach to institutionalisation

In the last few decades a lot of research has been done in examining theoretical approach to institution phenomena. Although the most comprehensive part explores political, health or educational institutions (the role they have in modern society and the way of their maintenance), it is of great interest for bioethics to invest efforts in exploring bioethical institutions.

The phenomena of establishing bioethical institution is not isolated from other social process, and can be compared with other similar examples. According to Arnold Gehlen's (1904-1976) philosophical-anthropological theory of institution, a man was always burdened with overcoming dualism of his mind and body. Being always jeopardised by natural environment, at one stage of his development, man had become aware of his own weakness and biological character, of his incompleteness and a lack of own possibilities and resources to gain his full integrity. As a fact of social life and a product of collectivity, institutions originate as the mediators in creating man meaning and need, force of his stabilisation and "shelter" for vulnerable one<sup>44</sup>.

Gehlen published his most important works in Germany just several years after the Second World War, which is probably relevant for his theory of institutions and role

<sup>41</sup> Comprehensive analysis of the content and role of his document is a subject of another article (Iva Rinčić-Lerga, "Deset godina Konvencije o ljudskim pravima u biomedicini Vijeća Europe (1997.-2007.) Postignuća i perspektive/Ten years of the Convention on Human Rights and Biomedicine (1997-2007). Achievements and perspectives", in: Velimir Valjan (ed.), *Integrativna bioetika i interkulturalnost*, Bioetičko društvo u BiH, Sarajevo 2009., p. 297-310.).

<sup>42</sup> Additional Protocol to the Convention on Human Rights and Biomedicine, on the Prohibition of Cloning Human Beings (CETS 168); Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin (CETS 186); Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (CETS 195); Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes (CETS 203).

<sup>43</sup> Map of signatures and ratifications available at [http://www.coe.int/t/dg3/healthbioethic/Activities/01\\_Oviedo%20Convention/ETS164map.pdf](http://www.coe.int/t/dg3/healthbioethic/Activities/01_Oviedo%20Convention/ETS164map.pdf) (last updated 15 October 2010).

<sup>44</sup> In Croatian, the main part of Gehlen's work was collected in a book *Čovjek i institucije/Man and institutions* (edited by Hotimir Burger), Nakladni zavod Matice Hrvatske, Filozofski fakultet, Humanističke i društvene znanosti – Zavod za filozofiju, Zagreb 1994., comprising of Gehlen's book *Urmensch und Spätkultur* (1956) and his public lecture *Man and institutions* (University of Freiburg, 1960). There is, of course, a lot more to be discussed regarding Gehlen: the differences between archaic and modern institutions, the grounds of institutionalising subjectivity, the maturity of modern man in creating modern institutions, but all this needs to be a part of some future research.

they have in a society. His orientation toward archaic institution still needs to be explored in more details regarding modern institutions, including bioethical ones. The first notion of bioethics comes from Gehlen's contemporary, Fritz Jahr (1927) who also has several notes regarding institution.

Beside Jahr's view upon professional press to be "... a medium to establish or at least strongly influence public opinion, ... it becomes even an obligation to take part in this type of character formation (Gesinnungsbildung) ..."45, (is a press, for Jahr, a trace of an institution?), Jahr offers the most interesting remarks within different forms of social life.

"Our entire life and activities in politics, business, in the office and in the laboratory, in the workshop, in the field farms are ... not based on love in the first place, but many times on competition with other competitors. Quite often we are not cognizant of this fight as long as we proceed without hate and in a fair, legal and accepted manner. Similarly, as we cannot avoid the fight with our fellow humans, we cannot avoid the struggle for life with other living beings. Nevertheless, we will not want to lose the ideal of responsibility as a guiding point, neither for the first nor for the latter."46

Jahr's search for the ways of implementing his *Bioethical Imperative* (1927, 1928) in all aspects of life is not limited to persons, or natural living environments but also to cultural environments. Being artificially established, such cultural artefacts are product of society, or in other words, institution. Their struggle for life with other forms of institutional life is not out of other demand and need to follow the same principle and virtues of responsibility. Limitation of Bioethical Imperative only to individual relations, weakens its strength and reach, as well as chances of success. Only its universal application in all forms of life (including social one, like health care institution, corporations, and even more committees) set up the grounds and preconditions of full realisation of Bioethical Imperative.

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<sup>45</sup> Fritz Jahr, Social and Sexual Ethics in Daily Press, *Medizinethische Materialien* (188/2011), p. 12. (translation by Irene M. Miller and Hans Martin Sass).

<sup>46</sup> Hans Martin Sass, "European Roots of Bioethics: Fritz Jahr's 1927 Definition and Vision of Bioethics", in: Ante Čović, Nada Gosić, Luka Tomašević (ed.), *From New Medical Ethics to Integrative Bioethics – Dedicated to Ivan Šegota in Occasion of His 70th Birthday*, Pergamena, Hrvatsko bioetičko društvo, Zagreb, 2009, p. 24.; Hans Martin Sass, Asian and European Roots of Bioethics: Fritz Jahr's Definition and Vision of Bioethics, *Asian Bioethics Review* 1 (3/2009), p. 10., according to Fritz Jahr, Tierschultz und Ethik in ihren Beziehungen zueinander, *Ethik. Sexual-und Gesellschaftsethik. Organ des ,Ethikbundes'* 4 (6-7/1928), p. 101.

## Opportunities and perspectives of practical bioethical institutionalisation in Europe

As previously mentioned, the process of bioethical institutionalisation represents an important step in the process of bioethical development. Before this stage, according to Fagot Largeault, the 1960s were characterized by spurn (due to terrifying scandals in biomedical research); followed by the period of institutionalisation (provided by the first documents and committees at different levels). This phase of the 1990s proceeds another one - the level of implementation, when earlier established rules became more concrete and standardised<sup>47</sup>.

Still, this is not the only side of the problem. Namely, social reality often shows the reverse side of medal: high standards of bioethical awareness and poor (or lacking) bioethical institutionalisation<sup>48</sup>. Although there is no doubt that this problem exists, there is another question - Is it possible to have the opposite situation: high level of bioethical institutionalisation and poor level of awareness (in the sense of implementing documents and in them claimed principles in to real life)? In the last few years, several articles were published regarding bioethical institutionalisation (Lafond, 2005, Rinčić, 2010), counting the elements and emphasising the importance of this process, but very few exploring the real problems: on what grounds will this process be implemented in every day practice and what is to be achieved by it in the long term?

One of the ways of promoting bioethics in European context by its institutionalisation was the establishing of the journal *JAHR – Annual of the Department of Social Sciences and Medical Humanities of University of Rijeka Faculty of Medicine*, with the international Editorial and Advisory Board's, Editor-in-Chief Amir Muzur (first issue published in May 2010, the 4th planned for September 2011).

After the first conference dedicated to Fritz Jahr and European bioethics, held at the University of Rijeka - Faculty of Medicine (Croatia) in March 2011, the EUROBI-ONETHICS group was established<sup>49</sup> and the next conference is already planned to be held during 2012<sup>50</sup>.

<sup>47</sup> A. Fagot - Largeault, "L'émergence de la bioéthique", p. 345-348.

<sup>48</sup> Ante Čović, "Bioetika je znak nove epohe/Bioethics is a sign of a new epoch" , *Vjesnik* (13 April/1999).

<sup>49</sup> See <http://www.eurobionethics.com>

<sup>50</sup> According to current information, the host of this meeting will be Martin Luther's University Halle-Wittenberg Institute of Medical Ethics and History of Medicine, under the supervision of Florian Steger.

Another important fact to be mentioned and hopefully accomplished by the end of 2011 is the book *Fritz Jahr and Foundations of Global Bioethics: The Future of Integrative Bioethics* (edited by Amir Muzur and Hans-Martin Sass), Lit Verlag (Münster).

As the a host of the project "*Fritz Jahr and European Roots of Bioethics: Establishing the International Network of Scholars*", Department of Social Sciences and Medical Humanities of University of Rijeka Faculty of Medicine continuously works on collecting documents and literature for *Fritz Jahr Documentation center* to be a database for students, but also scholars in the field of European bioethics.

Finally, the idea on establishing Fritz Jahr Award for Promoting and Research of European Bioethics is still open. For the first time presented at Rijeka conference in March 2011, this initiative presents one of the possible manners not only in promoting bioethics in European context, but also in institutionalisation it on permanent basis<sup>51</sup>.

## Conclusion

Institutionalisation is the important and necessary phase in the bioethical development, and a precondition of further trend of implementing bioethical principles and ideas in every day life. In the USA, bioethics was "saved" by institutionalisation in different aspects of social life, but at the same time narrowed in its application (medical and clinical ethics).

European roots of bioethics (Fritz Jahr's concept of Bioethical Imperative) opens not only a new chapter in the bioethics history, but also calls for reconsideration and setting up of new theoretical and practical approaches to European bioethical institutionalisation.

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<sup>51</sup> In addition to the official ceremony (every year on occasion of Fritz Jahr birthday, 18 January), it is planned that several months professorship at Martin Luther's University Halle-Wittenberg would constitute a part of this Award. More details regarding current parameters and chronology of this initiative can be found on [www.eurobioethics.com](http://www.eurobioethics.com).