#### EDITORIAL

### A TALE OF TWO CONTINENTS: A LIFE OF BIOETHICS AMID AMERICAN AND EUROPEAN PERSPECTIVES<sup>1</sup>

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This special issue of "Social Ecology" is the outcome of the international bioethics conference "Price of Health" that was held 12-14 August 2016 in Dubrovnik at the Inter-University Centre and organized by the four major partners: New York based Global Bioethics Institute, the Scientific Centre of Excellence for Integrative Bioethics, and Andrija Štampar School of Public Health, University of Zagreb School of Medicine and Institute of Public Health. The issue comprises of six papers and fifteen authors: *Ivan Pristaš, Damir Ivanković, Maja Valentić, Srđan Golubović, Borna Pleše, Marko Brkić, Boris Barto and Tamara Poljičanin "Kultura zdravstvenih informacija u Hrvatskoj"; George W. Rutherford and Robert Schechter "The Vaccine Wars: What Can Be Learned from California's Experiences with Mandatory Immunisation of School Children?"; Krunoslav Capak and Vedran Poljak "Procjena utjecaja na zdravlje – metodologija i načela*"; *Ivica Kelam "GMO 2.0: Novi naziv – stari problem"; Amir Muzur "European Bioethics: A New History Guaranteeing a New Future"; Marija Selak "Moral Enhancement and the Reduction of Evil: How Can We Create a Better World?"*.

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What is bioethics? Answering this question is not an easy feat, and it depends on where you come from.

<sup>1</sup> The title of the article is borrowed from Abraham Pais's book "A Tale of Two Continents: A Physicist's Life in a Turbulent World." Pais was one of the world's leading theoretical physicists and contemporaries who wrote controversial and historical books about Albert Einstein, Niels Bohr, J. Robert Oppenheimer, Andrei Sakharov, Paul Dirac, Werner Heisenberg, and John von Neumann. Pais viewed America and Europe as disparate social and political worlds, commenting just as insightfully on Oppenheimer's baptism of fire during the McCarthy era, the struggles of his European colleagues or his own ordeals during World War II. His sentence "People like myself, who truly feel at home in several countries, are not strictly at home anywhere" can be applied as a metaphor for the intellectual destiny of bioethicists such as Hans Jonas and Van Rensselaer Potter.

A broader understanding of bioethics can be used to apply to an entire array of moral questions and issues related to life sciences concerning human beings, animals, and nature as a whole. Bioethics research is a useful tool that can help us when facing common fears, concerns and hopes as well as in facing situations of the start and end of life, understanding the consequences of the development of modern medicine, and the impact of biomedical and biotechnological advancements on our life. Fast growing academic, institutional and political interest in bioethics is the consequence of public apprehension on the ethical aspects of morally and ethically complex cases. Continuous progress in life sciences, medicine, and biotechnology has provided us access to new ways of treating, preventing and curing diseases.

The impact of these advancements is at the same time becoming focused on individuals (precision medicine), collecting sensitive data about special groups and communities (population genetics), and making it available for policy makers and industries (evidence based practice in healthcare). Developments in the area of gene technology, the technical capacity to intervene in the beginning and end of life, the production of human cells and tissues that includes therapeutic and reproductive cloning, as well as the idea of the creation of androids in the form of bionic man and cyborgs are also raising bioethical questions and concerns and not only something that ends up in hospital surgical theaters or pharmaceutical laboratories. Androeides, from the Greek word defining man-like creatures, have already materialized in the world's first walking, talking bionic man complete with a circulatory system and beating heart. The creature, called Frank (for Frankenstein), is a six-foot cyborg made up of 200 processors and covered in over a million sensors. The artificial body parts were donated by various research centers from around the world.<sup>2</sup> This story is an example of industry 4.0 products connecting robots and physical objects and integrating human resources with physical machines into cyberphysical networks with unprecedented ethical consequences that are capturing media attention and generating public controversies.

Bioethicists "come" from various disciplines, each with their own distinctive set of experiences, methods, and assumptions. Bioethics is both an interdisciplinary and multidisciplinary field as it aims to connect philosophy, sociology, behavioral science and history with the medical law, medicine, nursing and health policy in various complicated and practical situations of medical care. Insights from different disciplines are brought forward in the complex interaction of human life, science, and technology.

Bioethicists, in addition to conducting research on ethical, social, and legal issues arising in biomedicine and biomedical research, also teach courses and give seminars, help draft hospital institutional policies, run ethics committees, and provide consultation and advice on ethical issues through both theoretical and practical endeavors. Bioethics, as a

<sup>2</sup> Woolaston, W. (2013). Meet Frank, the world's first walking, talking bionic man complete with artificial limbs and a beating heart. *Daily Mail*. URL: http://www.dailymail.co.uk/sciencetech/article-2465853/Meet-Frank-worlds-walking-talking-bionic-man-complete-artificial-limbs-beating-HEART.html (3 July 2017).

particular way of moral reasoning and decision-making, integrates empirical data from medicine and creates another applied discipline. The most common or frequent issues of recent bioethical debates, capturing the attention of leading bioethical, clinical, health policy, or social science journals, usually address the moral permissibility of specific actions and practices related to the beginning and end of human life, medical procedures, technologies and treatments, biomedical research, status of patients and vulnerable social groups in the risk of communicable disease and their access to health care.

Applied bioethics elaborates arguments from a critical examination of the medical practice, considerations in discussions and debates about the organization and financing of health care, and offers ethical guidance in medicine and health care to medical professionals, institutional leaders, and patients. There are very few reasons to question, challenge or dispute the contribution and importance of applied bioethics and its contribution to the improvement of relations between physicians, nurses, and patients, the status of patients in the process of health care delivery, and treatment of patients with disabilities and vulnerable groups. However, its high-level visibility and growing presence in the health care system does not necessarily imply theoretical and methodological consistency. Namely, it does not deal with the question of whether morality exists, but rather with the reasoned construction of fundamental principles of morality.

This special issue on bioethics is not an attempt to follow the common understanding of bioethics that supports ethical issues related to new technologies and does not vanquish disciplinary boundaries of ethics as applied to different fields of research such as social, feminist, information, business, research, political ethics, and ethics of law. While such an approach facilitates new and valuable perspectives, it also causes problems for a more integrated approach to bioethics. Rather, the objective here is to address different bioethical problems in the context of an emerging global society organizing the interdisciplinary debate between clinical medicine and public health, law, philosophy, sociology and political sciences, psychology, psychiatry and behavioral sciences and to encourage international debates at the intersection of health, biotechnology, and medicine. The professional and disciplinary background of the contributing authors covers all the above mentioned health-related fields of bioethics. The cultural, geographical and academic background and experience of the participants and the authors alike was a unique opportunity to have an open discussion on the various aspects and controversies of bioethics from both an American and European bioethical perspective. The concepts of global bioethics and integrative bioethics were used as theoretical platforms to consider the differences in the origins, concepts, academic and disciplinary history and methodology of contemporary bioethics from different disciplinary positions, in the line with the interdisciplinary character of our journal.

Three major issues were at the forefront in the discussion about conceptual question-related history and the future of bioethics. The first question was about the history and inception of bioethics both from an American and European perspective. The second was the question of the meaning, concept, content, and possibility of a "global bioethics" by employing both cultural and "continental" perspectives. The third area of discussion was related to recent controversial bioethical issues on both sides of the Atlantic such as organ transplantation, vaccination, and human enhancement. The major conceptual questions in the discussion focused on: What is bioethics? What is global bioethics? When was the inception of bioethics and who is / are its founding fathers? Are there any "essential" or fundamental principles that bioethics, and in particular global / international bioethics, would rest on? How to integrate different levels, methods and various parts of bioethics in clinical and public health practice around the globe on issues such as infectious disease surveillance, control and prevention, vaccination of a population, organ transplantation, human physical and moral enhancement, information technologies and social ecology?

### WHAT IS BIOETHICS, WHEN DID IT START, WHO WAS THE FOUNDING FATHER AND HOW DOES ALL THIS INFLUENCE OUR CONTEMPORARY THINKING?

When the term "bioethics" was "again" coined in 1971, it signified the combination of biology and bioscience with humanistic knowledge and was centered on the normative analysis of bioethical issues, arguing for or against the moral permissibility of a particular policy, medical practice or health technology. Twenty years later, by the mid-1990s, bioethics began to attract social and behavioral scientists as well as public health and primary care doctors, nurses and clinicians. Both the interests and methods of bioethics began to mirror the methodologies of the new disciplines becoming central to this field. However, the field of bioethics now encompasses a full range of concerns "from difficult private decisions made in clinical settings, to controversies surrounding stem cell research, to implications of reproductive technologies, to broader concerns such as international human subject research, to public policy in health care, and to the allocation of scarce resources".<sup>3</sup> With this shift, bioethics has come to include not only the normative analysis but also the empirical study of bioethical questions. Arthur Caplan argued, from the perspective of the history of science and philosophy of science, that bioethics seeks to collect, systematize and interpret empirical data using either qualitative or quantitative social science methodology. Bioethics attempts to make persuasive bioethical arguments needed to shed light on bioethical problems and current and controversial subjects such as managed care, abortion, cloning, needle exchange programs to prevent the transmission of HIV, the latest technologies and developments in medical research, and to analyze potential ethical, legal, and social repercussions.<sup>4</sup>

The National Institute for Environmental Health Sciences, which is the closest academic and bioethical neighboring enterprise to "Social Ecology", defines bioethics as "the

<sup>3</sup> Center for Practical Bioethics – CFPB. (2017). *What is Bioethics?* URL: https://www.practicalbioethics.org/what-is-bioethics (29 June 2017).

<sup>4</sup> Caplan, A. (2008). Smart Mice, Not-So-Smart People: An Interesting and Amusing Guide to Bioethics. Lanham, Maryland: Rowman & Littlefield Publishers.

study of ethical, social, and legal issues that arise in biomedicine and biomedical research" and includes different fields of "medical ethics which focuses on issues in health care, research ethics, which focuses on issues in the conduct of research: environmental ethics, which focuses on issues pertaining to the relationship between human activities and the environment, and *public health ethics*, which addresses ethical issues in public health".<sup>5</sup> There have been very few attempts to stand outside a disciplinary approach to study the origins, history, controversies, and understanding of the bioethics field itself. These historians, sociologists or philosophers of science usually scrutinize the language and discourse of a certain scientific field in an attempt to disclose partisanships, prejudices, biases and hidden assumptions. Such an insightful process mitigates the process of making the field more self-reflective about its motives and goals. The first great controversy related to bioethics is its very origin, the question of the founding father and the different schisms and rifts that followed in the history after the very first day of its inception. It may be of interest and significance (or perhaps not) that the same "omen" applies to all widespread religions, including Christianity and Islam. In particular, social scientists, historians and philosophers of science have initiated a vigorous debate in the last two decades about the drivers behind the development of bioethics.

Alistair Campbell started the dispute over the history of bioethics by claiming that a unified account was possible by neglecting developments outside of the US.<sup>6</sup> Robert Baker's review developed another argumentation of this Anglo-centric abandonment,<sup>7</sup> along with that of David Rothman at an earlier stage,<sup>8</sup> and later Jennifer K. Walter and Eran P. Klein.<sup>9</sup> The dispute centers on how the theoretical and cultural background, theoretical principles and research methods of American bioethics were not the same as the principles and methods of European, Asian or African bioethics. The same applies to the question whether the four principles proposed in Beauchamp's and Childress's *Principles of Biomedical Ethics* have the potential for universal / global implementation.<sup>10</sup> The controversy started from when the first bioethics institute was founded in 1971. It was first named the Joseph and Rose Kennedy Center for the Study of Human Reproduction and Bioethics. Today it is called the Kennedy Institute of Ethics. Professor Amir Muzur from the University of Rijeka in his article "European Bioethics: A New History Guaranteeing a New Future" disputes this "oft-repeated story about the origin

<sup>5</sup> National Institute for Environmental Health Sciences – NIEHS. *What is Bioethics?* URL: https://www.niehs.nih.gov/research/resources/bioethics/what\_is\_bioethics/index.cfm (29 June 2017)

<sup>6</sup> Campbell, A. V. (2000). "My country tis of thee" – the myopia of American bioethics. *Medicine, Health Care and Philosophy*, 3(2): 195-198.

<sup>7</sup> Baker, R. (2005). Getting agreement: How bioethics got started. *Hastings Centre Report*, 35(3): 50-51.

<sup>8</sup> Rothman, D. J. (1991). Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making. New York: Basic Books.

<sup>9</sup> Walter, J. K. and Klein E. P. (2003). *The Story of Bioethics: From Seminal Works to Contemporary Explorations*. Washington D.C.: Georgetown University Press.

<sup>10</sup> Beauchamp, T. L. and Childress, J. F. (2009). *Principles of Biomedical Ethics*. New York: Oxford University Press.

of the term bioethics" as incorrect. Hans Martin Sass developed a convincing analysis and argument that German theologian Fritz Jahr was the first to use the German term "Bio-Ethik." Jahr established the new academic discipline arguing for a new ethical approach to issues concerning human beings and the environment and proclaimed a new bioethical imperative.<sup>11</sup> Jahr's imperative "respect every living being, in principle, as an end in itself and treat it accordingly wherever it is possible" led to, according to Sass, the conclusion that "new science and technology requires new ethical and philosophical reflection and resolve may contribute toward clarification of terminology and of normative and practical visions of bioethics, including understanding of the geoethical dimensions of bioethics". <sup>12</sup>

#### WHAT IS GLOBAL BIOETHICS?

The precise meaning of the term "global bioethics" has often been unclear. Is there such a science or discipline as global bioethics? Would it be correct to aspire for a globally unified field of bioethics? For some, it has been a call to globalize the concerns of bioethics by focusing more attention on, for example, issues of resource developing countries, public health, or global justice and equity.<sup>13</sup> There is a tendency to interpret global bioethics using the one and right / universal set of principles employing academic disciplines in the same way philosophy, sociology, medicine, or engineering have arguably shared academic languages, agreed upon canonical texts, and facts and values that are no longer in dispute.<sup>14</sup> The problem with global bioethics is that the idea of global bioethics as a rationally constructed and negotiated moral order that respects culturally and individually defined areas of moral principles that are universally accepted in all eras and cultures "collapses under a variety of multicultural and postmodern critiques".<sup>15</sup> Further, the theory of a negotiated moral order that is "consistent with traditional ideals about human rights, is flexible enough to absorb the genuine insights of multiculturalism and postmodernism, and yet is strong enough to justify transcultural and transtemporal moral judgments".<sup>16</sup> If bioethics is a unified global field, or at the very least, a shared way of thinking, then we would expect common methodology, language, major research topics, the standard editorial policy of leading journals and program subjects of the conferences.

<sup>11</sup> Muzur, A. (2017). European Bioethics: A New History Guaranteeing a New Future. *Socijalna ekologija*, 26(1-2): 61-70.

<sup>12</sup> Sass, H. M. (2007). Fritz Jahr's 1927 concept of bioethics. *Kennedy Institute of Ethics Journal*, 17(4): 279-295, at 279.

<sup>13</sup> Holm, S. and Williams-Jones, B. (2006). Global bioethics – myth or reality? *BMC Medical Ethics*, 7:10. DOI: 10.1186/1472-6939-7-10. 14 Ibid.

<sup>15</sup> Baker, R. (1998). A Theory of International Bioethics: The Negotiable and Non-Negotiable. *Kennedy Institute of Ethics Journal*, 8(3): 233-273, at 254. 16 Ibid.

Instead, by paying attention to what might be called "publicly observable behavior" within the field, Søren Holm and Bryn Williams-Jones investigate whether bioethicists in different regions of the world behave in the same way in their academic activities anywhere in the world.<sup>17</sup> Would it be possible to create a global bioethics by analogy, emphasizing Immanuel Kant's point from *Religion within the Boundaries of Mere Reason*<sup>18</sup> that we already have all the *(bioethical?)* "ingredients necessary and we just have to mix them together in the right way? Not so simple!" As Selak states in the article "*Moral Enhancement and the Reduction of Evil: How Can We Create a Better World?*" it is "also where all the fun starts: discovering the 'banality' of the paradox of having all we need but not knowing (comprehending) what we have".<sup>19</sup>

# BIOETHICS AT WORK: THE IDEA AND PRACTICE OF INFORMED CONSENT

The idea of patient consent to medical procedures represents the evolutionary process from paternalistic medicine to patient-centered medicine. Consent is needed for a range of medical interventions or procedures from a simple blood test to organ donation and vaccinations, which represents the principle wherein individuals must give their permission before receiving a medical intervention or procedure.<sup>20</sup> A patient's consent and a physician's duty to disclose information have long been central issues of debate between doctors and lawyers. Now it has become an issue of debate between law and medicine historians and bioethicists. This first struggle is related to the two different reasons why a physician may be required to disclose information to a patient. The first one is consent for therapeutic purposes and which has a long history in medical practice (from the Hippocratic Oath to Henry de Mondeville, Benjamin Rush, Thomas Percival and Worthington Hooker) with the idea that the function of the disclosure is to enable a patient's self-determination.

The second is the history of informed consent as related to medical research, a practice which started on the eve of the 20<sup>th</sup> century. This offers another controversy on who was the first to start the important biomedical procedure, almost identical to the controversy about the history of the term bioethics. Was it in America or Europe, the United States or Germany, the American Army or the Prussian Bureaucracy, in 1900 or 1901, Walter Reed or Albert Neisser? Until recently there was a widespread understanding

<sup>17</sup> Holm, S. and Williams-Jones, B. (2006). Global bioethics – myth or reality? *BMC Medical Ethics*, 7:10. DOI: 10.1186/1472-6939-7-10.

<sup>18</sup> Kant, 1998:50 quoted in Selak, M. (2017). Moral Enhancement and the Reduction of Evil: How Can We Create a Better World? *Socijalna ekologija*, 26(1-2): 71-82.

<sup>19</sup> Selak, M. (2017). Moral Enhancement and the Reduction of Evil: How Can We Create a Better World? *Socijalna ekologija*, 26(1-2): 71-82.

<sup>20</sup> World Health Organization – WHO. (2014). *Considerations regarding consent in vaccinating children and adolescents between 6 and 17 years old*. URL: http://www.who.int/immunization/programmes\_systems/policies\_strategies/consent\_note/en/ (8 July 2017).

that "the development and role of informed consent to medical treatment common law jurisdiction is well documented. As a legal doctrine, informed consent originated in the United States and spread in modified form to Canada (...)".<sup>21</sup>

Before addressing the issue of the historical origins of informed consent as applied to medical research, and in order to understand what the potential consequences of the understanding and application of informed consent at the population level medical intervention are, here we will analyze the example of informed consent as applied to vaccination. The benefits of vaccination are clear and undisputable, and the evidence from various epidemiological and historical studies confirms such a firm position. Why then is consent for vaccination required in some countries before public health or medical interventions can take place? In some countries consent may be waived only in very few, well-described circumstances, such as life threatening emergencies. Consent has its origin in the principle of autonomy and establishes an important part of medical and public health ethics. It is also an important part of international law. The idea and concept of consent is the reflection of the right to autonomy. It is, to some extent, a manifestation of individualism as a key value of the Western culture which favors self-actualization. In this context the right to consent should be understood from the perspective of autonomy and individual rights. For consent to be valid, it must be informed, understood and voluntary, and the person consenting must have the capacity to make the decision.<sup>22</sup> Based on the concept of vaccines as a tool for disease elimination and outbreak control, a significant number of countries identify one or more vaccines as mandatory under law. "Whether consent is needed for mandatory vaccination depends on the legal nature of the regulations. When mandatory vaccination is established in relevant provisions in the law, consent may not be required, and if the mandatory nature of vaccination is based only on policy, informed consent needs to be obtained as for any other vaccines. Some countries allow individuals to express non-consent (opt-out) and receive an exemption for mandatory vaccines".<sup>23</sup>

In the article "The Vaccine Wars: What Can Be Learned from California's Experiences with Mandatory Immunisation of School Children?" George W. Rutherford and Robert Schechter from the Department of Epidemiology and Biostatistics School of Medicine University of California, San Francisco demonstrate, based on an analysis undertaken in both the Netherlands and USA, that the years of life lost fell steadily in both countries due to the vaccination of children. For example, mortality in the Netherlands "declined for diphtheria and pertussis resulting in 3,000 fewer deaths and 38,000 fewer years of life lost before age 20 from diphtheria, and 6,000 fewer deaths and 103,000 fewer years of life lost before age 20 from pertussis after the introduction of mass va-

<sup>21</sup> Shaw, J. (1986). Informed Consent: A German Lesson. *The International and Comparative Law Quarterly*, 35(4): 864-890, at 860.

<sup>22</sup> World Health Organization – WHO. (2014). *Considerations regarding consent in vaccinating children and adolescents between 6 and 17 years old*. URL: http://www.who.int/immunization/pro-grammes\_systems/policies\_strategies/consent\_note/en/ (8 July 2017). 23 Ibid.

ccination programmes for these agents in 1953 and 1954 respectively. In the United States of America, for example, due to the introduction of a single-dose polysaccharide vaccine in 1986 and then a multi-dose conjugate vaccine series in 1990, the incidence of *Haemophilus influenzae* type b very invasive disease declined from a high of 25 cases per 100,000 children under 5 years of age in 1984 to almost 0 in 1997".<sup>24</sup>

If we attempt to include utilitarian principles into the vaccination discussion, and the utilitarian objective would be to maximize the total utility of all beings (to be measured against its ethical acceptability) affected by vaccination, or if the moral rightness and wrongness of vaccination are defined by the greatest possible service for the greatest possible number of people vaccinated or not vaccinated, or even if the clinical or public health consequences of vaccination are evaluated against its moral consistence, vaccination will continue to take place in both the above-mentioned countries and around the globe. Even the *hedonistic principle would not create further obstacles* to public health intervention bearing in mind that the consequences of a given action are evaluated concerning a particular value if the value would be avoiding pain, or satisfaction of interests or considered preferences, or appreciation of some objective criteria of well-being.<sup>25</sup>

## INDIVIDUAL INFORMED CONSENT: PRUSSIAN AND AMERICAN PERSPECTIVES

What might be an interesting historical fact and additional argument for the discussion about the history of bioethics and its principles on both sides of the Atlantic, in Europe and the United States, is the statement that "the informed consent doctrine was thus initially a regulatory innovation created by Prussian bureaucrats. It was a German solution to problems created by the advances of German biomedical science".<sup>26</sup> The Prussian bureaucratic regulations of 1900/01 "that appeal to the case of Dr. Albert Neisser in 1896 who publicly announced his concern about the possible dangers to the experimental subjects whom he vaccinated with an experimental immunizing serum",<sup>27</sup> the extent to which this principle became ingrained in the ethics of research by the mid-twentieth century is a matter of historical controversy.

Another different understanding and interpretation of the history of informed consent at the turn of the century states that it was already on July 1<sup>st</sup>, 1900, when American army surgeon Walter Reed's yellow-fever medical experiments involved formal procedures for obtaining consent from both local authorities and, what is more important, from potential subjects. At the time there were contemporary standards of disclosure

<sup>24</sup> Rutherford, G. W. and Schechter R. (2017). "The Vaccine Wars: What Can Be Learned from California's Experiences with Mandatory Immunisation of School Children? *Socijalna ekologija*, 26(1-2): 23-35. 25 Gordon, J. S. (2012). Bioethics. In: Fieser, J. and Dowden, B. (eds.), *Internet Encyclopedia of Philosophy*. URL: http://www.iep.utm.edu/bioethic/ (6 July 2017). 26 Ibid.

<sup>27</sup> Baker, R. (1998). A Theory of International Bioethics: The Negotiable and Non-Negotiable. *Kennedy Institute of Ethics Journal*, 8(3): 233-273, at 250.

and consent, and it was routine practice in medical research that prisoners, the mentally ill, people of color, the indigent, and sometimes also children, were used as experimental subjects without their consent. Sometimes this was happening even without their knowledge. At the beginning of the century, there were no government or military regulations that covered medical research. In an unprecedented act, "Reed developed a written consent document in Spanish, so subjects would be fully aware of the risks and would have signed documentation promising care and compensation. The U.S. Army Yellow Fever Board is considered the first research group in history to use consent forms".<sup>28</sup> Although both Reed's and Neisser's breakthrough ideas and practices of informed consent are not identical to the contemporary sense of informed consent, they do prove that it is not the exclusive product of individualist values, the sanctity of individual conscience which was central to Puritans and other radical Protestant groups as some would argue.<sup>29</sup> The individualistic values and sanctity of individual conscience are essential but not all necessary ingredients. The unique allempt to extend Kant's moral imperative to all forms of life, ("respect every living being, including animals, as an end in itself and treat it, if possible, as such!") may serve as a broader guidance for our moral actions.<sup>30</sup> Treating the patients with respect and "as such" including the right to consent implies the concept of self-government and autonomy developed to defend individuals from opression by others and to offer the potential of free an rational choice based on personal preferences and values. From this we may conclude that the history of informed consent was, in fact, a long process of widespread changes from paternalistic medicine to patient centered medicine under the influence of social actors and values, moral norms and legal requirements. As an evolving process of changes, it was largely influenced by philosophical, social and legal developments and medical practices on both sides of the Atlantic.

<sup>28</sup> Cutter, L. (2016). Walter Reed, Yellow Fever and Informed Consent. *Military Medicine*, 181(1): 90-91, at 90.

<sup>29</sup> Berg, J., Appelbaum, P. S., Lidz, S. W. and Parker, L. S. (2001). *Informed Consent. Legal Theory and Clinical Practice*. New York: Oxford University Press.

<sup>30</sup> Sass, H. M. (2009). Asian and European Roots of Bioethics: Fritz Jahr's 1927 Defrinition and Vision of Bioethics. *Asian Bioethics Review*, 1(3): 187-193.