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STEM CELLS THERAPY AND RESEARCH. BENEFITS AND ETHICAL CHALLENGES

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Abstract: The research on stem cell-based therapies has greatly expanded in recent years. Our text attempts to seek those religious and ethical challenges that stem cell therapy and research bring into debate. Our thesis is that bioethics can defend its principle without a religious background. We will develop our argumentation on three major points: firstly, a comparison between secular ethics and religious views will clarify why stem cell therapy and research are important from a scientific point of view, addressing the very center of the human being; in our view, being based on secular society, bioethics can answer the challenges of stem cell therapy and research; secondly, following Hans Jonas' perspective on experimenting on humans, we seek to understand the philosophical guidance that sciences dealing with stem cell need; thirdly, we will map the ethical guidelines for clinical translational research that have been adopted by the International Society for Stem Cell Research.

Key Words: stem cell research, stem cell therapy, bioethics, human embryonic stem cells, induced pluripotent stem cells, regenerative medicine, religious challenges, ethical challenges

Recently, stem cell research and therapy have significantly expanded¹. As a result, stem cells-based therapy has become an option for various medical conditions. Yet, from an ethical perspective, even if the controversy about the source of human embryonic stem cells has diminished along with the development of alternative techniques of obtaining stem cells, the new developments in stem cell research cannot avoid ethical controversy, on the whole, and scientists are confronted with a different set of ethical concerns. Stem cell-based therapies have become the clinical standard of cure for some conditions such as hematopoietic stem cell transplants for leukemia.

Several contemporary authors claim that bioethics cannot defend its principles without a religious background. This attitude is obvious even in highly specialized and strictly regulated fields, such as stem cell therapies and research. However, bioethical principles can equally be based on philosophical grounds, as proved by the pioneering example of Hans Jonas' writings on experimentation with human subjects. An even more telling example is that of the ethical guidelines adopted by the International Society for Stem Cell Research.

Between Secular Ethics and Religion

By definition, "a stem cell is an unspecialized cell that can both self-renew (reproduce itself) and differentiate into functional phenotypes. Stem cells can originate from embryonic, fetal, or adult tissue and are broadly categorized accordingly"². Thus, "regenerative medicine is an emerging branch of medicine whose goal is to restore organ and/or tissue function using a biological approach"³. In order to avoid the ethical dilemmas raised by human embryonic stem cells (hES), alternative sources of stem cells are used. There is an increased support on behalf of religious groups towards the adult stem cell research in order to reduce the utilization of human embryonic stem cells. These alternative sources have initiated the reaction of scientists because of the different properties of the embryonic stem cells vis-à-vis the adult stem cells, the therapeutic potential of the former being higher⁴. Therefore, our approach, on the one hand, will have in mind this strict definition when approaching stem cell research and therapy and, on the other hand, our paper will focus on the religious and ethical challenges that stem cell therapy and research call into play.

In an introductory article, King-Tak IP stipulates that regenerative medicine formulates a Promethean promise, i.e. "being able to redesign human biological nature in terms of the goals and concerns of humans"⁵, while H. Tristram Engelhardt equally considers that "regenerative medicine promises to ameliorate, if not cure, a wide range of human injuries, disabilities, and diseases". Of course, such a "promise" cannot neglect the direct ethical and religious implications that it brings with it.

Needless to say that as physicians, we cannot neglect the existing evidence that stem cell therapy and research produce benefits for our patients but, at the same time, the usage of stem cells might cause ethical and religious dilemmas both for us and for our patients.

It is beyond doubt that our culture (as a set of interconnections of religious, modern, secular and post secular factors) remains the background for decision making, including medical decisions. Among other individual and societal factors, the cultural ones equally shape our decisions. Although this might not be obvious, culture is present even in fields that seem dominated by purely technological developments, such as stem cell therapy and research. There are authors attempting to prove that stem cell research might not be incompatible with a monument of our culture, the Bible⁶. It is at this point that religious and ethical aspects interfere; stem cell therapy can modify the human cell, which, from a cultural point of view, involves religion and ethics by nature. Or, to put it more simply, stem cell therapy deals with a “cell” that belongs to culture not to nature.

In fact, the main issue in bioethical debates is not at all the “bios” of the human but the “sacred”, that indefinable part of the human being. Thus, although its scopes are strictly defined, stem cell therapy compasses that “indefinable” that makes us humans. Strange as it may seem, stem cell therapy acts onto our most indefinable reality: a reality which is formed of religious and moral elements. That is to say that stem cell therapy, as one of our most advance technologies, initiates an endless debate: how can we conceive human nature? More accurately: in a postsecular world, a world infused by rationality and technology, why does stem cell therapy still call into play religious and ethical debates? Did we not understand, after Nietzsche and his successors, that human nature is a human invention? Did we not understand, after the death of God⁷ and the death of metaphysics⁸, that the human being is at last free to think without the violent ideology that such concepts (e.g. God, metaphysics) impose to our conscience? In one word, why does stem cell therapy initiate such an endless debate into the field of religion and ethics? A possible answer is that of Francis Fukuyama: “our contemporary technologies threaten to recast fundamentally our relationship to early human life, human reproduction, and human evolution”⁹. Or, as H. Tristram Engelhardt puts it: “The debates regarding the use of human embryos and the engagement of human germ-line genetic engineering are (...) unlikely to abate: they involve incompatible ways of regarding and experiencing reality, sustained within moral communities that experience themselves as locked in a moral struggle.”¹⁰

Nevertheless, if we understand that stem cell therapy must be regarded through the lenses of secular culture, together with H. Tristram Engelhardt, we have to stress three major points:

“1. The assertion of radical metaphysical and moral immanence—God is culturally dead for this bioethics in the sense that the horizon of human concerns is no longer anchored in being as it would be known and affirmed by God, and is rather lodged in being as it is known and experienced within a particular cultural framework (i.e., all being has its being in a particular narrative or life-world).

2. The assertion of the foundational centrality of persons—man and humanism are culturally dead in the sense that there is no recognition of a normative human nature or a canonical humanum to ground natural law, to serve as the basis for morality, to give content to bioethics, or to guide policy decisions outside the commitments of a particular culture so that humans as persons by default become the articulators of morality and the cardinal source of secular moral authority.

3. The assertion of the radical immanence of the right and the good—the moral life and human flourishing are articulated within the horizon of the finite and the immanent so that transcendent claims must either be dismissed or reduced to the demands of the immanent.”¹¹

Thus, any kind of transcendental reference must be avoided when we engage in a debate regarding the ethical problems of stem cell therapy. The human ethical perspective, as an ethics of goods, as Vattimo calls it¹², will have to “decide” when confronted with such an issue. Therefore, this is about a “minimal ethics” based on tradition. And if we can speak about a sort of transcendence, we have to have in mind the “transcendence of tradition”¹³.

Nevertheless, we can adopt a second position based on our Christian tradition¹⁴:

“1. The recognition of ultimate historical orientation—all cosmic and human history are appreciated as proceeding from Creation through the Fall, the Incarnation, and Redemption to the final restoration of all things (Rev 21:1) so that everything, *sensu stricto*, has ultimate meaning and possesses this meaning independently of any particular human culture, tradition, or perspective.

2. The recognition of the normativity of human nature—humans are appreciated as created in the image and likeness of God as well as possessing a biological nature that was taken on by God through the Incarnation, conferring on this human nature a normative standing.

3. The recognition of the divine rootedness of human moral claims—morality is appreciated as rightly ordered insofar as it conforms to the requirements of the omnipotent, personal, Creator God.”¹⁵

H. Tristram Engelhardt’s conclusion is, in a way, ambivalent (not to name it misleading): “It would be a serious error to approach the bioethical disputes provoked by regenerative medicine within the narrow confines of this latter secular bioethics. Instead, one must appreciate the foundational diversity of moral, metaphysical, and epistemological commitments that lie at the roots of our contemporary debates”¹⁶. Why should we not adopt a secular perspective? The models proposed by authors such as Vattimo or Rorty¹⁷, not to name Caputo, Deleuze or Derrida (see the brilliant argumentation of Derrida from *Faith and Knowledge*¹⁸), are not without a firm basis (we can name it ethics or morality in the very strong sense of the word). To refute secular culture only because secular culture refutes the Christian God (the postmodern thinkers who view not the ontological argument of the existence of God but the onto-theological “tyranny” of such a concept over our consciousness) or any kind of strong metaphysical point is, in our opinion, redundant. Not to say that the interpretations proposed, for instance by Vattimo¹⁹, answer one of the major questions of H. Tristram Engelhardt: what about other types of culture, for example that of Eastern Asia?

To choose between secular or religious perspectives when we approach a subject like stem cell therapy is not, of course, without justification: “Issues and dilemmas in bioethics might be new as a result of remarkable advances in biomedical science, but the moral questions they raise are *among the oldest that human beings have asked themselves*.”²⁰ It is exactly at this point that religious and ethical views interfere. A strange mixture between moral and religious insights opens in front of us. A plausible explanation for such an ongoing debate raised by stem cell therapy, with religious and ethical challenges, is given by Fukuyama. In Fukuyama’s view, we have to understand that:

“...rather a fear that, in the end, biotechnology will cause us in some way to lose our humanity—

that is, some essential quality that has always underpinned our sense of who we are and where we are going, despite all of the evident changes that have taken place in the human condition through the course of our history. Worse yet, we might make this change without recognizing that we had lost something of great value.”²¹

The subject of debate is not some central but rather some marginal aspect of our life (e.g. should I or should I not intervene in a politic debate) or it might be the very core of our existence, i.e. “something of great value”. It is not important how we are going to define that “something” – in a secular manner or in a religious one. The fact is that religion and ethics are called into play: what one questions is *the ontological status of the human being*.

This is the reason why nobody will wonder why each country has a very concrete public policy when it comes to stem cell therapy and research. It does not matter if we have in mind a secular state or a religious one (from the United States of America to Iran)²², each of them establishes a clear “ground” from where scientists can work and manipulate embryonic or induced pluripotent stem cells (to our knowledge, there are very few scientific fields to be as “controlled” as this particular branch of medicine).

A Philosophical View: Hans Jonas on Experimenting on Humans

Hans Jonas’ essay *Philosophical Reflections on Experimenting with Human Subjects* is one of the major approaches of the issue of medical experimenting from a philosophical perspective. As Schafer puts it: “The near classical status of this article and the extensive influence of Jonas’ views – an influence encompassing both the scientific and philosophical research communities – render his article a suitable candidate for reconsideration and re-evaluation.”²³ Thus, more than forty years after its publication, Jonas’ analysis is still very topical and could represent a central point for the discussion of the ethical and religious aspects of stem cell research.

Jonas rejects the utilitarian perspective on the problem of human subjects used in medical experimenting in order to achieve a superior social good. Starting from the presupposition of personal dignity and sacrosanctity, the American philosopher states that: “human experimentation for whatever purpose is always *also* a responsible, nonexperimental, definitive dealing with the subject himself. And not even the noblest purpose abrogates the obligations this involves.”²⁴ In this context, Jonas emphasizes the sacrificial feature involved in “the selective abrogation of personal inviolability and the ritualized exposure to

gratuitous risk of health and life, justified by a presumed greater, social good.”²⁵

The conceptual framework of Jonas’ reflections is represented by the duality individual-society but he refuses to situate the issue of human experimentation within the context of the social contract. “Indeed”, says Jonas,

“we must look outside the sphere of the social contract, outside the whole realm of public rights and duties, for the motivations and norms by which we can expect ever again the upwelling of a will to give what nobody—neither society, nor fellow man, nor posterity—is entitled to. There are such dimensions in man with trans-social wellsprings of conduct, and I have already pointed to the paradox, or mystery, that society cannot prosper without them, that it must draw on them, but cannot command them.”²⁶

He distinguishes between moral obligations and moral values stating that: “The ethical dimension far exceeds that of the moral law and reaches into the sublime solitude of dedication and ultimate commitment, away from all reckoning and rule—in short, into the sphere of the *holy*.”²⁷

Jonas considers that the principle of recruitment should be “identification” and should be based on the commitment of subjects to the experiment and on their free and generous endorsement, on values such as “compassion with human suffering, zeal for humanity, reverence for the Golden Rule, enthusiasm for progress, homage to the cause of knowledge, even longing for sacrificial justification (do not call that “masochism,” please)”²⁸.

The principle of identification represents the main restriction of medical experimentation and allows the patient to commit to the cause of the scientific research. At this point of his argumentation, the terms used by Jonas (such as “related to his disease”, “his own kind of suffering and disease”) are vague and are open to different types of interpretation. At the same time, the principle does not give sufficient real guidance when it is applied to particular cases²⁹.

In Jonas’s vision, the rule of experimenting with human subjects is the rule of the descending order of permissibility and it has a significant anti-utilitarian character: “Departing from the august norm, the appeal must shift from idealism to docility, from high-mindedness to compliance, from judgment to trust. Consent spreads over the whole spectrum.”³⁰

The price that has to be paid by accepting the rule of the descending order is a possible diminution of progress. Nevertheless:

“Let us not forget that progress is an optional goal, not an unconditional commitment, and that its tempo in particular, compulsive as it may become, has nothing sacred about it. Let us also remember that a slower progress in the conquest of disease would not threaten society, grievous as it is to those who have to deplore that their particular disease be not yet conquered, but that society would indeed be threatened by the erosion of those moral values whose loss, possibly caused by too ruthless a pursuit of scientific progress, would make its most dazzling triumphs not worth having. Let us finally remember that it cannot be the aim of progress to abolish the lot of mortality. Of some ill or other, each of us will die. Our mortal condition is upon us with its harshness but also its wisdom—because without it there would not be the eternally renewed promise of the freshness, immediacy, and eagerness of youth; nor, without it, would there be for any of us the incentive to number our days and make them count. With all our striving to wrest from our mortality what we can, we should bear its burden with patience and dignity.”³¹

In his critical approach to Jonas’ essay, Schafer concludes that, despite some ambiguities, Jonas’ arguments offer an important reminder of the danger that the utilitarian principle emphasizes, the importance of the general social good that allows experiments which violate other important moral values (individual dignity or social justice). Moreover, the descending order of possibility provides a useful guideline. Nevertheless, Schafer considers that the absolutist tendency of Jonas’ argument is not a realistic approach that could be used in setting policy for human experimentation. Instead, he proposes a general principle according to which the greater the risk of harm to the subjects of experimentation and the greater the seriousness of the harm risked, the higher the level of competence required of subjects for valid consent³².

Jonas proves to be topical because, in the framework of organizational ethics, there is a more and more visible breakup between ethics and religious ethics, a fact that can be a result of the general secularization of society and it can be explained more accurately by following what Aurel Codoban describes as a phenomenon of the dialectics of the sacred in the society based on communication.³³ For such a secular ethics opts Sandu Frunză who analyzes the ethical problems of social responsibility in the system of public health in Romania and he reaches a separation point between the theological concerns for bioethics and those

carried out by various researchers in applied ethics. Thus, he states that those with theological visions must not involve themselves in formulating the public policies aimed at ruling specific bioethical problems:

“They may find their well defined role in the debates on the specific implementation of sector policies, but not in the process of the creation of these policies. At the level of ethics institutionalization, of the general strategies targeting the construction of a model of social responsibility and public action that should provide an ethical base for an adequate, ethical and efficient resource allocation in the public health system, religious expertise is not necessary. Moreover, religious reflection may still be relevant for the spiritual problems of individuals, for the responses they seek to varied personal problems but it must not be a reference in the modernization of the state, in institutional reconstruction, in the public policies of the state.”³⁴

Being based both on communication and on knowledge, contemporary society requires the development of deontology in a separate way, different from the religiously based morals. Thus, both in the institutional space of organizations concerned with the development of principles regarding various aspects of medical ethics, and in the individual space of the professionalization of experts in the medical field, professional ethics gets developed on a secular basis, without reaching a form of conflict with religion-based morals.

Regulation Politics: Ethical Guideline for Clinical Translational Research

The discussions referring to stem cell therapy have evolved from the controversies on human embryonic stem cells to the concerns about the ethical use of stem cells in clinical research. Along with the advance of stem cell research, other ethical issues will arise concerning the clinical translation of basic stem cell knowledge into therapies that are safe and efficient. In an attempt to avoid the ethical challenges raised by the usage of human embryonic stem cells, the scientists propose alternative sources of pluripotent stem cells that do not involve the destruction of human embryos, such as: stem cells obtained from already-deceased embryos; stem cells obtained from living embryos by nondestructive biopsy; stem cells obtained from bioengineered embryo-like artifacts; and stem cells obtained from dedifferentiated somatic cells. Each of these approaches sought to generate the functional equivalent of hES cells derived from

living blastocyst-stage embryos — pluripotent human stem cells that are genetically stable and long lived.³⁵

Thus, the discovery of human induced pluripotent stem (iPS) cells – dermal fibroblasts genetically engineered to behave like hES cells – is the most recent and promising development in stem cell research, praised by the opponents of hES cell research. Yet, at the same time, there are scientists who do not consider that iPS cells can prevent the need for ongoing hES cell research and the question, whether iPS cells are absolutely identical to stem cells harvested from early-stage embryos, still remains.³⁶

The collaboration of scientists is even more difficult because of the legislation that varies in different states. At present, the major bioethical considerations focus on *how* stem cell research ought to be conducted, rather than on *whether* it ought to be conducted. Hence, the new developments in stem cells research are not avoiding ethical controversy altogether, but are confronting the scientists with a different set of ethical concerns.³⁷

The research on the development of stem cell therapies poses ethical challenges for several reasons. First, stem cells are novel therapeutic agents whose development and manufacture require innovative procedures for ensuring purity and homogeneity. Cell types may differ in their ability to proliferate and safely implant in the body. Their use poses risks of infusional toxicity, severe immune responses, and tumorigenesis. Moreover, animal models may not accurately reflect toxicity in humans. Also, ethical difficulties are raised by the risk assessment and the safety standards for the donation, testing, procurement, processing, storage, distribution and preservation of tissue and cells (pure material, toxicology of the biomaterial, contamination, and diffusion in the body). Other problematical aspects are the relation between the clinician and the scientist, the links between academic research and industries and the issues concerning the patient's consent, surveillance of recipients, as well as social aspects.³⁸

In response to these challenges, in 2008, International Society for Stem Cell Research (ISSCR) proposed an ethical guideline for clinical translational research.

The guideline calls attention to the novelty and the expectations regarding stem cell research and it emphasizes that “in all areas of medicine, the maturation of an early-phase, experimental intervention into an accepted standard of medical practice is a long and complex process usually involving many years of rigorous preclinical and clinical testing and many setbacks and failures. Only with time and experience do most new clinical treatments come to be accepted by medical professionals.”³⁹

Ronald M. Green synthesizes the 39 recommendations that the ethical guideline for clinical translational research contain into five broad categories.⁴⁰

(1) Concerning cell processing and manufacture, the recommendations are that the process must be conducted under “scrupulous, expert, and independent review and oversight.” As a rule, minimally manipulated products (cells maintained in culture under non-proliferating conditions for short periods of time) require less oversight than those subjected to extensive manipulations, such as genetic alterations. The same is true of autologous versus allogenic use, and of homologous versus non-homologous functions. Donors of cells should be screened for infectious diseases and the donor should give written informed consent that covers the likely storage, future manipulations, analyses, and uses of their cells, their commercial potential and possible risks to the donor’s privacy, including exposure of genetic information.⁴¹

(2) Preclinical studies must provide evidence of product safety and proof-of-principle of therapeutic effect. This necessitates studies in animal models, including larger animals, in whose case the structural tissue needs to be tested in a load-bearing model. The evaluation of the risks of tumorigenicity for any cell product must be developed and implemented. Cell cultures and animal models should be used to test the interaction of cells with drugs to which recipients will be exposed, including the immunosuppressants planned for recipients.⁴²

(3) Clinical trials of stem-cell research must conform to internationally accepted principles in relation to the protection of human subjects (including regulatory oversight, peer review by an expert panel independent of the investigators and sponsors, fair subject selection, informed consent, and patient monitoring). The ethical issues of the clinical translational stage of stem cell research surpass the hES cells controversy because they encompass all stem cell types, and because they concern human subjects, who, despite what one may think about the moral status of embryos, are unequivocally moral persons with rights and interests that may be harmed⁴³. In addition, because of the undetermined risks, stem cell-based therapies, as a rule, must be clinically competitive or superior to existing therapies. The patients enrolled in these clinical trials are exposed to inappropriate stem cell migration, tumor formation, immune rejection of transplanted stem cells, complications of immunosuppressive therapy before and after transplantation, hemorrhages during transplantation, postoperative infection and medical tourism. Where there are already efficient therapies for a disease, the stem cell-based intervention must represent a lower risk and offer a potential advantage. Greater risks are permissible where there is no efficacious therapy and where the disease condition is severely disabling and life threatening. Patients need to be informed of the novelty of the treatment and of the fact that stem cell therapy may produce adverse

effects. Also, the patients should be informed about the source of the cells. In order to determine the consequences of stem cell therapy, and with consideration of cultural and familial sensitivities, subjects should be asked for autopsy in the event of death.⁴⁴

(4) The document condemns the practice of marketing of unproven stem cell interventions, but it recognizes a difference between “the commercial purveyance of unproven stem cell interventions and legitimate attempts at medical innovation outside the context of a formal clinical trial” (ISSCR, 2008). The administration of unproven stem cell interventions outside the regulated research protocols (a phenomenon known as “stem cell tourism”) represents a risk for the patients and for the legitimate development of translational stem cell scientific research. It would permit the latter in “exceptional circumstances” and only for “seriously ill patients who lack good medical alternatives.” Such unproven stem-cell interventions require a written plan explaining, among other things, the intervention’s scientific rationale, clinical justification, a description of procedures, and plans for follow-up, data collection, identification of adverse effects, and assessment of efficacy. The patient should be informed of the unproven nature of the intervention, there should be an action plan for handling adverse events, and provision should be made for insurance coverage or treatment of complications arising from the procedure. These risks include tumor formation, immunological reactions, unpredictable behavior of the cells, and long-term health effects yet unknown. Risks to future research participants may be further minimized through careful monitoring of patient-subjects and timely reporting of adverse events.⁴⁵

(5) Considerations of social justice refer to the public engagement in the policy making of governmental agencies, fair allocation of benefits and risks, and the need to promote fair and broad access to the new diagnostics and therapies. Another consideration referring to stem cell research is the establishment of stem cell collections with genetically diverse sources of cell lines.⁴⁶ With regard to clinical translational research, it is important to ensure that there is proper supervision of these novel and potentially harmful therapies maintaining a balance between the ethical issues of stem cell therapy and its advantages, yet to be determined.

Within the framework of the debates on the embryo status and the ethical issues implied by the use of stem cells obtained from different sources than the human embryo, the bioethical discourse centers on areas that have a much broader consensus-based shared values, as the ISSCR clinical translation guidelines stresses, such as patient and research subject protections and social justice.⁴⁷

The new developments in stem cell research change the emphasis of the ethical debate from the bioethics of *whether*, to the bioethics of *how*⁴⁸

and raise difficult questions for researchers, clinicians, patient advocates, regulators, and bioethicists.

Notes:

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¹² Sandu Frunză, *Comunicare Etică și Responsabilitate Socială*, (București: Tritonic, 2011).

¹³ Sandu Frunză, *Comunicare Etică și Responsabilitate Socială*, 22.

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⁴¹ Green, 1126.

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⁴⁴ Green, 1126.

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