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Background

In 2013, a Nigerian academician warned of Western biotech companies circumventing domestic and international laws to facilitate the trafficking of human embryos for the purpose of human embryonic stem cell (hESC) research. He further alleged that recent Nigerian legislation was "engineered" to include the classification of human embryos as Genetically Modified Organisms (GMO), thus allowing for their legal trade.

Dr. Philip C. Njemanze, Chairman of the Association of Catholic Medical Practitioners of Nigeria and the Global Prolife Alliance, penned a letter to Nigerian Senator David Mark expressing this grave concern for the dignity of human life in his home country. While he addressed several topics in the letter, the part most relevant to this investigation reads:

> Economic forecasters say that embryonic stem cell research, if successful, has a potential of raising a $30 Trillion US Dollar market, one-third of the World economy... This "human industry" will make and sell human organ parts made from embryonic stem cell research. However, to perfect the key procedure called the Somatic Cell Nuclear Transfer (SCNT) that will yield the organ, the industry will need about 100 million ovarian eggs per annum from at least 10 million African women, to make human embryos of Africans to be killed in these experiments in Western laboratories, in the next five years…Such laws like the National Health Bill 2012 (Section 51-58), Genetically Modified Organisms and Biosafety Bill (Sections 17-20) were engineered to facilitate human embryo trafficking in Nigeria.[1]

This paper will not address Dr. Njemanze's specific allegation with regard to Nigeria; rather, it will inves-

1 Sankara, EG. "Academician, Dr. Philip C. Njemanze, wants Bill & Melinda Gates Foundation expelled from Nigeria." The Gambia Echo 27 October 2013.

tigate the possibility, if not probability, that human embryos could be classified as GMO and international laws may permit their trafficking in the global market.

Genetically Modified Organism Classification

Acknowledging the moral and ethical implications of hESC research, some governments have placed restrictions on funding for research that requires the further destruction of human embryos. In the US, these restrictions exist with the exception of a limited number of human embryonic stem cell lines which had already been created. To maximize the usefulness of these lines, scientists have tried, successfully at times, to immortalize them—that is, to alter them in a way that enables continued propagation indefinitely. Several approaches can be used to facilitate this act, for example: "transfecting [the cells] with genes that encode growth factors or enzymes involved with regulating cell division."[2] However, these cells often display disrupted cell growth resulting in over-proliferation and tumor or tumor-life growth.

Therefore, scientists have turned to nuclear cloning or reprogramming, in particular Somatic Cell Nuclear Transfer (SCNT), which is of significant concern when investigating GMO classification. This procedure minimizes the need for human embryos yet requires a plurality of eggs; more precisely, immature eggs known as oocytes. During the SCNT process, genetic material from the oocyte is removed followed by the introduction of a somatic cell nucleus into the enucleated oocyte.[3] This somatic cell is a body cell which contains a complete set of chromosomes. "Under appropriate conditions the oocyte-somatic nucleus 'hybrid' can be stimulated to start dividing and has the potential to generate an intact embryo and produce a viable organism that is genetically identical to the donor of the somatic nucleus."[4] Scientists believe that the stems cells derived from the inner cell masses of these embryos are totipotent, or capable of forming any tissue within the human body. Further genetic modification of hESC can be achieved through a variety of gene transfer technologies; e.g. plasmid transfection or viral transduction. Both involve the introduction of outside genetic material, added to hasten egg maturation.[5]

Compounding the unethical nature of therapeutic cloning are the controversial methods of oocyte retrieval. The most common technique implements hormonal treatments often referred to as "fertility drugs." Following multiple injections of various gonadotropin-based hormones, the mature oocytes are removed via an ultrasound-guided transvaginal probe and hollow needle. This method often yields approximately twelve oocytes per cycle.[6]

Another ooctye retrieval method is in vitro maturation (IVM) from surgically removed ovaries. An oophorectomy, which removes one or both ovaries, is a medical procedure that treats women suffering from

2 Buttery, Lee, and Kevin M. Shakesheff. "A Brief Introduction to Different Cell Types." Book chapter in: Polak, Julia, Mantalaris, Sakis, and Harding Sian E. (eds.) Advances in Tissue Engineering. Imperial College Press, London. 2008.
3 Ibid.
4 Ibid.
5 Simonsson, Stina, and Dzeneta Vizlin-Hodzic. "Reprogramming of Somatic Cells." Book chapter in: Urbano, Kevin V. (ed.) Advances in Genetics Research, Volume 4. Nova Science Publishers, Hauppauge, NY. 2011.
6 Ibid.

conditions such as chronic salpingitis, endometriosis, and the growth of benign ovarian cysts. The majority of women who undergo oophorectomies do not elect to donate their ovaries for scientific research; however, the potential for a mass accumulation of oocytes remains if consent were to be given. Conservative estimates, for example, show at least 75,000 mature oocytes are removed annually through oophorectomic procedures. Following IVM, it is "technically feasible" that these oocytes would be receptive to SCNT.[7] In addition, scientists have also removed oocytes from cadavers and aborted fetuses as an alternative method to ovarian hyperstimulation and IVM post-oophorectomy.[8]

International Laws Governing Human Cloning

On August 2, 2005, the United Nations, in the 59th General Assembly, adopted the United Nations Declaration on Human Cloning by majority vote, but without achieving consensus. The Declaration stated, "Practices which are contrary to human dignity, such as the reproductive cloning of human beings, shall not be permitted." Furthermore, under the Declaration, the ratifying states solemnly declared; "to protect adequately human life in the application of the life sciences, to prohibit all forms of human cloning inasmuch as they are compatible with human dignity and the protection of human life, to adopt measures necessary to prohibit the application of genetic engineering techniques that may be contrary to human dignity, and to prevent the exploitation of women in the application of life sciences,"[9] among other articles.

This Declaration was adopted by the majority of states; however, 71 members either voted against or abstained from casting a vote entirely. Several of these states cited possible restrictions on therapeutic cloning as the motivating force that influenced their vote. China, for example, said, "Having voted against the Declaration, the Chinese Government would continue to adhere to its position against reproductive human cloning, while maintaining strict controls over therapeutic cloning." Likewise Belgium said, "It was essential that reproductive human cloning be prohibited. However, it was reasonable to preserve, at the national level, the possibility of carrying out therapeutic cloning." In total, ten states submitted official explanations citing their support of "strictly regulated therapeutic cloning."[10]

A similar declaration, adopted eight years prior at UNESCO's 29th General Conference, is the Universal Declaration on the Human Genome and Human Rights (UDHGHR). Article 11, in particular, states, "Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted."[11] This Declaration was endorsed by the United Nations General Assembly on December 9,

7 Kim, Mikyung, and Kyu Wond Jung. "Oophorectomy Specimens as a Potential Source of Oocytes for Human Embryonic Stem Cell Research." Book chapter in: Pace, Tyler N. (ed.) Bioethics: Issues and Dilemmas. Nova Science Publishers, Hauppauge, NY. 2010.

8 Mertes, H., and G. Pennings. "Oocyte Donation for Stem Cell Research." *Human Reproduction* 22 (3) (2007). http://humrep.oxfordjournals.org/content/22/3/629.full (Accessed 25 January, 2014)

9 United Nations. General Assembly. 59/280 United Nations Declaration on Human Cloning. 2005. Web. 25 January 2014.

10 United Nations Press Release. General Assembly Adopts United Nation's Declaration on Human Cloning by Vote of 84-34-37. http://www.un.org/press/en/2005/ga10333.doc.htm (accessed 25 January 2014)

11 United Nations Educational, Scientific, and Cultural Organization. Universal Declaration on the Human Genome and Human Rights. 1997. http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/human-genome-and-human-rights/ (Accessed 25 January 2014.)

1998. Furthermore, the European Union also adopted its own document, the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine. This Convention was ratified in Paris on January 12, 1998. The protocol specific to cloning states, "Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited. For the purpose of this article, the term human being 'genetically identical' to another human being means a human being sharing with another the same nuclear gene set."[12]

International Laws Regulating Bio-Trade

The Convention on Biological Diversity is "the main international instrument for addressing biodiversity issues" as it provides a "comprehensive and holistic approach to the conservation of biological diversity, the sustainable use of natural resources and the fair and equitable sharing of benefits deriving from the use of genetic resources."[13] Following several years of work and negotiations throughout the 1990's, the Convention adopted the Cartagena Protocol on Biosafety with the objective of "ensuring an adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from modern biotechnology,"[14] focusing specifically on transboundary movement. The Protocol defines the following terms for purposes of the Convention:

> (g) "living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;
>
> (h) "living organism" means any biological entity capable of transferring or replacing genetic material, including sterile organisms, viruses and viroids;
>
> (i) "modern biotechnology" means the application of: a) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b) fusion of cells beyond taxonomic family that overcome natural physiological reproduction or recombination barriers and that are not techniques used in traditional breeding and selection;[15]

Some hold that the Cartagena Protocol is open to misinterpretation, especially regarding the definition of living modified organism (LMO) as well as "the understanding of what gene technology and biotechnology constitutes, something that may give rise to different regulations, including differences in legal coverage at the national level."[16]

12 Council of Europe. Additional Protocols to the Convention for the Procreation of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: On the Prohibition of Cloning Human Beings. 1998

13 Secretariat of the Convention on Biological Diversity. Cartagena Protocol on Biosafety to the Convention on Biological Diversity. Montreal: Secretariat of the Convention on Biological Diversity, 2000.

14 Ibid.

15 Ibid.

16 Husby, Jan. Definitions of GMO/LMO and Modern Biotechnology. Book chapter in: Traavik, T. and Lim, L.C. (eds.) Biosafety First: Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms, Tapir Academic Press, Trondheim. 2007.

Synthesis and Recommendation

This examination has affirmed the possibility that human embryos, created through the process of somatic cell nuclear transfer or manipulated through physical/ chemical transfection and viral transduction, may qualify as genetically modified organisms. Furthermore, it has demonstrated that in order to conduct genetic experiments such as SCNT, fresh oocytes are required. These early gametes are often retrieved from female patients following a period of hyperstimulation. Sadly, the fertility drugs prescribed to facilitate follicle growth often result in a condition known as Ovarian Hyperstimulation Syndrome; which side effects can include hepatic dysfunction, thrombosis and pulmonary edema.[17]

While the classification of human embryos as GMO facilitates trade, it is not necessary to circumvent the norms of scientific research as is evident in the large number of international states who either conduct or finance therapeutic cloning under their respective laws. The United Nations Declaration on Human Cloning failed to reach consensus and resulted in a non-binding set of guidelines that 71 member states did not ratify. Two other adopted international documents, the Universal Declaration on the Human Genome and Human Rights and the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, failed to restrict the practice of therapeutic cloning, with limits placed only on reproductive cloning or the cloning of a human being which is vaguely defined.

Furthermore, the UDHGHR has been criticized for both specific and general issues. For example, "Article 11 declares that cloning with a view to the reproduction of human beings is a practice contrary to human dignity and should not be allowed. Regrettably, this formulation does not exclude human cloning, equally unacceptable, for other purposes, e.g. research or therapy."[18] With regard to the document itself,

> The Declaration…does not define the bearers of the rights which it proclaims; it does not affirm that these rights belong to every human being from the moment when he or she emerges as an individual from his or her genetic heritage. Nor is there any reference to the embryo and the fetus. The question is delicate, especially as regards the embryo in the first 6-7 days of life. The fact that unborn human beings and human embryos are not explicitly protected opens the door, particularly in the field of genetic intervention, to the very forms of discrimination and the violations of human dignity which the Declaration seeks to ban.[19]

Prior to the UDHGHD, the Council of Europe adopted Recommendation 1100/1989 acknowledging considerations "that it is appropriate to determine the legal protection to be given to the human embryo from the time that the human egg is fertilized" and "that the human embryo, through displaying successive

17 Arikan, I., A. Barut, M. Harma. "A Severe Case of Ovarian Hyperstimulation Syndrome with Pulmonary Thromboembolism." The Internet Journal of Gynecology and Obstetrics Volume 13 Number 1. 2009. https://ispub.com/IJGO/13/1/5470 (accessed 25 January 2014.)

18 The Holy See. Observations on the Universal Declaration on the Human Genome and Human Rights. Paris, 1997. http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pa_acdlife_doc_08111998_genoma_en.html (Accessed 25 January 2014)

19 Ibid.

phases in development which are designated by different terms, displays also a progressive differentiation as an organism and none the less maintains a continuous biological and gene identity."[20] However, it can be argued that this Recommendation is rarely honored considering that of the forty-seven member states, "almost all countries allow abortion to save a woman's life, 90% to preserve mental or physical health, 88% if the fetus is thought to be impaired, nearly 80% for economic and social reasons, and slightly fewer allow abortion upon request."[21]

Also open to question is why the Cartagena Protocol did not restate Article 2 (2) of the European Union Directive 2001/18/EC, "Genetically modified organism (GMO) means an organism, with the exception of human beings, in which genetic material has been altered in a way that does not occur naturally and/or natural recombination."[22] The Protocol did not make a single mention of the words "human," "oocyte" or "embryo" much less a distinction among them. Clearly the definition of human or human being has never been a source of agreement within the international community. If it were and legislative bodies were to recognize the preimplanted human embryo as a person due certain inalienable rights; specifically the "right to life, liberty and security" as outlined in the United Nations Universal Declaration of Human Rights,[23] then in vitro fertilization, therapeutic cloning, and human embryonic stem cell research would be vilified as abominations to humanity. Therefore, it is possible that under current international law; human embryos, through verbal manipulation, may qualify as a GMO/LMO as many states across the globe fail to recognize embryos as human beings with inherent rights.

Recognizing the grave implications of therapeutic cloning and the trade of living human organisms, it is paramount that individuals, organizations, and states speak out against the continued experimentation on and destruction of embryonic human life. Elio Cardinal Sgreccia, former president of the Pontifical Academy of Life, clearly articulated the moral gravity of such experimentation in his book Manuale de bioetica. He argued:

> The matter of experimentation on human embryos was declared ethically inadmissible, regardless of the type and purposes of the experimentation. Whether it is genetic experimentation (recombinant DNA) or chromosome substitutions, whether pharmacological research or an experimental study in embryonic biology, the judgment from the ethical viewpoint is still negative, because the experimentation often involves bringing a human being to life with the sole purpose of making him or her an "object" of the experiments. The depravity of the end infects the morality of the entire act.[24]

20 The Parliamentary Assembly of the Council of Europe. Recommendation 1100/1989 On the Use of Human Embryos and Foetuses in Scientific Research. 1989.

21 World Health Organization. Facts and Figures about Abortion in the European Region. http://www.euro.who.int/en/health-topics/Life-stages/sexual-and-reproductive-health/activities/abortion/facts-and-figures-about-abortion-in-the-european-region (Accessed 25 January 2014.)

22 The European Parliament and the Council of the European Union. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms and repealing Council Directive 90/220/EEC. 2001. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32001L0018 (Accessed 25 January 2014)

23 The Commission on Human Rights. The Universal Declaration of Human Rights. 1948. http://www.un.org/en/documents/udhr/ (Accessed 25 January 2014)

24 Sgreccia, Elio. Manuale de bioetica Trans. John Di Camillo and Michael J. Miller. The National Catholic Bioethics Center,

It is therefore recommended that future treaties, declarations, and conventions specifically recognize the embryo as a human being, affording it rights and protection under international law, from the moment of sperm-egg fusion—including the stages of zygote and blastocyst as well as those engendered through scientific intervention—including SCNT. Furthermore, in an effort to respect these rights, governing bodies both at national and international levels must resist the altruistic temptation of therapeutic cloning by explicitly prohibiting its exercise to the same extent as reproductive cloning; which has garnered robust support throughout the world.

Philadelphia. 2012. (Page 610.)

Andrew Kubick is a graduate of Holy Apostles College & Seminary with a degree in Theology, concentrating in Bioethics. He has served as a research intern, policy analyst, and Edmund Burke Fellow for C-Fam. He is currently enrolled in post-graduate studies at Holy Apostles and is an instructor of Religion in Northern Virginia.

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