TRUTH AND CLONING: POLITICAL IDEOLOGY, SCIENTIFIC INTEGRITY, AND THE ADVENT OF THREE PARENT CHILDREN

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Abstract

Pope John Paul II taught that the truth cannot be changed by linguistic techniques designed to shape one's perceptions. This paper examines the various linguistic means statutory definitions of human cloning employ, sometimes with the obvious purpose of advancing a political, ideological, and/or research agenda. This reveals a trend of substituting arbitrary definitions at the expense of recognizing scientific truth and the humanity of the cloned entity. It has given way to a reality where one can clone an embryo, harvest its cells for research purposes, and deny that the process is cloning. This has not prevented us from reaching a political reality where the birth of a cloned human being could soon become a reality via three-parent embryo creation. As three-parent embryo techniques gain traction in the United States, legislatures will need to confront arbitrary definitions of human cloning and decide whether to continue hiding scientific truth.

Introduction

Advances in human cloning herald significant success in scientific mastery over nature and are marked by subjectivity of compassion. Nonetheless, these advancements bring the peril of dehumanization. Cloning has created a moral crisis calling society to balance the good of medical advancement with the inherent dignity of human life.[2] Truthful dialogue about human cloning and its implications in three-parent embryo creation demands respect for scientific fact.

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[2] Dr. Leon Kass, MD, explains that Aldous Huxley, in his novel Brave New World, predicted that novel techniques to manipulate human life would lead to a dystopia, a world plagued by devaluation of human life. "Huxley shows us a dystopia that goes with, rather than against, the human grain." (See Leon R. Kass, "Preventing a Brave New World," *The Human Life Review* 27, no. 3 (2001): 14-15. ISSN: 00979783).

Moral Considerations: Protecting Human Life

Scientific evidence establishes the moment of conception as the precise, non-arbitrary moment when human life begins. At conception, the zygote contains complete instructions providing a developmental pathway upon which human life proceeds. Unlike an ordinary body cell, the zygote proceeds along a pattern of organized behavior that can lead to birth. This self-organization is the "hallmark of an organism."[3]

Some contend that since fertilization is a process itself, it is unclear whether the embryo exists prior to the end of fertilization.[4] Still, fertilization is part of the trajectory of self-organized embryonic development that marks a distinct organism. The zygote's behavior is not fundamentally altered at the completion of fertilization, or syngamy, therefore, human life is present at the outset of fertilization.[5] Even if considering the embryo to exist only after syngamy, scientific evidence establishes that the embryo exists five to six days before implantation.[6]

Cloning, creating a genetic copy of a human being, has been achieved via somatic cell nuclear transfer (SCNT), "a technique in which the nucleus of an oocyte is replaced with the

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[3] Maureen L. Condic, "When Does Human Life Begin? A Scientific Perspective," *Westchester Institute White Paper Series* 1, no. 1 (2008): 6-11. http://bdfund.org/wp-content/uploads/2016/05/wi_whitepaper_life_print.pdf. Other scientific sources affirm that a unique individual forms at conception (for example, Keith L. Moore, T.V.N. Persaud, and Mark G. Torchia, *The Developing Human: Clinically Oriented Embryology* (Philadelphia: Elsevier, Inc., 2016), 11).

[4] *See* Brief of Catholic Medical Association as Amicus Curiae Supporting Respondents at 6-8, Sebelius v. Hobby Lobby Stores, Inc., 134 S.Ct. 1536 (2014) (No. 13-354), 2014 WL 1093909 (discussing fertilization as a process).

[5] "From a biological perspective, the breakdown of nuclear membranes at syngamy is a relatively mundane event along an *already progressing* developmental trajectory. The material composition of the cell does not change from the instant prior to syngamy to the instant after it takes place. There is no substantive change in the behavior of the cell at syngamy; all the preparations for cell division … are already underway … Nuclear membrane breakdown is not a unique, 'zygote-forming' event, but rather it is part of every round of cell division that occurs through life." (Condic, "When Does Human Life Begin?," 8).

[6] Brief of Catholic Medical Association, *supra* note 4, at 7 (citing WILLIAM J. LARSEN, HUMAN EMBRYOLOGY 21-22 (3d ed. 2001); K.L. MOORE & T.V.N. PERSAUD, THE DEVELOPING HUMAN: CLINICALLY ORIENTED EMBRYOLOGY 37 (7th ed. 2003)).

nucleus of a somatic cell".[7] As technology advances, cloning could be achieved in unexpected and novel ways. The nuclear genetic material could potentially derive from a deceased human being[8] or be performed without the donor's knowledge or involvement.[9] SCNT, or substantially similar processes, initiates a trajectory of embryonic development parallel and equivalent to that of the sperm-egg union (see Figure 1).[10] Cloning, thereby, generates "a living human entity."[11] It does not alter the analysis of when human life begins.[12]

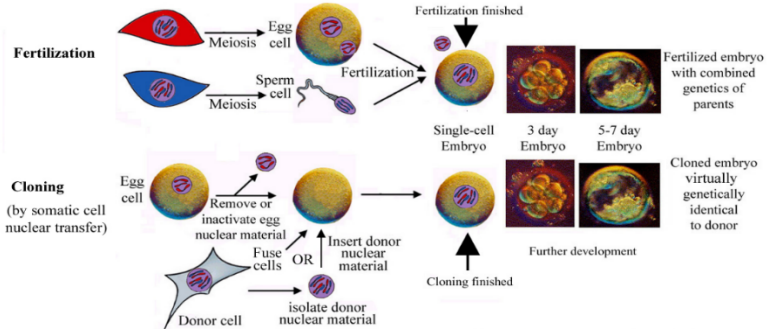

Figure 1. Somatic Cell Nuclear Transfer[13]

For those who hold that human life has special status, respect for human life cannot with any consistency be precluded at life's earliest moments. Internationally recognized standards of ethical scientific research recognize the inherent inviolability connected with human life. For

[7] Neb. Rev. Stat. Ann. § 71-8802(3). Prof. Kerry Lynn Macintosh notes that humans born via cloning will be their own unique individuals and will not have the exact same DNA as the donor. Factors such as genetic mutations, differences in mitochondrial DNA, environmental influences, and epigenetic dynamics will distinguish the individual from his or her donor. (Kerry Lynn Macintosh, "Human Cloning: Four Fallacies and Their Legal Consequences," (New York: Cambridge University Press, 2013), 54-57).

[8] *See Testimony on SB 2302 Before the S. Judiciary Committee*, 2013 Leg., 63rd Sess. (ND 2013) (submitted testimony of David A. Prentice, Ph.D, Senior Fellow for Life Sciences, Family Research Council), *http://www.legis.nd.gov/files/resource/63-2013/library/sb2302.pdf.* (explaining that the nuclear genetic material used in SCNT can produce "a human embryo who is virtually genetically identical to an existing or previously existing human being").

[9] Kass, "Preventing a Brave New World," 20.

[10] Condic, "When Does Human Life Begin?," 10.

[11] *Human Cloning and Human Dignity: An Ethical Inquiry* (Washington, DC: The President's Council on Bioethics, 2002), 46, https://repository.library.georgetown.edu/bitstream/handle/10822/559368/pcbe_cloning_report.pdf?sequence=1&isAllowed=y.

[12] Condic, "When Does Human Life Begin?," 10.

[13] Courtesy of David A. Prentice, Ph.D., Charlotte Lozier Institute. Image used with permission.

instance, the Helsinki declaration prioritizes protection of the individual over medical progress.[14] Even though this declaration provides that informed consent can protect against exploitation,[15] authors have noted that consent cannot define what is permissible in terms of human subjects' research. If this were the case, then any experiment would be permissible where the participant consents.[16] The Nuremberg Code, established in response to the human experimentation atrocities conducted in Nazi concentration camps, expressly condemns research "where there is an a priori reason to believe that death or disabling injury will occur."[17]

While the Nuremberg Code and Helsinki Declaration do not by their own terms refer to human embryos, legal protections to human fetuses and embryos have been implemented. At least one author believes that regulations adopted in 1975 by the Department of Health, Education, and Welfare incorporated the Nuremberg Code's prohibition against death-inducing human subjects' research,[18] inasmuch as they only permitted research on a human fetus where a number of requirements are met, including minimal risk to the fetus.[19] More recent legislation,

[14] "While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interest of individual research subjects." ("WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects," World Medical Association, accessed June 22, 2016, http://www.wma.net/en/30publications/10policies/b3/.)
[15] "The voluntary consent of the human subject is absolutely essential." (Ibid.).
[16] "Since consent merely identifies the people who are willing to undergo the experiment, it cannot define the scope of permissible research" (Wendy K. Mariner, "AIDS Research and the Nuremberg Code," in *The Nazi Doctors and the Nuremberg Code*, eds. George J. Annas and Michael A. Grodin (New York: Oxford University Press, 1992), 296).
[17] "The Nuremberg Code," *Journal of Law, Medicine, & Ethics* 19, no. 3-4 (1991): 266.
[18] "Interestingly, the 1975 regulations regarding fetal research *do* adopt these Nuremberg Code provisions [prohibiting studies that will result in death]" (Mariner, "AIDS Research and the Nuremberg Code," 189).
[19] 45 CFR § 46.204 (b) ("The risk of the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means"); (See also, Mariner, "AIDS Research and the Nuremberg Code," 189).

the Dickey-Wicker Amendment of the Omnibus Appropriations Act prohibits federal funding for research that involves destruction of embryos.[20]

Intellectual integrity should compel the application of internationally recognized principles of ethical human subjects' research to embryonic human life.[21] As 2002 President's Council on Bioethics (PCBE) member Robert George contended: "To deny that embryonic human beings deserve full respect, one must suppose that not every whole living human being is deserving of full respect."[22] If the Helsinki Declaration and Nuremberg Code do not protect embryonic human life, then their use of the term "human" is contrary to the scientific truth that human life begins at conception.[23] They would fail to fully honor their underlying purpose to "embody society's profound sense that human beings are not to be treated as experimental guinea pigs for scientific research."[24] Further, their inapplicability to human life at its most vulnerable stages would contradict their underlying purpose to "defend the weak against the strong and uphold the equal dignity of all human beings."[25]

Even before the development of IVF and destructive experimentation on embryonic human beings, the Catholic Church affirmed that embryonic life must not be treated as an object, but instead, as inviolable human life.[26] The embryo is the epitome of innocent human life and, as

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[20] Omnibus Appropriations Act, 111 P.L. 8, § 509(a)(2), 123 Stat. 524, 803 (2009) (Funds are not available for "research in which a human embryo or embryo are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).").
[21] *See* Marion Hilligan, Nelson P. Miller, Don Peterson, & Chris Hastings, *Superhuman – Bioetechnology's Emerging Impact of the Law*, 24 T. M. COOLEY L. REV. 1, 59 (2007) (citing John Finnis, *Some Fundamental Evils in Generating Human Embryos by Cloning*, *in* ETHICS AND LAW IN BIOLOGICAL RESEARCH 99, 102 (Cosimo Marco Mazzoni ed., 2002) (stating that therapeutic cloning is a violation of the Declaration of Helsinki)).
[22] *Human Cloning and Human Dignity*, 259.
[23] See Condic, "When Does Human Life Begin?," 6-11.
[24] *Human Cloning and Human Dignity*, 88.
[25] Ibid., 89.
[26] "We proclaim … no one, not even the father or mother, can act as its substitute – *even if it is still in the embryonic stage* – to choose in the child's name, life, or death" (Congregation for the Doctrine of the Faith, *Declaration on Procured Abortion*. Vatican Website. June 28. 1974, § 14, accessed July 23, 2016,

Pope Pius XII recognized even before even the Nuremberg Declaration, it is never licit to destroy innocent human life.[27] Thus, if international protections against destructive human subjects' research are applied to the embryonic human being, then they are in accord with the teachings of Pope Saint John Paul II that all innocent human life is to be protected as "equal to all others," and "the deliberate decision to deprive an innocent human being of his life is always morally evil and can never be licit as either an end in itself or as a means to a good end."[28]

To this end, processes that destroy embryonic human life for research purposes are of fundamental moral concern. One such process is commonly called therapeutic cloning. With this process, the laboratory creates an embryo through SCNT. Once the embryo consists of 100-200 cells, a few days after initiation of embryonic development, the laboratory takes it apart to harvest its pluripotent stem cells for purposes of conducting human embryonic stem cell research (hESCR).[29]

Therapeutic interventions derived from cloning and subsequent hESCR are meant to benefit the donor of the nuclear genetic material, namely, the person being cloned. The cloned embryo would not be the beneficiary. Accordingly, the PCBE found it "misleading" to use the term "therapeutic cloning."[30] Instead, the PCBE described what is commonly called therapeutic

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http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19741118_declaration-abortion_en.html (emphasis added)).

[27] "'As long as man is not guilty, his life is untouchable, and therefore any act directly tending to destroy it is illicit, whether such destruction is intended as an end in itself or only as a means to an end, whether it is a question of life in the embryonic stage or a stage of full development or already in its final stages.'"(Ibid., § 9, ftnt. 15, citing *Discourses and Radio-messages*, VI, 183ff).

[28] John Paul II, *Evangelium Vitae*. Vatican Website. March 25, 1995, § 57, http://w2.vatican.va/content/john-paul-ii/en/encyclicals/documents/hf_jp-ii_enc_25031995_evangelium-vitae.html.

[29] For further description of the therapeutic cloning process see *Human Cloning and Human Dignity*, 69-70, citing J.B. Cibelli, et al., "Somatic Cell Nuclear Transfer in Humans: Pronuclear and Early Embryonic Development," e-biomed: *The Journal of Regenerative Medicine* 2, (2001): 25-31. A pluripotent cell is "[a] cell that can give rise to many different types of differentiated cells." (Ibid., 233). "Stem cells are undifferentiated multipotent precursor cells that are capable both of perpetuating themselves as stem cells and of undergoing differentiation into one or more specialized types of cells." (Ibid.).

[30] Ibid., 44-45.

cloning as "cloning-for-biomedical-research." This term accounts for the investigatory nature of this process while recognizing that its purpose is "to seek cures and treatments for human diseases."[31]

The prospect of new therapeutic interventions raises tension between the desires to move forward with cloning and reluctance to gestate cloned embryos to birth.[32] Cloning-to-produce-children,[33] or reproductive cloning,[34] raises several concerns. Leon Kass has noted that mass-produced clones, replacements for a deceased individual, or parent-child twins, each of which are possible with cloning, tend to shock one's sense of right and wrong and represent "profound defilement of our given nature as pro-creative human beings."[35] In addition, cloning-to-produce-children raises concern about its potential to yield birth defects.[36] The PCBE weighed policy options ranging from banning cloning-to-produce children while regulating cloning-for-biomedical purposes, to a "moratorium or temporary ban on all human cloning, whether to produce children or for biomedical research."[37] Each consideration is opposed to reproductive cloning.

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[31] Ibid., 45.
[32] Ibid., xxxi – xxxii.
[33] "Cloning-to-produce-children" refers to "Production of a cloned human embryo, formed for the (proximate) purpose of initiating a pregnancy, with the (ultimate) goal of producing a child who will be genetically virtually identical to a currently existing or previously existing individual" (Ibid., 229).
[34] "Some object to the term 'reproductive cloning' used as a term of distinction, because they argue that *all* cloning is reproductive. Their reason: all human cloning intends and issues in the production of a cloned human embryo, a being distinct from the components used to generate it, a new human being in the earliest stage of development or 'reproduction' (Ibid., 44).
[35] Kass, "Preventing a Brave New World," 22.
[36] For instance, the President's Bioethics Council cautioned that in animal studies, "a substantial portion of those live-born [animal] clones have suffered complications that proved fatal fairly quickly. Some serious though nonfatal abnormalities in cloned animals have also been observed, including substantially increased birth-size, liver and brain defects, and lung, kidney, and cardiovascular problems." (*Human Cloning and Human Dignity*, 90, citing "Application of animal cloning data to human cloning." Paper presented at Workshop: Scientific and Medical Aspects of Human Cloning, National Academy of Sciences, Washington, DC, August 7, 2001; Hill, J. "Placental defects in nuclear transfer (cloned) animals," Paper presented at Workshop: Scientific and Medical Aspects of Human Cloning, National Academy of Sciences, Washington, DC August 7, 2001).
[37] For a discussion of policies the President's Bioethics Council considered, see Ibid., xxxv.

In order to fully appreciate what is at stake, it is essential to discuss cloning in light of scientific truth. The PCBE noted, "Where the moral stakes are high, we should not … regard the subject in question as being anything less than it might truly be."[38] They were careful to describe the cloned entity using terms that give due regard to the moral questions at stake.[39] In light of scientific evidence that human life begins at conception and is manifest in the self-organizing pattern of development initiated at this point,[40] truthful dialogue about human cloning recognizes that the product of SCNT is a "cloned human embryo."[41]

The PCBE's definition of human cloning is informed by this scientific truth. Human cloning is: "The asexual production of a new human organism that is, at all stages of development, genetically virtually identical to a currently existing or previously existing human being."[42] In contrast, statutory definitions utilize various linguistic means to evade the reality of a cloned embryonic human being. This process reveals a trend of substituting arbitrary, politically-driven definitions at the expense of scientific accuracy and truth.

In light of this trend, the words of John Paul II in *Evangelium Vitae* call us to "look the truth in the eye and to call things by their proper name, without yielding to convenient compromises or to the temptation of self-deception."[43] Thus, truthful discourse on cloning must

[38] Ibid., 52-53.
[39] Ibid., 52.
[40] See Condic, "When Does Human Life Begin?" 6-11.
[41] *Human Cloning and Human Dignity*, 52-53. "Some worry that the term 'cloning' unfairly prejudices people against the activity when it is used to describe research activities." Ibid., 39. Also, there is ongoing debate regarding the closeness of the genetic match between the donor and the embryonic clone. Even so, the purpose of SCNT is to produce either "a blastocyst-stage cloned embryo … or a child who is genetically virtually identical to the donor … otherwise there would be no reason to produce a cloned embryo by SCNT rather than an (uncloned) embryo by ordinary IVF." (Ibid., 53-54).
[42] Ibid., 54.
[43] *Evangelium Vitae*, § 58. The Nuremberg Code also explains that voluntary consent is not truly obtained where experimentation proposals utilize deceit ("The Nuremberg Code").

recognize the cloned embryo's humanity.[44] It then follows that the cloned human embryo is due the moral status of a human being.[45]

Recent advancements in multi-parent embryo creation challenge the moral analysis of cloning, as these new methodologies establish a path to cloning-to-produce-children. These new processes that mimic or are substantially similar to cloning garner support around their potential applications as treatment that eliminates genetic disease.[46] The lure of these techniques is their potential future application for reproductive purposes.[47] At the same time, amidst a trend of evading scientific terms to describe cloning, these procedures could result in legal affirmation of unequal status among human embryos.[48]

Statutory Regimes Mandating Destruction of Cloned Embryonic Human Life

The following sections will examine the manner in which various state laws define cloning and corresponding policy on hESCR. Sometimes the obvious purpose of the statutory definition is to evade truth-telling, so as to advance a political, ideological, and/or research agenda.

California: Proposition 71

[44] Cloning does not alter the point at which human life begins. Condic, ("When Does Human Life Begin?," 10); "Fertilization produces a new and complete, though immature, human organism. The same is true of successful cloning." (*Human Cloning and Human Dignity*, 258).

[45] While Council member Dr. Charles Krauthammer believed that embryos do "not command inviolability," (Ibid., 280-81) Krauthammer contended that "[r]esearch cloning is the ultimate in conferring thingness up on the human embryo … Creating a human embryo just so it can be used and then destroyed undermines the very foundation of the moral prudence that informs the entire enterprise of genetic research: the idea that, while a human embryo may not be a person, it is not nothing. Because if it is nothing, then everything is permitted. And if everything is permitted, then there are no fences, no safeguards, no bottom." (Ibid., 284-85).

[46] Britain's Human Fertilization and Embryology Authority advised that refusal to move forward with these new techniques would "restrict the reproductive options of people with serious mitochondrial disease" ("Mitochondria Replacement Consultation: Advice to Government," *Human Fertilization and Embryology Authority*, March 2013, http://www.hfea.gov.uk/docs/Mitochondria_replacement_consultation_-_advice_for_Government.pdf).

[47] For a discussion of various perspectives advocating multi-parent embryo techniques for reproductive purposes, see *Novel Techniques for Prevention of Mitochondrial DNA Disorders: An Ethical View* (London: Nuffield Council on Bioethics, 2012), 61, http://nuffieldbioethics.org/wpcontent/uploads/2014/06/Novel_techniques_for_the_prevention_of_mitochondrial_DNA_disorders_compressed.pdf.

[48] Some ascribe higher moral status to embryos that have a set of genetic material unique from the parents than to those that are a genetic copy of the donor of nuclear genetic material (Ibid., 63).

On November 2, 2004, California voted to enact Proposition 71 into law.[49] Proposition 71 established a public fund for hESCR and SCNT.[50] It separated cloning into two categories: reproductive cloning and therapeutic cloning.[51] Presently, California statutes ban reproductive cloning, imposing penalties for individuals who engage or assist in this act.[52] However, Proposition 71 supported furthering SCNT research, in hopes that this will promote discovery of therapeutic medical interventions for various maladies.[53]

Despite the good end sought, Proposition 71 operated under an internally inconsistent rationale that the means are compatible with respect for human embryos.[54] To the contrary, in order to prevent reproductive cloning, California statutes mandate destruction of the human embryo and mask this effect by re-defining cloning as a procedure that only occurs upon implantation. This definition is rooted in politics and propaganda, not science. In concealing the

[49] Proposition 71 is currently codified under Cal. Health & Saf. Code §§ 125118, 125119, 125119.3, 125119.5, and 125300.
[50] Cal. Health & Saf. Code § 125291.25.
[51] "The [California Advisory] committee [on Human Cloning] … came to five unanimous recommendations on issues of human cloning. The two most important of those recommendations were, first, that California should continue its ban on reproductive human cloning … Our second recommendation was that human nonreproductive cloning – human cloning done for the purpose of creating cloned embryonic stem cells – should not be banned by Califonia but should be regulated." *Impact of Federal Policy on Realizing the Potential of Stem Cell Research*, *Hearing Before the S. Health and Human Services Subcomm.* 2001-2002 Sess. (Cal. 2002) (statement of Prof. Henry T. Greely, California Advisory Committee on Human Cloning) (*transcript available* at http://shea.senate.ca.gov/sites/shea.senate.ca.gov/files/STEMCELL_TRANSCRIPT_MAR_8_2002.doc - 202k - 2010-12-07).
[52] "Any license issued to a business pursuant to this chapter shall be revoked for a violation of Section 24185 of the Health and Safety Code, relating to human cloning." Cal. Business and Professions Code § 16004 (West 2008).
[53] Regulation of "non-therapeutic cloning," or SCNT, meant: "No research should go beyond the appearance in the embryo of what's called the 'primitive streak' – a feature in human embryos that appears at about day 14, 15, or 16 … Those were the views of the California Advisory Committee on Human Cloning ... We cannot be confident that we have the right answers, but we have an obligation to ourselves, to our children, and our grandchildren to, with great humility, seek to do the best we can based on what we know now." *Id.* (statement of Prof. Henry T. Greely, California Advisory Committee on Human Cloning).
[54] "I believe every member of our committee felt that a human embryo was something more than just another clump of cells; that it had some status, that it was entitled to be treated for its sake and for all our sakes with some respect, but we felt that that respect was consistent with appropriate research use of those embryos that could potentially – and, again, I have to stress 'potentially' – bring relief from human suffering for millions of people in California and around the world." *Id.* (statement of Prof. Henry T. Greely, California Advisory Committee on Human Cloning).

scientific truth, Proposition 71 concealed its implicit mandate to destroy cloned embryos.[55] As the President's Bioethics Council explained: "the invoking of a 'special respect' owed to nascent life seems to have little or no operative meaning if cloned embryos may be created in bulk and used routinely with impunity."[56]

Connecticut: Prioritizing hESCR

On June 15, 2005, Connecticut became third to establish a state-funded hESCR program when it passed the misleadingly titled "Act Permitting Stem Cell Research and Banning the Cloning of Human Beings."[57] Analysis of Connecticut's statutory definition of human cloning reveals that the statute does not prohibit the initiation of a cloned embryo. Instead, it arbitrarily selects a point in a cloned embryo's development before which it declares that the biological entity is not something "cloned," but after which it is. Specifically, Connecticut's statutory definition of "cloning of a human being" provides that an embryonic human being created through SCNT is not a "clone" if destroyed or frozen before gastrulation.[58]

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[55] California's statutes define cloning as "the practice of creating or attempting to create a human being by transferring the nucleus from a human cell from whatever source into a human or nonhuman egg cell from which the nucleus has been removed *for the purpose of, or to implant, the resulting product to initiate a pregnancy."* Cal. Health and Safety Code § 24185(1) (West 2006) (emphasis added). The statute prohibits "The culture in vitro of … any product of SCNT … after the appearance of the primitive streak, or after 12 days, whichever is earlier. The 12 day prohibition does not include any time during which the embryos or cells have been stored frozen." *Guidelines for Human Stem Cell Research Pursuant to Health and Safety Code § 125118*, CAL. DEP'T PUB. HEALTH, http://www.cdph.ca.gov/services/boards/HSCR/Documents/MO-HSCR-Guidelines-11-2010.pdf. (Last revised December 5, 2011). This requirement makes Proposition 71 a "clone-and-kill-bill," whereby, "The authors of Proposition 71 systematically and repeatedly tried to hide that their bill will fund cloning … despite, the emphasis it will not fund reproductive cloning. A clone is a clone is a clone." *Informational Hearing on Proposition 71, Hearing Before the S. Health and Human Services Subcomm.* 2003-2004 Sess. (Cal. 2004) (statement of Dr. Vincent Fortanasce, President, No on 71) (transcript *available at* http://shea.senate.ca.gov/sites/shea.senate.ca.gov/files/PROP_71_INIATIVE_TRANSCRIPT.doc - 337k - 2010-12-14).

[56] *Human Cloning and Human Dignity*, xxxiii.

[57] For a brief background of this act, see "Stem Cell Research Program," http://www.ct.gov/dph/cwp/view.asp?a=3142&q=389702&dphNav_GID=1825. The Act is currently codified under Conn. Gen. Stat. §§ 32-41jj - mm.

[58] *Id.* § 32-41jj(2) ("'Cloning of a human being' means inducing or permitting a replicate of a living human being's complete set of genetic material to develop after gastrulation commences."). *See also Id.* § 32-41jj(3) ("'Gastrulation' means the process immediately following the blastula state when the hollow ball of cells

One of the bill's prominent proponents, Dianne Krause, indicated that the statute writers intentionally avoided scientific terminology.[59] The statutes operate under a non-scientific presumption that "a new human being … has not been initiated until you put it into the uterus."[60] Statute writers were aware that SCNT starts a process of development that could result in "a viable human being," if implanted into the womb, and arranged the statutory language so as to "make sure that never happens."[61] The result of this legislation, as Michelene Matthews-Roth testified, the act permits cloning for human embryonic stem cell research (hESCR), but mandates the laboratory to "destroy … a five to seven day old [embryonic] human being."[62]

Connecticut's Regenerative Medicine Research Fund allocates "not less than ten million dollars" annually toward regenerative medicine research, including stem cell research.[63] In order

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representing the early embryo undergoes a complex and coordinated series of movements that results in the formation of the three primary germ layers, the ectoderm, mesoderm and endoderm.").

[59] "The [statutory] wording [of the definition of human cloning] has been a little bit tricky because we tried to stay away from scientific terms." *Public Hearing on S.B. 934 An Act Permitting Stem Cell Research and Banning the Cloning of Human Beings*, *Hearing Before the S. Public Health Comm.*, 2005 Sess. (Conn. 2005) (statement of Dr. Dianne Krause, Yale University School of Medicine), (transcript *available* at https://www.cga.ct.gov/2005/PHdata/chr/2005PH-00131-R001000-CHR.htm).

[60] "So what you're referring to is the creation of a new human being. And we would say no, that has not been initiated until you put it into the uterus." *Id.* (statement of Dr. Dianne Krause, Yale University School of Medicine).

[61] "We worked really hard on the wording of this [statutory definition of human cloning] because we're not trying to hide anything in this legislation so that researchers can do things that you otherwise wouldn't want them to do… So what's cloning? What's cloning is that if you took that unfertilized egg with its new nucleus and you implanted it into a uterus, then it's incredibly wrong… if that egg that now has this other nucleus and it implants in the nucleus, theoretically, it can grow into a new human being. It would go through many stages of development before it becomes a viable human being. So what we're trying to do with the wording is make sure that never happens. So what we've said is, you cannot under any circumstances, implant this into a uterus." *Id.* (statement of Dr. Dianne Krause, Yale University School of Medicine).

[62] *Id.* (statement of Dr. Matthews-Roth, Harvard Medical School and Brigham and Women's Hospital).The embryo's development may be frozen after a set period of development. Since time does not stand still, the embryo could be in existence for five to seven *years* while frozen at five to seven *days* of development. Other statutes similarly mandate destruction of a cloned embryo via prohibitions on reproductive cloning. *See, e.g.*, 410 Ill. Comp. Stat. Ann. 110/40 (prohibiting cloning; cloning only occurs when done "for the purpose of initiating a pregnancy"); MD. Code Ann., Econ. Dev. § 10-429 (prohibiting clone development "beyond an embryo"); Mo. Const. art. III, § 38(d)(3) (adopted 2006) (Prohibiting use of stem cells from a blastocyst after day 14 of development); Iowa Code Ann. § 707C (excluding SCNT for hESCR purposes from the definition of "human reproductive cloning"). For a chart outlining various cloning statutes, visit http://bdfund.org/wordpress/wp-content/uploads/2012/07/CLONINGChart-BDF2011.docx.pdf.

[63] "Commencing with the fiscal year ending June 30, 2006, and for each of the thirteen consecutive fiscal years thereafter, until the fiscal year ending June 30, 2019, not less than ten million dollars shall be available from the Regenerative Medicine Research Fund for financial assistance to eligible institutions for the purpose of conducting

to obtain state grant money from the Regenerative Medicine Research Fund, an applicant submits an application for financial assistance containing:

> "(1) a complete description of the applicant's organization, (2) the applicant's plans for regenerative medicine research and proposed funding for such research from sources other than the state, (3) proposed arrangements concerning financial benefits to the state as a result of any patent, royalty payment or similar rights developing from any proposed research made possible by the awarding of such financial assistance, and (4) a form attesting to compliance with subsections I and (d) of section 32-41jj if the regenerative medicine research involves the use of embryonic stem cells."[64]

Before awarding financial assistance, a peer review committee scores each application's "ethical and scientific merit,"[65] and advises the Regenerative Medicine Research Advisory Committee (RMRAC)[66] accordingly. The RMRAC establishes guidelines for rating and scoring of applications.[67]

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regenerative medicine research." Conn. Gen. Stat. § 32-41kk(c). With the passage of 2014 Ct. P.A. 98 on May 22, 2014, the Connecticut Stem Cell Research Advisory Committee became the Regenerative Medicine Research Advisory Committee. Even though the Committee's name changed, they still fund projects for stem cell research, including hESCR. *See Id.* § 32-41jj(a)(7) ("'Regenerative medicine' means the process of creating living, functional tissue to repair or replace tissue or organ function lost due to aging, disease, damage or congenital defect. Regenerative medicine includes basic stem cell research.").

[64] Conn. Gen. Stat. § 32-41kk(b) (The Regenerative Medicine Advisory Committee is responsible for developing the application for financial assistance: "The Regenerative Medicine Research Advisory Committee … shall develop an application for financial assistance under this section and for the purpose of conducting regenerative medicine … .").

[65] *Id.* § 32-41mm(a) ("Prior to the awarding of any financial assistance in response to an application submitted pursuant to section 32-41kk, the Regenerative Medicine Research Advisory Committee, established pursuant to section 32-41ll, shall contract with a third party for the selection of peer reviewers to review such application and make recommendations to said advisory committee with respect to the ethical and scientific merit of such application."). *See also Id.* § 32-41mm(b) (providing a list peer reviewer required credentials). Statutorily, it would not be considered a conflict of interest if a committee member with a financial interest in one institution votes against allocating funds to a competing institution. *See Id.* § 32-41ll(d) (While "no member shall participate in the affairs of said advisory committee with respect to review or consideration of any application for financial assistance filed by such member or by any eligible institution in which such member has a financial interest, or with whom such member engages in any business, employment, transaction or professional activity," it also "shall not constitute a conflict of interest for a trustee, director, partner, officer, stockholder, proprietor, counsel or employee of any eligible institution, or for any other individual with a financial interest in any eligible institution, to serve as a member of said advisory committee.").

[66] *See Id.* § 32-41ll(a)(1)-(2) (prescribing the statutorily mandated composition of the RMRAC).

[67] "The Regenerative Medicine Research Advisory Committee shall establish guidelines for the rating and scoring of such applications. In establishing such guidelines, said advisory committee may consult with a third party contracted for the selection of peer reviewers pursuant to subsection (a) of this section." *Id.* § 32-41mm(e).

Among other selection criteria, proposals are evaluated based on their alignment with the RMRAC's own research priorities.[68] When the commission was first established, federal funds could only be used for research on existing embryonic stem cell lines, not for the derivation of new lines.[69] The commission, then called the Connecticut Stem Cell Research Advisory Committee (SCRAC), made a concerted effort to bypass federal funding restrictions and prioritize hESCR proposals.

During the initial months following SCRAC's formation, SCRAC member William Lensch noted: "the role of the Connecticut state funds are not to supplement the stuff that could otherwise be funded with NIH [National Institutes of Health] money."[70] The SCRAC believed Connecticut could profit financially from by-passing this federal ban,[71] and recognized that this could be achieved by prioritizing funding for hESCR proposals then ineligible for federal funds.[72] Lensch proposed:

> "I think, just to illustrate it, if we had two worthy projects, one for human embryonic stem cells, one for adult stem cells, yielding equivalent scientific merit scores, I would favor the human embryonic stem cell project, because that's where the greatest need lies, in terms of funding, if that clarifies."[73]

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[68] Selection Criteria includes "Alignment with funding priorities as determined by the Connecticut Regenerative Medicine Research Advisory committee," ("State of Connecticut Regenerative Medicine Research Grants Program - 2015 RFP," 4, http://ctinnovations.com/pdf/2015%20RegenMed%20RFP%20FINAL%2011-3-14_v2.pdf).

[69] "Human Embryonic Stem Cell Policy Under Former President Bush (Aug. 9, 2001 – Mar. 9, 2009)," *National Institutes of Health*, accessed July 23, 2016, http://stemcells.nih.gov/policy/pages/2001policy.aspx.

[70] See Verbatim Proceedings, "Connecticut Stem Cell Research Advisory Committee," February 14, 2006, comments of William Lensch, Ph.D., 97, transcript at http://www.ct.gov/dph/cwp/view.asp?a=3142&q=389708&dphNav=|&dphNav_GID=1825.

[71] *See, e.g.*, *Id.*, comments of Commissioner Robert Galvin, 110 ("What we want to do is something that we can't do. We want to get some stem cell lines that are viable and that are not old … and we want to make some money out of this, too."). *See also Id.*, comments of Milton B. Wallack, D.D.S., 22-23, ("[O]ur Chairman keeps reminding us that we're to fill in where the federal government is falling down relative to embryonic stem cell research … it's I think the intent to channel and focus on the embryonic stem cell part.").

[72] *See Id.*, comments of Commissioner Robert Galvin, 100.

[73] *Id.*, comments of William Lensch, Ph.D., 100.

This rationale led the committee to carry a motion establishing hESCR as the initial funding priority.[74]

The SCRAC was not obliged to make hESCR their funding priority. The bill establishing funds for stem cell research did not expressly state a preference for one particular research modality.[75] Under proposals to ascribe priority to hESCR over other stem cell research projects of equal scientific merit, it is difficult to determine which scores ultimately reflect equal scientific merit.[76] The SCRAC justified prioritizing hESCR by noting that the bill allowed them to use discretion in determining the allocation of funds.[77] They believed this policy was consistent with what they interpreted as legislative intent to promote hESCR not eligible for federal funds.[78]

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[74] The Connecticut Stem Cell Advisory Committee carried a motion "that this committee established that an initial funding priority is the funding of [non-NIH] fundable human embryonic stem cell research." *Id.*, comments of William Lensch, Ph.D., 112-13, *See also Id.*, at 91, 97 (stating Dr. Lensch's initial suggestion to establish funding of non-NIH fundable hESCR as the SCRAC's initial funding priority).

[75] The text of the original act read: "Commencing with the fiscal year ending June 30, 2006, and for each of the nine consecutive fiscal years thereafter, until the fiscal year ending June 30, 2015, not less than ten million dollars shall be available from the Stem Cell Research Fund for grants-in-aid to eligible institutions for the purpose of conducting *embryonic or human adult stem cell research*, as directed by Stem Cell Research Advisory Committee established pursuant to section 3 of this act. Any balance of such amount not used for such grants-in-aid during a fiscal year shall be carried forward for the fiscal year next succeeding for such grants-in-aid." 2005 Ct. P.A. 149 § 2(c). Emphasis added.

[76] Under proposals to ascribe different priority scores to projects of equal scientific merit, it is difficult to determine which scores ultimately reflect equal scientific merit. See Verbatim Proceedings, "Connecticut Stem Cell Research Advisory Committee," February 14, 2006, comments of Dr. Ernesto Canalis, M.D., 101, transcript at http://www.ct.gov/dph/cwp/view.asp?a=3142&q=389708&dphNav=|&dphNav_GID=1825 ("Equal scientific merit, again, is going to be very difficult to define, because unless you have precisely the same priority score, you have unequal merit. And you have a scientific committee that is going to score these grants, so what is equal, 140 and 150? Are they the same? What is the disparity here?").

[77] *See Id.*, comments of Milton B. Wallack, D.D.S., 105-06 ("Page three of the bill, and I think it's Section 2C, and it does talk about for granting and aid to eligible institutions for the purpose of conducting embryonic or human adult stem cell research, as directed by the Stem Cell Research Advisory Committee, so that it clearly states both of those issues, and it clearly states as directed by this Advisory Committee … I would choose to, as we've been hearing, to interpret that and direct those funds to be spend for embryonic stem cell research. The bill says I'm allowed to do that.").

[78] *Id.*, comments of Commissioner Galvin, 10 ("[I]t is my understanding of the intent that it has to be used for this purpose, which I've gone over, and for the purpose of advancing stem cell research using non-federally funded stem cell lines and for developing an aggressive policy of having a business interest in moving this forward and becoming a preeminent state.").

The emphasis remained on funding new hESCR proposals even after President Obama enacted Executive Order 13505 in March 2009. Executive Order 13505 superseded[79] and reversed, in part, prior limitations on federal funding on hESCR. This order permitted federal funding for hESCR on new stem cell lines, provided that the lines are: "(1) created by *in vitro* fertilization for reproductive purposes, (2) no longer needed for that purpose, and (3) voluntarily donated by individuals who owned them – even if that line was derived after 2001."[80] Even with this order, the Omnibus Appropriations Act, or the Dickey-Wicker Amendment, prohibited federal funds for: "(1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed … ."[81] Executive Order 13505 then bypasses the Dickey-Wicker Amendment by allowing federal funds for hESCR where the embryo was not created "for research purposes."

Even after 2009, the SCRAC's Request for Proposal (RFP) funding application continued to provide that the funding of hESCR otherwise precluded from federal funding remained a priority. The 2010 and 2011 RFPs stated "It is the intent of the Connecticut Stem Cell Research Advisory Committee to consider funding any form of stem cell research, but priority will be given to human embryonic stem cell research that is not currently eligible for federal funding."[82] The 2012 and 2014 RFPs stated, "A priority for the Connecticut Stem Cell Research Grants Program is to support research on hESC[R]. Such research that is not currently eligible for

[79] Exec. Order No. 13505, 74 Fed. Reg. 10668 (March 11, 2009) ("The Presidential statement of August 9, 2001, limiting Federal funding for research involving human embryonic stem cells, shall have no further effect as statement of government policy. (b) Executive Order 13435 of June 20, 2007, which supplements the August 9, 2001, statement on human embryonic stem cell research, is revoked.").
[80] Sherley v. Sebelius, 402 U.S. App. D.C. 178, 182 (2012) (citing 74 Fed. Reg. 32,170, 32,174).
[81] Omnibus Appropriations Act, 111 P.L. 8, §§ 508-509, 123 Stat. 524, 803 (2009).
[82] "Connecticut Stem Cell Research Grants Program – 2010 RFP," 1, http://www.ct.gov/dph/lib/dph/stem_cell/grants/2010_final_RFP.pdf; "Connecticut Stem Cell Research Grants Program – 2011 RFP," 1, http://www.ct.gov/dph/lib/dph/stem_cell/grants/2011_final_rfp.pdf.

federal funding is welcomed."[83] The SCRAC's decision to keep this language in the RFP kept in place a mechanism through which the SCRAC could anticipate and by-pass future federal-funding restrictions.[84]

Statutory Schemes Prohibiting Human Cloning

Arizona and North Dakota both ban cloning, outright, however, the following statutory analysis reveals variation in the way these states achieve this.

North Dakota

North Dakota's statutory definition of human cloning recognizes that this process produces human life at its outset. Their definition of human cloning is:

> "human asexual reproduction, accomplished by introducing the genetic material of a human somatic cell into a fertilized or unfertilized oocyte, the nucleus of which has been or will be removed or inactivated, to produce a living organism with a human or predominantly human genetic constitution."[85]

In contrast to statutes that define cloning as occurring after a named stage of embryonic development, North Dakota's definition of human cloning is synonymous with that of SCNT.[86] It accords with scientific truth that cloning is initiated upon formation of the one-celled zygote.[87]

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[83] "State of Connecticut Stem Cell Research Grants Program – 2012 RFP," 2, http://wwhttp://www.ct.gov/dph/lib/dph/stem_cell/grants/stem_cell_2014_rfp.pdfw.ct.gov/dph/lib/dph/stem_cell/grants/stem_cell_2012_rfp__finalx.pdf; "State of Connecticut Stem Cell Research Grants Program – 2014 RFP," 2, http://www.ct.gov/dph/lib/dph/stem_cell/grants/stem_cell_2014_rfp.pdf.

[84] See, for example, Verbatim Proceedings, "Connecticut Stem Cell Research Advisory Committee," September 15, 2009, comments of Dr. Anne Hiskes, 15-16, transcript at http://www.ct.gov/dph/cwp/view.asp?a=3142&q=389708&dphNav=|&dphNav_GID=1825 ("something that has not been eligible for federal funding and is not eligible under the current NIH revised guidelines, is a derivation of new stem cell lines … If we want to do new stem cell lines of diseases, disease models, or for genetic diversity, that, again, cannot be funded by federal money. I think that's an argument for maintaining that priority [for non-federally-fundable research] … You cannot hurt an embryo that has – that's from the Dickey-Wicker amendment, anyway.").

[85] N.D. Cent. Code § 12.1-39-01(1). This came before the North Dakota legislature as H.B. 1424.

[86] *Compare* Conn. Gen. Stat. § 32-41jj(2) (providing that human cloning occurs at gastrulation) *with* N.D. Cent. Code § 12.1-39-01(1) (explaining that human cloning occurs upon introduction of the human somatic cell into the unfertilized oocyte).

[87] "*The technique of cloning is finished once that first cell, the one-celled embryo (zygote) is formed.* Anything beyond that step is simply growth and development." *Testimony on SB 2302 Before the S. Judiciary Committee*,

North Dakota's statute draws no distinction between therapeutic and reproductive cloning, as it recognizes that one's purpose for cloning bears no relevance upon the scientific definition of the process.[88] Regardless of the purpose for cloning, the product of SCNT is a human being.[89]

While testimony informing North Dakota's definition recognized that cloning generates new human life,[90] the statutory prohibitions apply only to creation of human embryos via cloning.[91] It neither prohibits IVF nor cloning techniques that produce "cells other than human embryos."[92] Further, the statute is tacit on stem cell research.[93]

A subsequent bill introduced in North Dakota, S.B. 2302, proposed that "Any medical procedures, scientific or laboratory research, or other kinds of investigation that kill or injure the human subject at any stage of development …" should be "prohibited human research."[94] While the bill did not explicitly ascribe rights to the embryo or expressly deem the embryo as equivalent to a human-being, it did provide that "A living in vitro human embryo is a biological human being," and that physicians and medical facilities handling them "owe a high duty of care

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2013 Leg., 63rd Sess. (ND 2013) (submitted testimony of David A. Prentice, Ph.D, Senior Fellow for Life Sciences, Family Research Council), *http://www.legis.nd.gov/files/resource/63-2013/library/sb2302.pdf.* Original emphasis.

[88] "*Both 'reproductive' and 'therapeutic' cloning use exactly the same techniques to create the clone, and the cloned embryos are indistinguishable.* The process, as well as the product, is identical. The only distinction is the purpose for use of the embryo" *Id.* Original emphasis.

[89] "[A] human clone would have human genetic material and therefore, clinically they would be human … ." *Hearing on H.B. 1424, Hearing of the H. Education Comm.*, 2003 Sess. (N.D. 2003) (statement of Rep. Kim Koppelman, District 13, West Fargo).

[90] *Id.*

[91] "This bill is specific to human cloning … ." *Hearing on H.B. 1424, Hearing of the S. Jud. Comm.*, 2003 Sess. (N.D. 2003) (statement of Sen. Dever).

[92] "Nothing in subsection 1 restricts areas of scientific research not specifically prohibited, including in vitro fertilization, the administration of fertility-enhancing drugs, or research in the use of nuclear transfer or other cloning techniques to produce molecules, deoxyribonucleic acid, tissues, organs, plants, animals other than humans, or cells other than human embryos." N.D. Cent. Code § 12.1-39-02(2).

[93] "[HB 1424] wouldn't effect stem cell research, ag research, GMO, animal research, it would only effect the reproduction of human beings as clones." *Hearing on H.B. 1424, Hearing of the H. Education Comm.*, 2003 Sess. (N.D. 2003) (statement of Rep. Kim Koppelman, District 13, West Fargo).

[94] 2013 Bill Text ND S.B. 2302, § 1, no. 24A.

to the living in vitro human embryo."[95] Despite this provision, testimony on S.B. 2302 explained that "[a]ny ongoing stem cell research in the state can continue unabated under this bill, including embryonic, induced pluripotent, and adult stem cell research."[96] This bill failed to pass in the North Dakota Senate.[97] In such, North Dakota's ban on cloning is not determinative of the embryo's per se moral status, nor does it foreclose hESCR in the state.[98]

Arizona

Arizona's ban on cloning utilizes more expansive statutory language than North Dakota. Arizona statutes deem it a class 1 misdemeanor to "intentionally or knowingly create or attempt to create an in vitro human embryo by any means other than fertilization through the combining of a human egg with a human sperm."[99] This prohibits SCNT and any other technique that would generate an embryo other than via sperm-egg union, while still permitting IVF.[100]

Once IVF is performed, Arizona allows embryo cryopreservation, but prohibits any cryopreserved embryo from being destroyed.[101] It is a class six felony to "intentionally or knowingly engage in destructive embryonic stem cell research."[102] The statutes define "destructive embryonic stem cell research" as "any research that involves the disaggregation of

[95] *Id.*, § 6, no. 1.
[96] *Testimony on SB 2302 Before the S. Judiciary Committee*, 2013 Leg., 63rd Sess. (ND 2013) (submitted testimony of David A. Prentice, Ph.D, Senior Fellow for Life Sciences, Family Research Council).
[97] 2013 Bill Tracking ND S.B. 2302.
[98] *See* N.D. Cent. Code § 14-02.2-01 (North Dakota does prohibit experiment on a live *fetus*, but the statute setting forth this prohibition does not specifically prohibit experimentation on a human *embryo*).
[99] A.R.S. § 36-2312(A),(D).
[100] Testimony on SB 1307 Before the H. Health and Human Services Comm., 49th Leg., 2nd Sess. (AZ 2010) (testimony of Nikolas Nikas, JD, President, Bioethics Defense Fund), http://azleg.granicus.com/MediaPlayer.php?view_id=13&clip_id=7287.
[101] *Id.*
[102] A.R.S. § 36-2313(A)-(B).

any human embryo for the purpose of creating human pluripotent stem cells or human pluripotent stem cell lines."[103]

Accordingly, Arizona's statutes provide potentially stronger life-protecting measures than North Dakota. If an IVF or SCNT embryo created in Connecticut was cryopreserved in North Dakota, then the embryo could potentially be destroyed via hESCR. Conversely, if the embryo was transferred to Arizona, statutes would not permit its destruction for research. A gap then exists in Arizona's statutes, as they provide no guidance as to whether an SCNT embryo cryopreserved in the state may be implanted in the womb. If one infers that a non-prohibited act is a permitted act, then Arizona statutes only prohibit cloning-for-biomedical-purposes, while leaving open the possibility of reproductive cloning.[104]

Prof. Kerry Lynn Macintosh notes that "Arizona is the only state that treats research cloning as a more serious crime than reproductive cloning."[105] She observes that this life-protecting measure could, in effect, be "a first step toward reducing the stigma that humans born through cloning will face on account of having been conceived via a prohibited technology … ."[106]

Future Implications

Legislative redefinition of cloning created an environment where it is legally permissible to produce life via SCNT, harvest cells from embryonic human beings, and then deny that it is cloning. Testifying in favor of North Dakota's ban on human cloning, Nigel M. de S. Cameron

[103] *Id.*, § 36-2311(1). While the term "any research" appears to prohibit more than only hESCR, an issue could exist as to whether the statute applies to only those procedures where embryo destruction is inherent in the process itself or to those procedures and also to any procedure where the embryo is consequentially destroyed, even if not destroyed as part of the procedure itself.
[104] On its face, A.R.S. § 36-2312(B) only prohibits transferring a human-animal hybrid or a nonhuman embryo into the womb.
[105] Macintosh, "Human Cloning: Four Fallacies and Their Legal Consequences," 217.
[106] Ibid.

argued: "Human dignity must frame the development of biotech – not the other way around."[107] Truthful discourse on cloning must recognize the scientific truth of what it means to be human and confront the duplicative statutory language that undermines this. As Pope John Paul II stated, "No word has the power to change the reality of things."[108]

The need for truthful dialogue on cloning persists as three-parent embryo proposals present the potential for a continuance of legislative trends substituting politically-driven definitions of cloning at the expense of scientific truth.

Three-Parent Embryos

In February 2015, British Parliament approved new methods of cloning human embryos.[109] The new techniques, pronuclear transfer (PNT) and maternal spindle transfer (MST), use genetic material from multiple parents to create embryos with altered mitochondrial DNA (mtDNA). Mitochondria are the cell's source of energy. Mutations in the mtDNA are implicated in a variety of genetic disorders.[110]

It is thought that by replacing an oocyte's or embryo's mutated mtDNA with non-mutated mtDNA donated from another oocyte or embryo, the newly constructed three-parent embryo will develop free of mtDNA mutation.[111] MST combines genetic material from three adults: the maternal spindles from the intended mother whose egg contains mutated mtDNA, the

[107] *Testimony on H.B. 1424, Hearing of the H. Education Comm.*, 2003 Sess. (N.D. 2003) (submitted testimony of Nigel M. de S. Cameron, Dean, The Wilberforce Forum; Director, Council for Biotechnology Policy; Founding Editor, *Ethics & Medicine*).
[108] *Evangelium Vitae* § 58.
[109] In February 2015, the House of Lords voted to approve three-parent embryo proposals, consequently, "the first babies could be born as early as 2016" (James Gallagher, "UK approves Three-Person Babies," at BBC News (24 February 2015), at http://www.bbc.com/news/health-31594856).
[110] *Novel Techniques*, vii.
[111] These techniques are commonly referred to as three-parent embryo creation techniques. However, professional discourse debates whether the mtDNA truly confers genetic identity. Some have likened MST and PNT to simply "changing the batteries" in electronic device (see *Novel Techniques*, 78).

non-mutated mtDNA from an egg donated by another female, and the father's sperm (see Figure 2).[112]

Maternal Spindle Transfer
Eggs from the intended mother (with mutated mitochondria, Mom 1) and eggs from a donor (with non-mutated mitochondria, Mom 2) are harvested. The nucleus from Mom 1, which at this stage is arranged as chromosomes on a mitotic spindle, is removed from egg of Mom 1 and from the donor egg (Mom 2). The nucleus from genetic Mom 1 is placed into the ooplasm containing non-mutated mitochondria of the donor egg (Mom 2), and the genetically reconstructed egg is fertilized with the genetic father's sperm. **The newly created embryo is a "3-parent embryo."** As of June 2015, this technique had been attempted to create human embryos as well as animal embryos.

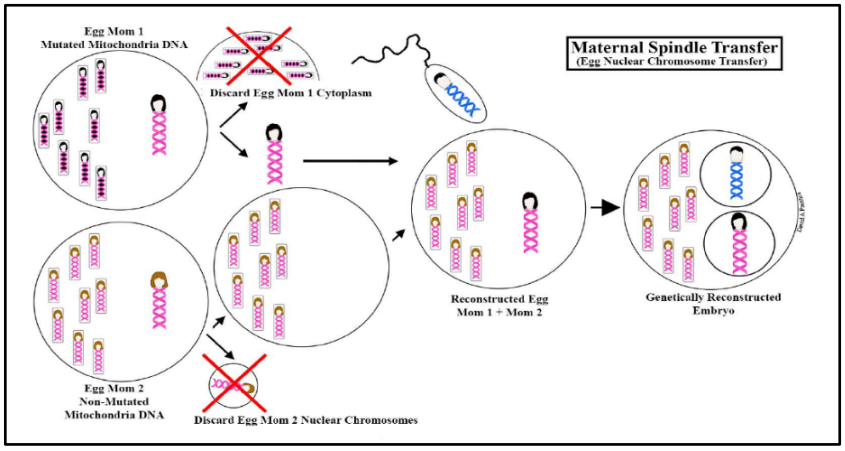

Figure 2. Maternal Spindle Transfer[113]

PNT involves two embryos created via IVF: one embryo from the intending parents (containing mutated mtDNA) and one embryo from donor parents (unaffected by mtDNA disease). Pronuclei, containing genetic information from the parents, from both embryos are removed. The pronuclei from the donor parents' embryo are removed and discarded, resulting in the destruction of this embryo. Meanwhile, the pronuclei from the intending parents' embryo are removed, also resulting in this embryo's destruction, and inserted into the cytoplasm of the donor parents' embryo. Consequently, two embryos are destroyed in order to construct a new one that

[112] Ibid, 34-36.
[113] Courtesy of David A. Prentice, Ph.D., Charlotte Lozier Institute. Image and text notes used with permission.

contains genetic material from the intending parents' nuclear genetic material and the non-mutated mtDNA from the donor embryo's mother (see Figure 3).[114]

Pro-Nuclear Transfer
Two single-cell embryos are created using IVF. Embryo 1 uses Mom 1's egg (which contains mutated mitochondria DNA) and intended father's sperm. Embryo 2 uses a donor egg cell from Mom 2 (that contains non-mutated mitochondria) and donor sperm (or sperm from the intended father). The pro-nuclei (egg and sperm nucleus, prior to their fusion into a zygote nucleus) are removed from both embryos. The pro-nuclei from Embryo 1 (from the intended parents) are placed into the cytoplasm of the donor embryo. The genetically recombined embryo now has the intended mother's (Mon 1) and father's nuclear genetics and non-mutated mitochondria from the embryo donor (mom 2). **The newly created embryo is a "3-parent embryo."** As of June 2015, this technique had been attempted with human embryos as well as animal embryos.

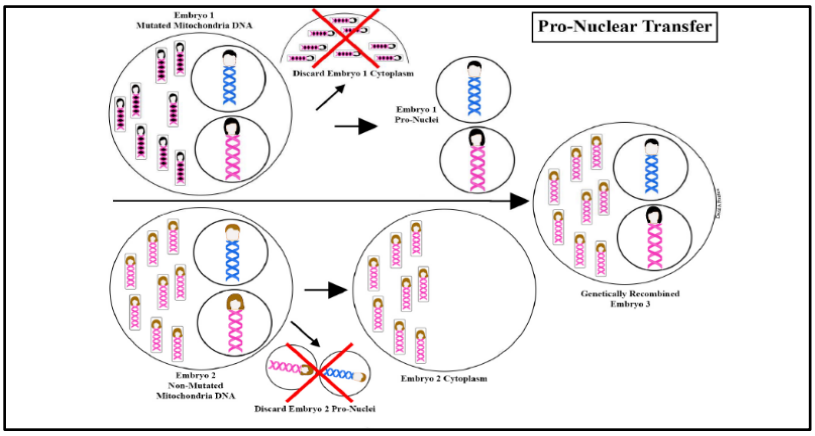

Figure 3. Pronuclear Transfer[115]

Researchers hope PNT and MST will be offered as treatments that could potentially prevent transmission of mtDNA disease to one's offspring and future generations.[116] In order to achieve this goal, the embryo must be implanted into the womb and allowed to proceed along the full sequence of human development, including birth. Unlike SCNT, the lure of multi-parent

[114] See Ibid, 32-34.
[115] Courtesy of David A. Prentice, Ph.D., Charlotte Lozier Institute. Image and text notes used with permission.
[116] Depending on the supply of eggs donated for further MST and PNT research, these techniques could soon be offered as treatments. (*Novel Techniques*, vii).

embryo creation is the reproductive purpose.[117]A barrier to advancing PNT and MST, these techniques had been unlawful under Britain's prohibition against implantation of embryos with genetic modifications.[118] To bypass this barrier, MST and PNT embryos needed to be deemed "permitted embryos" under Britain's Human Fertilization and Embryology Act.[119] Since Parliament's approval of PNT and MST, Britain's Human Fertilisation and Embryology Authority (HFEA) now has guidelines in place for centers seeking to provide PNT and MST.[120]

With the globalization of knowledge, multi-parent embryo developments are not restrained by oceans and political boundaries. Now that the technique exists, the National Academies of Sciences, Engineering, and Medicine (NAS) advocates proceeding to employ the techniques in the United States.[121] As the techniques gain traction in the United States, this will prompt states to re-evaluate existing cloning laws to determine how PNT coincides with the rules and regulations already in place.[122] This will require an honest evaluation of what PNT is and what it entails.

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[117] For example, perspectives in support of three-parent embryo techniques point to a perceived right to give birth to genetically-identical children (Ibid, 61).

[118] Britain prohibited implantation of PNT or MST embryos, since these techniques involve germline modifications. *See* Human Fertilisation and Embryology Act 2008, § 3ZA (2)(a)-(b) ("No person shall place in a woman (a) an embryo other than a permitted embryo (as defined by section 3ZA), or (b) any gametes other than permitted eggs or permitted sperm (as so defined)"). Only eggs that have not been genetically modified are deemed appropriate for implantation. *See* Human Fertilization and Embryology Act 2008, § 3ZA(5)(2) ("A permitted egg is one – (a) which has been produced by or extracted from the ovaries of a woman, and (b) whose nuclear or mitochondrial DNA has not been altered").

[119] The Secretary of State for Health may, at his/her discretion, bypass the prohibitions and permit implantation of a particular embryo or category of embryos. (See *Novel Techniques*, 44-46 (explaining that it may be compelling for the Secretary for Health to deem PNT and MST embryos appropriate for implantation, since these techniques are intended to prevent transmission of mtDNA disease)).

[120] These guidelines, modifying the Human Fertilisation & Embryology Act, are available at http://www.hfea.gov.uk/9931.html?fldSearchFor=HFEA Guidelines section 33.

[121] BEC Crew, "An Expert Panel Just Gave the Go-Ahead for Three-Parent Babies in the US – But Only Boys," (5 February 2016), at http://www.sciencealert.com/an-expert-panel-just-gave-the-go-ahead-for-three-parent-babies-in-the-us-but-only-boys.

[122] MST is not considered a form of cloning (Maureen L. Condic, "Mitochondrial Donation: Serious concerns for Science, Safety, and Ethics," (2015): 3-4. http://bdfund.org/wp-content/uploads/2016/05/3Parent-BDFBioethicsBriefingFINAL.pdf.) Accordingly, the following analysis will focus on PNT. Lane and Nisker note that mitochondrial replacement would fall under prohibitions on nuclear transfer and reproductive cloning that are in place in several countries and also counteracts prohibitions against germline genetic modifications (Alyssa Lane &

According to the Anscombe Bioethics Centre, "PNT is a particularly destructive form of human cloning."[123] Unlike standard IVF, that implants the same embryo produced via sperm-egg union, PNT generates a new embryo by harvesting and combining genetic material from two embryos created via IVF. This process destroys two IVF embryos.[124] Thus, a narrow reading of A.R.S. § 36-2313(A)-(B) as only prohibiting "destructive embryonic stem cell research,"[125] would not extend these protections against destruction of embryos for PNT. More likely, PNT would fall under Arizona's prohibition on generating an embryo by means other than sperm-egg union.[126]

With PNT, "a *new* embryo is produced by transferring the pronuclei from the intended parents to the healthy cytoplasm derived from the 'host' embryo."[127] This implicates PNT in reproductive human cloning.[128] Comparison of PNT with North Dakota's definition of human cloning reveals substantial overlap. PNT asexually creates a "*new*" embryo;[129] introduces nuclear genetic material from the parent's embryo into a fertilized oocyte;[130] and the resulting embryo is of human genetic composition.[131]

Jeff Nisker, "'Mitochondrial Replacement' Technologies and Human Germline Nuclear Modification," Journal of Obstetrics and Gynaecology Canada 38, no. 8 (2016): 731).

[123] *Novel Techniques*, 63, quoting Anscombe Bioethics Centre, responding to the Working Group's call for evidence.

[124] Condic, "Mitochondrial Donations," 4.

[125] A.R.S. § 36-2313(A)-(B).

[126] *Id.* § 36-2312(A),(D).

[127] Condic, "Mitochondrial Donation," 3-4 (original emphasis).

[128] "[T]he nuclear DNA of one human being is used to create a genetic copy or 'clone' of that individual by transfer to egg-derived cytoplasm from a host embryo, killing the original embryo and the host embryo in the process." (Ibid., 4).

[129] Ibid. (original emphasis). While PNT utilizes pronuclei created by sperm-egg union (*Novel Techniuqes*, 64) and the original two embryos are created via IVF, the embryo intended for implantation is not created by sperm-egg union. (See Ibid., 32-34). On this point, PNT uses an agent "not normally used in reproductive embryology. Pronuclear transfer uses Nocadazole (to restabilise the cytoskeleton after penetration of the membrane of the egg with the micropipette used to transfer the two pronuclei) … ." (Ibid. 66-67).

[130] Ibid., 32-34.

[131] "[P]eople born from PNT or MST would be amongst the first to be born with a genetic connection to three people, albeit with a very much smaller genetic contribution coming from the donor. The resulting people would inherit nDNA (circa 20,000 – 30,000 genes) from their parents' sperm and egg, and healthy mitochondrial mtDNA

In contrast to SCNT, PNT does not transfer a human somatic cell.[132] Some contend that this means PNT does not copy a pre-existing or deceased human and is, thereby, not cloning.[133] However, this does not foreclose PNT from being defined as cloning,[134] it only means PNT and SCNT are different procedures, albeit, substantially similar. North Dakota statutes recognize that SCNT is synonymous with cloning,[135] and, thus, would need to expand its definition if the legislature desires to account for new methods of cloning.

This brings the discussion full-circle, to a review of the clear definition of human cloning: one based on science, and not on propaganda or other goals. New means to clone human embryos will likely be discovered in the future. Even if the means differ from SCNT, cloning as a procedure asexually produces a genetic copy of another human life. Both PNT and SCNT are cloning.[136]

Proponents of PNT may still contend it is distinct from SCNT based on consequential, arbitrary reasons. Current proposals argue that multi-parent embryos are due a "higher moral status" than embryos created by other nuclear transfer techniques because PNT embryos would contain DNA distinct from their parents.[137] This moral distinction is merely pretext seeking to justify what amounts to human cloning for reproductive purposes.[138]

(37 genes) from the donor of the enucleated egg or embryo. It's also possible that they may receive a very small amount of mitochondria from their mother's egg, dependent on the level of carry-over involved in the technique used." (Ibid., 70).

[132] "In reproductive SCNT, the nucleus taken from a somatic cell … must be 'reprogrammed' to behave as if it were in an embryonic state. No such manipulation of the pronuclei (nor any other part of the reconstructed embryo) is required in PNT." (Ibid., 64).

[133] "PNT does not transfer a fully-formed nucleus, nor 'clone' a pre-existing 'original' individual or entity." (Ibid., 64).

[134] PNT reconstructs a pre-existing embryonic human via transfer of nuclear genetic information (see Ibid., 32-34, 64); (see also Condic, "Mitochondrial Donation," 4).

[135] *See* N.D. Cent. Code § 12.1-39-01(1).

[136] Condic, "Mitochondrial Donation," 3-4.

[137] "'For some people… the merging of the [pronuclear] DNA from the parents to create an embryo with a unique genetic identity is morally significant. Those holding this view are likely to find [pronuclear transfer] morally preferable [to nuclear transfer] because of the higher moral status afforded to the embryo once this stage of

If Connecticut, or states with similar cloning laws, considers permitting implantation of PNT embryos, then this will force the legislature to confront the arbitrariness of current cloning definitions. The legislature could identify PNT as cloning and, thereby, subject it to the same regulations. This would defeat the reproductive purpose of PNT, likely prompting outcry over denial of reproductive choice.[139]

Alternatively, the legislature could lift bans on reproductive cloning. This would re-new the debate on reproductive cloning while also affirming concerns that therapeutic cloning was the precursor to birth of a cloned human.[140] The issue of whether and how to lift reproductive cloning bans may soon come to the forefront amidst news of a New York fertility doctor traveling to Mexico to employ a mitochondrial replacement technique to create and give birth to a baby created with three genetic parents.[141]

Legislative trends of re-defining cloning support a prediction that the legislature will forego recognizing scientific truth and insist PNT is not reproductive cloning. Already, proposals garner support around the prospect of multi-parent embryo creation (both PNT and MST) serving as medical treatment.[142] Deeming multi-parent embryo techniques as treatment, and not

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development has been reached" (*Novel Techniques*, 63, quoting British Medical Association response to Working Group's call for evidence. Original bracketed text.)

[138] This form of reproductive cloning may carry with it eugenic consequences, as well, given that it is meant to prevent transmission of genetic disorder to future generations (See, for example, Lane & Nisker, 733). "Producing three-parent embryos is a form of eugenic, human experimentation" (Condic, "Mitochondrial Donation," 10).

[139] For a discussion of arguments supporting three-parent embryo proposals based on one's perceived right to give birth to a genetically-related child (see *Novel Techniques*, 61).

[140] *See* June Mary Zekan Makdisi, *The Slide From Human Embryonic Stem Cell Research to Reproductive Cloning: Ethical Decision-Making and the Ban on Federal Funding*, 34 RUTGERS L.J. 463, 511 (2003) (arguing that advancing therapeutic cloning under utilitarian motives will "inevitably lead to funding research on reproductive cloning).

[141] See Rob Stein, "New York Fertility Doctor Says He Created Baby With 3 Genetic Parents," at WNPR News (27 September 2016), at http://www.npr.org/sections/thetwo-way/2016/09/27/495668299/new-york-fertility-doctor-says-he-created-baby-with-3-genetic-parents.

[142] "Patient groups and medical research funders are pressing the Government to offer Parliament the opportunity to vote to approve the use of regulation-making powers already in place which would allow such techniques for use in preventing the transmission of mitochondrial DNA disorders in the UK, at such time as they can be considered

cloning, would constitute a legislative win-win: it would distance PNT from reproductive cloning while simultaneously advancing what many see as a promising development in medicine.

However, this would create a crisis of integrity with regard to the future of cloning. It would implicitly embrace eugenics. Additionally, it would result in a legally-sanctioned dichotomy between embryos deemed worthy for implantation (PNT and MST embryos) and those that are not (SCNT embryos).[143] Statutes would reflect a skewed value system that deems human life worthy of birth only when it is free of malady,[144] while the authorities deciding which embryos are suitable for implantation would have discretion over the fate of a given embryo.[145] Thus, legislatures will be confronted with a question Pope John Paul II posed: "In the name of what justice is the most unjust of discriminations practiced: some individuals are held to be deserving of defense and others are denied that dignity?"[146]

Science Will Prevail

Scientific principles are currently shaping discourse on multi-parent embryo proposals in the United States. For instance, recent findings suggest three-parent embryo techniques could

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acceptably safe and effective. The granting of a license by the Human Fertilization and Embryology Authority (HFEA), the UK's fertility treatment and associated research regulator, to carry out research investigating PNT using human embryos to the Newcastle Fertility Center at LIFE in 2005, and the promising results there, have fueled this pressure" (*Novel Techniques*, 7). Under the guise that these procedures would constitute a form of treatment, proponents are led to believe that it would be unethical not to proceed with multi-parent embryo proposals (See Barber and Border, "Mitochondrial Donation," 13).

[143] PCBE member Robert George noted that unequal treatment of embryos poses a moral problem: "Fertilization produces a new and complete, though immature, human organism. The same is true of successful cloning. Cloned embryos therefore ought to be treated as having the same moral status as other human embryos." (*Human Cloning and Human Dignity*, 258).

[144] Pope Saint John Paul II cautioned about the moral tragedy of eugenics, describing "a mentality – mistakenly held to be consistent with the demands of 'therapeutic interventions' – which accepts life only under certain conditions and rejects it when it is affected by any limitation, handicap, or illness." (*Evangelium Vitae* § 14). Laws that ascribe differing moral status among embryos runs contrary to moral principles that hold all innocent human life as morally equivalent, with no distinction based on genetics. (Ibid. § 57).

[145] This is already the case with Britain's HFE Act granting the Secretary of Health discretion authority to determine whether an embryo is suitable for implantation.

[146] *Evangelium Vitae* § 20.

result in carry-over of diseased mtDNA.[147] It has prompted a call to "freeze" advancements on these techniques, raising question as to whether three-parent embryo techniques will reliably result in the birth of children free of mtDNA disease.[148]

In addition, embryos may be distinguished based on more than the means used to generate them. The NAS recently offered its support of advancing three-parent embryo techniques (referred to as mitochondrial replacement techniques) under the condition that the techniques only be used to gestate male embryos.[149] Their advice is guided by scientific findings that mtDNA disease is maternally inherited, such that males born from multiple genetic parents would be at decreased risk of passing mtDNA disease to their children.[150]

Conclusion

Politically and ideologically driven manipulation of language has not prevented us from reaching a new dilemma. Reproductive three-parent human beings are now a reality. Pressure to permit their full gestation will grow. The coming choice will be between continued manipulation of language designed to hide the scientific truth or an honest discussion of what we have allowed, mandated, and are about to choose between.

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[147] For example, a recent study by Yamada et al. describes mtDNA genotypic drift, a phenomenon whereby the mtDNA transferred via three-parent embryo creation techniques can revert to the original genotype (Yamada, et al., "Genetic Drift Can Compromise Mitochondrial Replacement by Nuclear Transfer in Human Oocytes," Cell Stem Cell, Vol. 18, Issue 6, 749-754, June 2016).

[148] "I believe the UK is now going to have to step back and authorities there should now freeze all clinical efforts at 3-person IVF/mitochondrial transfer for the time being … the nuclear transfer from the mom-to-be's egg into the donor's enucleated egg would bring some diseased mitochondria with it and those faulty mitochondria could amplify" ("UK Should Freeze Mitochondrial Replacement as Egli Paper ID's Serious Problem," *The Niche* (Knoepfler lab stem cell blog), May 19, 2016, http://www.ipscell.com/2016/05/uk-should-freeze-mitochondrial-replacement-as-egli-paper-ids-serious-problem/.)

[149] Mutations to the mtDNA are not inherited via sperm (*Mitochondrial Replacement Techniques: Ethical, Social, and Policy Considerations* (The National Academies of Sciences, Engineering, and Mathematics, 2016), 2. http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2016/Mitochondrial%20Replacement%20Techniques/MitoEthics-RIB.pdf).

[150] Ibid.