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Synthetic Cells, Synthetic Life, and Inheritance

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SYNTHETIC CELLS, SYNTHETIC LIFE, AND INHERITANCE

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I. INTRODUCTION

"This is the first self-replicating species that we've had on the planet whose parent is a computer."[1]

In May 2010, J. Craig Venter and his team announced the creation of a "synthetic cell," or as the team described it, a process of "synthesis, assembly, cloning, and successful transplantation [of a synthetic genome] to create a new cell controlled by this synthetic genome."[2] They chose to start with a simple bacterium, *Mycoplasma genitalium* ("*M. genitalium*") because it has "the smallest complement of genes of any known organism capable of independent growth in the laboratory."[3] Using chemical enzymes and live bacteria, they were able to replicate the genome sequence of *M. genitalium* and then transplant it into a natural cell controlled by the synthetic genome.[4] Although the team had not created a new cell entirely from chemicals, their research demonstrates progress towards that end.

The creation of a synthetic genome is an important advancement in synthetic biology, "an emerging field of research that combines elements of biology, engineering, genetics, chemistry, and computer science."[5] Synthetic biology research often begins with a "[t]op-down" approach, using existing genes and other materials as parts to be analyzed or possibly reconfigured.[6] For Venter's team, that included sequencing the

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1 *See generally* J. Craig Venter Inst., *Craig Venter Unveils "Synthetic Life"*, TED: IDEAS WORTH SPREADING (May 2010), http://www.ted.com/talks/craig_venter_unveils_synthetic_life.html (announcing the first fully functioning, reproducing cell controlled by synthetic DNA).

2 Daniel G. Gibson et al., *Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome*, 329 SCI. 52, 55 (2010).

3 *Id.* at 52.

4 *Id.* at 55–56.

5 PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, NEW DIRECTIONS: THE ETHICS OF SYNTHETIC BIOLOGY AND EMERGING TECHNOLOGIES 36 (2010), http://www.bioethics.gov/documents/synthetic-biology/PCSBI-Synthetic-Biology-Report-12.16.10.pdf [hereinafter NEW DIRECTIONS].

6 *Id.*

genome of *M. genitalium* in 1995.[7] Synthetic biology also includes "[b]ottom-up" research to create new organisms using only chemical reagents.[8]

Synthetic biology is used today in the field of assisted reproduction to analyze existing genes. An example of such "top-down" synthetic biology is preimplantation genetic diagnosis ("PGD") to screen for human immunodeficiency virus, cystic fibrosis, or other diseases.[9] This Article will focus on the "bottom-up" use of synthetic biology in the context of assisted reproduction. One day, scientists may be able to create synthetic human gametes or embryos for purposes of assisted reproduction.[10] It is impossible to forecast when this may occur; as the 2010 Presidential Commission for the Study of Bioethical Issues noted, "the pace of discovery is unpredictable."[11] But instead of deferring the discussion until synthetic sperm or ova actually appear, we should anticipate the risks and benefits now. This Article will focus on the practical and regulatory issues that may encourage or inhibit the use of Venter's technology to create synthetic gametes and the legal issues of parentage and inheritance for a synthetically created child.

Part II of this Article sets the stage by briefly discussing infertility in the United States, the development of assisted reproduction technologies to counteract infertility, and other additional uses of assisted reproductive technologies ("ART") such as PGD, which is also used by fertile couples. Part III examines the existing laws and regulations that may apply to the development of synthetic human gametes or embryos. With the market demands from Part II and the regulatory structure from Part III in mind, Part IV will look at the parentage and inheritance issues if a synthetic gamete results in a living child. Part V concludes the Article by exploring two approaches to regulatory issues.

This Article will follow Recommendation Fifteen from the Presidential Commission regarding Information Accuracy:

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7 Gibson et al., *supra* note 2, at 52.

8 NEW DIRECTIONS, *supra* note 5, at 36.

9 *Id.* at 66. Preimplantation genetic diagnosis ("PGD") is used to screen for certain genetic or chromosomal diseases, while preimplantation genetic screening ("PGS") can be used for other purposes, such as genetic characteristics. Jaime King, *Predicting Probability: Regulating the Future of Preimplantation Genetic Screening*, 8 YALE J. HEALTH POL'Y L. & ETHICS 283, 284 (2008). This Article will use the term "PGD" to encompass both concepts.

10 Already, "new developments in basic science have led to new understandings about how to create and manipulate human gametes—only recently, scientists have discovered how to create artificial mouse eggs from embryonic stem cells." Gail H. Javitt & Kathy Hudson, *Regulating (for the Benefit of) Future Persons: A Different Perspective on the FDA's Jurisdiction to Regulate Human Reproductive Cloning*, 2003 UTAH L. REV. 1201, 1208.

11 NEW DIRECTIONS, *supra* note 5, at 67.

> When discussing synthetic biology, individuals and deliberative forums should strive to employ clear and accurate language. The use of sensationalist buzzwords and phrases such as "creating life" or "playing God" may initially increase attention to the underlying science and its implications for society, but ultimately such words impede ongoing understanding of both the scientific and ethical issues at the core of public debates on these topics. To further promote public education and discourse, a mechanism should be created, ideally overseen by a private organization, to fact-check the variety of claims relevant to advances in synthetic biology.[12]

II. INFERTILITY AND ASSISTED REPRODUCTION

The infertility industry in the United States is big business. A Centers for Disease Control and Prevention ("CDC") report presented the latest data on infertility:

- Of the approximately 62 million women of reproductive age in 2002, about 1.2 million, or 2%, had an infertility-related medical appointment within the previous year and an additional 10% had received infertility services at some time in their lives. (Infertility services include medical tests to diagnose infertility, medical advice and treatments to help a woman become pregnant, and services other than routine prenatal care to prevent miscarriage.)
- Additionally, 2.1 million couples or about 7% of married couples, in which the woman was of reproductive age reported that they had not used contraception for 12 months and the woman had not become pregnant.[13]

Just one aspect of assisted reproduction, the exchange of eggs (ova), has been estimated to be worth $4.5 billion in the United States.[14]

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12 *Id.* at 15.

13 CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., 2006 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS 3 (2008), http://www.cdc.gov/ART/ART2006/508PDF/2006ART.pdf [hereinafter 2006 ART SUCCESS RATES] (providing data from the 2002 National Survey of Family Growth).

14 Sunni Yuen, Comment, *An Information Privacy Approach to Regulating the Middlemen in the Lucrative Gametes Market*, 29 U. PA. J. INT'L L. 527, 546 (2007).

Donated ova are used in about 12% of the assisted reproduction procedures reported to the CDC.[15]

The first widely available technology for infertility was assisted or artificial insemination ("AI"), in which semen is inserted into the woman's cervix or uterus via syringe. The first report of AI for human use was published in 1884, but the technique had been used long before in animal husbandry.[16]

AI solves only a limited range of fertility problems, prompting scientists to work on other methods of assisted reproduction in which both the sperm and the egg (ovum) can be handled in the laboratory. Worries about possible birth defects, the discarding of gametic material, and other issues led to a ban on the use of federal funds for such research in 1973, but research funded from non-federal sources and in other countries continued.[17] Drs. Steptoe and Edwards of the United Kingdom radically altered the discussion when they introduced the first "test tube" baby in a 1978 press release.[18] Similar to Venter's synthetic genome, the success of in vitro fertilization ("IVF"), in which the egg and sperm are joined in a Petri dish and later implanted in a woman's uterus,[19] was termed the "medical media event of the year" in a Hastings Center Report.[20] After roughly one hundred attempts, the process ended successfully with the birth of Louise Brown.[21] Once an apparently healthy baby was born, the U.S. Ethics Advisory Board, at the urging of Joseph Califano, Secretary of Health, Education, and Welfare,[22] recommended reversing the ban on federal research funds, but otherwise left oversight of IVF to the states.[23] Since 1978, more than three million

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15 2006 ART SUCCESS RATES, *supra* note 13, at 56.

16 Carolyn Sappideen, *Life After Death – Sperm Banks, Wills and Perpetuities*, 53 AUSTL. L. J. 311, 311 (1979).

17 Robert Toth, *Panel To Consider Ethics of Test-Tube Baby Research*, L.A. TIMES, Sept. 15, 1978, at B1.

18 *1978: First 'Test Tube Baby' Born*, BBC: ON THIS DAY http://news.bbc.co.uk/onthisday/hi/dates/stories/july/25/newsid_2499000/2499411.stm (last visited Apr. 14, 2011).

19 *See* Kerry Lynn Macintosh, *Brave New Eugenics: Regulating Assisted Reproductive Technologies in the Name of Better Babies*, 2010 U. ILL. J.L. TECH. & POL'Y 257, 264–65 (explaining the standard IVF procedure).

20 Daniel Callahan, *In Vitro Fertilization: Four Commentaries*, HASTINGS CTR REP., Oct. 1978, at 7.

21 Walter Sullivan, *Doctor in Laboratory Conception Says First 100 Attempts Failed*, N.Y. TIMES, Dec. 1, 1978, at A21.

22 Robert Toth, *Califano Urges Debate on Baby Research*, L.A. TIMES, Sept. 16, 1978, at A2.

23 Dena Kleiman, *Anguished Search To Cure Infertility: Medical Advances Offer New Hope, But Infertility Affects More Couples Than Ever*, N.Y. TIMES, Dec. 16, 1979, at SM38.

babies have been born worldwide using assisted reproduction technologies.[24]

Cryopreservation, the ability to store sperm, ova, and embryos for later use, is widely used today. The ability to successfully freeze sperm has been available for over fifty years.[25] However, cryopreservation of embryos is more recent and widely available, with 100% of fertility clinics reporting to the CDC that they offer this service as part of assisted reproduction.[26] Freezing unfertilized eggs is now possible, but it is considered experimental by the American Society of Reproductive Medicine and the American College of Obstetrics and Gynecologists.[27]

Sperm and ova can be retrieved after a person's death or while a person is in a persistent vegetative state. Cappy Rothman first reported his method to extract sperm postmortem in 1980.[28] Although it is possible to retrieve ova after a woman has died, no such instance has been reported to date. A recent article in the *New England Journal of Medicine* considered the ethics of granting a husband's request to keep his wife, who was on life support, alive long enough to retrieve her eggs; the request was ultimately denied.[29]

Along with ART such as IVF, clinics also offer services evidencing "top-down" synthetic biology such as sex selection and PGD. Commercial techniques such as MicroSort separate male-producing sperm from female-producing sperm.[30] The woman is then inseminated with sorted sperm of the desired gender.[31] PGD involves removing one cell from an early-stage embryo and testing that cell either for various traits including sex or for genes that cause diseases such as cystic fibrosis.[32]

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24 Macintosh, *supra* note 19, at 259.

25 Sappideen, *supra* note 16, at 311.

26 *See* 2006 ART SUCCESS RATES, *supra* note 13, at 89 (finding that 100% of the reporting clinics offered cryopreservation of embryos as one of their services).

27 Judy Foreman, *Health Sense: Success Rate Elusive on Frozen Eggs*, L.A. TIMES, Aug. 16, 2010, at E3.

28 Cappy Miles Rothman, *A Method for Obtaining Viable Sperm in the Postmortem State*, 34 FERTILITY & STERILITY 512, 512 (1980).

29 David M. Greer et al., *Case 21-2010—A Request for Retrieval of Oocytes from A 36-Year-Old Woman with Anoxic Brain Injury*, 363 NEW ENG. J. MED. 276, 279, 282 (2010).

30 *See MicroSort®*, GENETICS & IVF INST., http://www.microsort.net (last visited Apr. 3, 2011) (discussing the Microsort technique, related clinical studies, and eligibility requirements for interested parties).

31 Rob Stein, *A Boy for You, a Girl for Me: Technology Allows Choice*, WASH. POST, Dec. 14, 2004, at A1.

32 Judy Peres, *High Stakes of High-Tech Medicine: Who Is At Fault When Cutting-Edge Technology Fails and Who Must Pay the Price? A Couple's Lawsuit Looks at the Issues of Consent and Experimentation in Assisted Reproductive Technologies*, CHI. TRIB., Nov. 1, 1998, at C1.

Current techniques allow ART users to select an embryo with the desired characteristics and discard another. If a synthetic sperm or ovum is created, the user could select for a wide range of genetic characteristics, even those not present in the intended parents.

III. EXISTING REGULATIONS

If researchers begin using Venter's techniques to create a synthetic gamete, would federal and state regulations encourage or hinder their efforts? Existing laws and regulations on synthetic genomes primarily focus on biosafety concerns to ensure that the new creations are not released into the wild and that villains are not trying to concoct hazardous substances such as anthrax or small pox. The PATRIOT Act[33] expanded 18 USC § 175 (prohibitions with respect to biological weapons) by adding the following subsection:

> (b) ADDITIONAL OFFENSE.—Whoever knowingly possesses any biological agent, toxin, or delivery system of a type or in a quantity that, under the circumstances, is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose, shall be fined under this title, imprisoned not more than 10 years, or both. In this subsection, the terms "biological agent" and "toxin" do not encompass any biological agent or toxin that is in its naturally occurring environment, if the biological agent or toxin has not been cultivated, collected, or otherwise extracted from its natural source.[34]

Regulations issued by federal agencies such as the CDC, the Department of Agriculture, and the Department of Commerce have listed the biological agents, toxins, and so on that would violate the PATRIOT Act.[35] Vendors synthesizing DNA use screening software

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[33] Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT Act) Act of 2001, Pub. L. No. 107-56, 115 Stat. 272 (codified in scattered sections of the U.S.C.).

[34] 18 U.S.C. § 175(b) (2006).

[35] *See* 7 C.F.R. § 331.3 (2010) (providing the Department of Agriculture's list of toxins and agents capable of producing harm to plants and plant products); 9 C.F.R. § 121.3 (2010) (providing the Department of Agriculture's list of toxins and agents capable of producing harm to public health and safety, animals, and animal products); 15 C.F.R. pt. 774 (2010) (outlining the relevant sections: 1C351, 1C353, 1C354 and 1C991); 42 C.F.R. § 73.3 (2011) (listing the specific agents and toxins considered by the Department of Health and Human Services to pose serious risks and dangers to the public).

such as "BlackWatch" to test whether the requested DNA sequence is on the list of banned agents.[36] The list of pathogens tested includes seventy-five organisms and twenty-two toxins:[37]

Host	**Human/ Animal**	**Animal Only**	**Plant**	**Total**
Pathogen Type				
Viruses	19	12	2	33
Bacteria	15	3	8	26
Fungi	2	0	2	11
Rickettsiae [parasite related]	4	0	9	4
Prions [proteins that cause degenerative brain disease, like mad cow]	0	1	0	1
Toxins	22	0	0	22

These current regulations would have little effect on the creation of synthetic sperm or ovum; although researchers would need to check their DNA sequences against the list of pathogens, it is not their goal to create one of them. A more significant impact on synthetic gamete research may be found in the regulations on assisted reproduction, which impose limitations on sperm banks, fertility clinics, and other providers of infertility services. How much of an impact these regulations would have depends in part on whether creating a synthetic gamete is seen as akin to processes such as PGD or more like oocyte transfer or cloning. These questions, in turn, require examination of the regulations regarding both gametes and embryos. Most regulation today is focused on controlling communicable diseases, inhibiting the sale of genetic material, or avoiding the destruction of embryos. IVF clinics report to the CDC, and states have various regulations incidentally affecting IVF, such as bans on the sale of ova or refusals to enforce surrogacy contracts. However, generally speaking, the free market has reigned.[38] By determining that the procedure used by Louise Brown's

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[36] Robert Jones, *Sequence Screening*, *in* WORKING PAPERS FOR SYNTHETIC GENOMICS: RISKS AND BENEFITS FOR SCIENCE AND SOCIETY 1, 2 (MS Garfinkel et al. eds., 2007), *available at* http://www.jcvi.org/cms/fileadmin/site/research/projects/synthetic-genomics-report/Jones-Sequence-Screening.pdf.

[37] *Id.* at 10.

[38] *See* Jaime King, *Predicting Probability: Regulating the Future of Preimplantation Genetic Screening*, 8 YALE J. HEALTH POL'Y L. & ETHICS 283, 357 (2008) (noting that "a technological revolution in reproduction is coming" and suggesting that the time to regulate is now).

mother was a treatment for her infertility rather than medical experimentation on human subjects, the IVF industry has been allowed to develop with little restriction in the United States.

A. ART/Embryos

In 2004, the President's Council on Bioethics observed in its report, *Reproduction & Responsibility: The Regulation of New Biotechnologies*, that new reproductive technologies "move from the experimental context to clinical practice with relatively little oversight or deliberation. . . . Current professional guidelines dictate only that there be two peer-reviewed papers showing an acceptable risk-benefit ratio before the status of a new practice is elevated from 'experimental' to 'clinically acceptable.'"[39] PGD and preimplantation genetic screening ("PGS")[40] have remained largely unregulated, arguably due to political reasons[41] and constitutional concerns regarding intrusion upon recognized procreative liberties.[42] Less controversial experimental techniques such as intracytoplasmic sperm injection "have entered clinical practice with limited prior testing and limited monitoring of their effects on the children produced with their aid."[43] Consequently, ART remains largely unregulated by both the federal government and states.[44]

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[39] PRESIDENT'S COUNCIL ON BIOETHICS, REPRODUCTION & RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES 176 (2004) [hereinafter 2004 PRESIDENT'S COUNCIL REPORT]. Furthermore, "[o]nce in practice, these techniques are used at clinicians' discretion, with little or no external oversight. Use of effective technologies becomes widespread rapidly." *Id.*

[40] *See* King, *supra* note 38, at 290–96 (describing the technologies involved in PGS).

[41] Jaime King states that

> [o]ne of the main reasons the United States has not regulated PGS is because American politicians do not find it politically advantageous. The lack of political interest has occurred for three reasons: 1) few studies have demonstrated harm to children from PGS; 2) the current technological limitations of PGS have restricted both patient demand and the frequency of its use for controversial purposes; and 3) PGS regulation is politically divisive. As a result, politicians have effectively tabled the issue until a significant harm or risk demands political action.

Id. at 321.

[42] *See id.* at 326–29 (discussing the constitutional considerations regarding procreative liberties); *see also* Susannah Baruch, *Preimplantation Genetic Diagnosis and Parental Preferences: Beyond Deadly Disease*, 8 HOUS. J. HEALTH L. & POL'Y 245, 261–62 (2008) (noting that the political and legal challenges on regulating the use of PGD are similar to the debates over abortion).

[43] 2004 PRESIDENT'S COUNCIL REPORT, *supra* note 39, at 174–75. Intracytoplasmic sperm injection ("ICSI") is "a procedure in which a single sperm is injected directly into an egg . . ." 2006 ART SUCCESS RATES, *supra* note 13, at APPENDIX B, GLOSSARY OF TERMS].

[44] *See infra* Parts III.A.1 and III.A.2 (discussing federal and state regulation of ART).

1. Federal Regulation of ARTs

Currently, there are three significant restrictions at the federal level regarding research on embryos and the practice of ART: (1) the reporting requirement administered by the CDC; (2) a ban on federal funding for research involving the destruction of human embryos; and (3) the regulation of practices such as somatic cell nuclear transfer, commonly known as cloning.

a. The CDC Reporting Requirement

The Fertility Clinic Success Rate and Certification Act of 1992 ("FCSRCA")[45] requires each ART program handling ova or embryos to report annually to the CDC the "(1) pregnancy success rates achieved by such program through each assisted reproductive technology, and (2) the identity of each embryo laboratory . . . used by such program and whether the laboratory is certified . . . or has applied for such certification."[46] The FCSRCA further directs the CDC to annually publish, among other information

> pregnancy success rates reported to the [CDC] under section 263a-1(a)(1) of this title and, in the case of an assisted reproductive technology program which failed to report one or more success rates as required under such section, the name of each such program and each pregnancy success rate which the program failed to report.[47]

Although the FCSRCA instructs the CDC to "develop a model program for the certification of embryo laboratories . . . to be carried out by the States,"[48] it further provides that "[i]n developing the certification program, the [CDC] may not establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs."[49]

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[45] Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, 106 Stat. 3146 (codified as amended at 42 U.S.C. §§ 263a-1 to -7 (2006)).

[46] 42 U.S.C. § 263a-1(a)(1) to (2). The Act defines "assisted reproductive technology" as techniques handling ova or embryos, and thus excludes sperm banks and assisted insemination, in which only the sperm is handled outside the body. 42 U.S.C. § 236a-7(1).

[47] *Id.* § 263a-5(1)(A).

[48] *Id.* § 263a-2(a)(1).

[49] *Id.* § 263a-2(i)(1). Similarly, the FCSRCA provides that "[i]n adopting the certification program, a State may not establish any regulation, standard, or requirement which has the

If an ART clinic began using synthetic gametes or embryos, the clinic would simply need to include the outcomes of the implantations in its statistics. One question would arise as to which category to place the synthetic materials; the current report is broken into two parts: those with "non-donor eggs" and those with "donor eggs." There is no separate category for "donor sperm." Thus if synthetic sperm were used to create the embryo through in vitro fertilization, that fact would go unmentioned. If a synthetic egg were used, perhaps a third reporting category would be created, or the synthetic ovum might be included in the "donor egg" category since the birth mother would not be the genetic mother in either case.

b. The Ban on Federal Funding

Since 1996, appropriations acts have been restricted by the Dickey-Wicker Amendment, which prohibits the National Institutes of Health ("NIH") from funding research that results in the destruction of human embryos.[50] Specifically, Dickey-Wicker bans the use of federal funds for the following:

> (1) the creation of a human embryo or embryos for research purposes; or
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> (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 C.F.R. 46.208(a)(2) and 42 U.S.C. 289g(b).[51]

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effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs." *Id.* § 263a-2(i)(2).

[50] Balanced Budget Downpayment Act, I, Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996). This ban has been included annually in subsequent appropriations bills. *See, e.g.*, Consolidated Appropriations Act, 2001, Pub. L. No. 106-554, § 510(a), 114 Stat. 2763, 2763A-71 (2000); Consolidated Appropriations Act, 2000, Pub. L. No. 106-113, § 510(a), 113 Stat. 1501, 1501A-275 (1999); Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Pub. L. No. 105-277, § 511(a), 112 Stat. 2681, 2681-386 (1998); Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations Act, 1998, Pub. L. No. 105-78, § 513(a), 111 Stat. 1467, 1517 (1997); Omnibus Consolidated Appropriations Act, 1997, Pub. L. No. 104-208, § 512(a), 110 Stat. 3009, 3009-270 (1996).

[51] Balanced Budget Downpayment Act, I § 128. Courts have defined "the term 'research' as used in the Dickey-Wicker Amendment [as having] only one meaning, *i.e.*, 'a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.'" Sherley v. Sebelius, 704 F. Supp. 2d 63, 70 (D.D.C. 2010) (quoting 45 C.F.R. § 46.102(d) (2009)); *see also* 42 U.S.C. § 289g(b) (explaining that the risk standard is to "be the same for fetuses which are intended to be aborted and

The Amendment further provides that "the phrase 'human embryo or embryos' shall include any organism, not protected as a human subject under 45 C.F.R. 46 as of the date of enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes."[52]

President Barack Obama attempted in 2009 to remove restrictions against federal funding for research that results in the destruction of human embryos.[53] The Dickey-Wicker Amendment, however, arguably prohibits funding for such research,[54] which also extends to cloning research.[55] The Dickey-Wicker Amendment likely would require research on synthetic gametes joined with human gametes to be conducted with non-federal funds. Thus, the impact could be similar to that found in the 1970s when the federal government banned the use of federal funds for research on in vitro fertilization: the research continued with non-federal funds and in other countries, resulting in the birth of Louise Brown in Great Britain in 1978.

If both synthetic sperm and synthetic ovum were used to create a synthetic embryo, the Dickey-Wicker Amendment would not apply. The amendment defines human embryos to include any organism derived by "any other means from one or more human gametes,"[56] but a synthetic embryo has *no* human gametes.

c. FDA Regulation of Human Reproductive Cloning

The FDA has effectively banned research on cloning in the United States since 1998.[57] Somatic cell[58] nuclear transfer ("SCNT") cloning "entails removing the original nucleus from an egg cell and replacing that nucleus with one from a somatic cell, such as a skin cell. The egg cell, now containing a *new* (for the egg cell) nucleus, is then induced to

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fetuses which are intended to be carried to term"); 45 C.F.R. § 46.204(b) (2010) (prohibiting research on fetuses in utero unless "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").

52 Balanced Budget Downpayment Act, I § 128.

53 *See* Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 11, 2009).

54 *See Sherley*, 704 F. Supp. 2d at 70 (granting a preliminary injunction enjoining the Secretary of Health and Human Services from implementing NIH guidelines allowing embryonic stem cell research after finding that plaintiffs were likely to succeed on the merits of their claim that the guidelines violated the Dickey-Wicker Amendment).

55 JUDITH A. JOHNSON & ERIN D. WILLIAMS, CONG. RESEARCH SERV., RL 31358, HUMAN CLONING 7–8 (2006), *available at* http://www.fas.org/sgp/crs/misc/RL31358.pdf.

56 Balanced Budget Downpayment Act, I § 128.

57 Javitt & Hudson, s*upra* note 10, at 1202.

58 Somatic cells are non-reproductive cells, while germ cells are reproductive cells (sperm cells and egg cells). *Id.* at 1214.

divide under laboratory conditions to form an embryo."[59] If the embryo is subsequently implanted in a uterus and "successfully gestated, the result is an organism that is a virtually identical genetic copy (with the exception of the mitochondrial DNA) of the source of the somatic cell."[60]

If researchers wish to perform SCNT, they must first apply to the FDA for an investigational new drug application. The FDA has stated that it will not approve an application for such research until the safety concerns involved with cloning have been resolved.[61]

Although a synthetic embryo might well raise safety concerns, the process to create one would not involve cloning. Unlike SCNT, the synthetic gamete would be joined with either a human gamete or another synthetic gamete, so that the resulting embryo would not be an identical genetic copy of the synthetic material.

The FDA also has authority to regulate the fertility drugs and medical devices used in ART, including "instrumentation intended for use in IVF and related ART procedures."[62] This could limit the research into synthetic genetic material only if drugs or medical devices not currently used in assisted reproduction are created specifically for this synthetic process. This seems unlikely to occur.

2. State Regulation of ARTs

Although states have been more active than the federal government in regulating research on human embryos and fetuses, existing state laws would have limited impact on the creation of synthetic gametes or embryos. Some states prohibit research on human embryos and fetuses,[63] others prohibit the sale of embryos and fetuses,[64] and others

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59 *Id.* at 1203.

60 *Id.* at 1204.

61 *Id.* at 1202.

62 Obstetric and Gynecologic Devices; Reclassification and Classification of Medical Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures, 63 Fed. Reg. 48,428, 48,428 (Sept. 10, 1998) (to be codified at 21 C.F.R. pt. 884).

63 *See, e.g.*, LA. REV. STAT. ANN. § 9:122 (2008) ("The use of a human ovum fertilized in vitro is solely for the support and contribution of the complete development of human in utero implantation. No in vitro fertilized human ovum will be farmed or cultured solely for research purposes or any other purposes."); ME. REV. STAT. ANN. tit. 22, § 1593(1) (2004) ("A person may not use, transfer, distribute or give away a live human fetus, whether intrauterine or extrauterine, or any product of conception considered live born, for scientific experimentation or for any form of experimentation."); N.M. STAT. ANN. § 24-9A-3(A) (LexisNexis 2007) ("No fetus shall be involved as a subject in any clinical research activity unless the purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs or no significant risk to the fetus is imposed by the research activity."); *see also* N.M. STAT. ANN. § 24-9A-5(A) (outlining very limited exceptions to the general ban on "clinical

impose mandatory reporting requirements on IVF facilities[65] or require IVF facilities to adhere to professional society guidelines.[66] At least one state has set forth rules for the performance of IVF and has established eligibility requirements for IVF recipients.[67] Louisiana goes so far as to identify embryos as juridical persons and prohibit their intentional destruction.[68] In addition, as of January 2008, fifteen states regulated

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research activity involving fetuses, live-born infants or pregnant women"); R.I. GEN. LAWS § 11-54-1(a) (2002) ("No person shall use any live human fetus, whether before or after expulsion from its mother's womb, for scientific, laboratory research, or other kind of experimentation."); S.D. CODIFIED LAWS § 34-14-17 (2004) ("No person may knowingly conduct nontherapeutic research that subjects a human embryo to substantial risk of injury or death.").

64 *See, e.g.*, IND. CODE ANN. § 35-46-5-3(a) (West Supp. 2010) ("A person who knowingly or intentionally purchases or sells a human ovum, zygote, embryo, or fetus commits unlawful transfer of a human organism, a Class C felony."); LA. REV. STAT. ANN. § 9:122 (2008) ("The sale of a human ovum, fertilized human ovum, or human embryo is expressly prohibited."); S.D. CODIFIED LAWS § 34-14-17 (2004) ("No person may sell or transfer a human embryo with the knowledge that the embryo will be subjected to nontherapeutic research.").

65 *See* 18 PA. CONS. STAT. ANN. § 3213(e) (West 2000) ("All persons conducting, or experimenting in, in vitro fertilization shall file quarterly reports with the department, which shall be available for public inspection and copying . . . .").

66 In Louisiana,

> [o]nly medical facilities meeting the standards of the American Fertility Society and the American College of Obstetricians and Gynecologists and directed by a medical doctor licensed to practice medicine in this state and possessing specialized training and skill in in vitro fertilization also in conformity with the standards established by the American Fertility Society or the American College of Obstetricians and Gynecologists shall cause the in vitro fertilization of a human ovum to occur. No person shall engage in in vitro fertilization procedures unless qualified as provided in this Section.

LA. REV. STAT. ANN. § 9:128 (2008).

67 In New Hampshire,

> [i]n vitro fertilization and preembryo transfer shall be performed in accordance with rules adopted by the department of health and human services and shall be available only to a woman:
>
> I. Who is 21 years of age or older;
>
> II. Who has been medically evaluated and the results . . . demonstrate the medical acceptability of the woman to undergo the . . . procedure;
>
> III. Who receives counseling . . . and provides written certification of the counseling and evaluation to the health care provider performing the . . . procedure; and
>
> IV. Whose husband, if the recipient is married, receives appropriate counseling . . . and [satisfies other requirements].

N.H. REV. STAT. ANN. § 168-B:13 (LexisNexis 2010).

68 In Louisiana,

> [a] viable in vitro fertilized human ovum is a juridical person which shall not be intentionally destroyed by any natural or other

cloning in some way, either by banning the use of public funds for cloning or by outright prohibition of therapeutic and/or reproductive cloning.[69] A proposed law, Georgia's Ethical Treatment of Embryos Act, sought "[t]o amend Chapter 7 of Title 19 of the Official Code of Georgia Annotated . . . to provide that it shall be unlawful for any person or entity to intentionally or knowingly create or attempt to create an in vitro human embryo by any means other than fertilization of a human egg by a human sperm or intracytoplasmic sperm injection."[70] None of these enacted or proposed state laws would impact research on synthetic genetic materials as long as the creation of synthetic gametes is not considered "research," and the resulting embryo is not defined as "human."

3. Professional Societies' Recommendations on ARTs

Professional societies would likewise have little impact on the research of synthetic embryos. The American Society for Reproductive Medicine ("ASRM"), in conjunction with its sister organization, the Society for Assisted Reproductive Technology, "provides guidance by means of published statements, opinions, and guidelines issued by its practice and ethics committees. The chief values ASRM seeks to promote through its opinions and guidelines are safety (of ART participants), efficacy (of techniques and procedures), and privacy (of ART patients)."[71] ASRM issues both practice guidelines and ethical guidelines on a variety of issues related to ART.[72] Because compliance is voluntary, however, professional guidelines are generally unenforceable.[73]

> juridical person or through the actions of any other such person. An in vitro fertilized human ovum that fails to develop further over a thirty-six hour period except when the embryo is in a state of cryopreservation, is considered non-viable and is not considered a juridical person.

LA. REV. STAT. ANN. § 9:129 (2008).

[69] *See Human Cloning Laws*, NAT'L CONF. ST. LEGISLATURES (Jan. 2008), http://www.ncsl.org/default.aspx?tabid=14284. Those fifteen states are Arizona, Arkansas, California, Connecticut, Indiana, Iowa, Maryland, Massachusetts, Michigan, Missouri, New Jersey, North Dakota, Rhode Island, South Dakota, and Virginia. *Id.*

[70] S.B. 169, 150th Gen. Assemb., Reg. Sess. (Ga. 2009), *available at* http://www1.legis.ga.gov/legis/2009_10/pdf/sb169.pdf. The Act passed the Georgia State Senate by a vote of 34-22 on March 12, 2009, but it did not proceed to a vote within the House. *See Senate Vote 216*, GA. GEN. ASSEMB., http://www1.legis.ga.gov/legis/2009_10/votes/sv0216.htm (last visited Apr. 16, 2011).

[71] 2004 PRESIDENT'S COUNCIL REPORT, *supra* note 39, at 72.

[72] *See, e.g.*, *2008 Guidelines for Gamete and Embryo Donation: A Practice Committee Report*, 90 FERTILITY & STERILITY S30, S30 (Nov. 2008) [hereinafter *2008 Guidelines for Gamete and Embryo Donation*]; Ethics Committee of the American Society of Reproductive Medicine, *Disposition of Abandoned Embryos*, 82 FERTILITY & STERILITY S253 (Sept. 2004); *Guidelines on*

B. Gametes

Although the government has occasionally asserted authority to regulate specific practices,[74] gametes (sperm and ova) remain largely unregulated by both the federal government and states.[75] The FDA is mainly concerned with keeping infectious reproductive tissue out of the market through regulations on screening, processing, and record keeping.[76]

1. Federal Regulation of Gametes

Semen and other reproductive material, including oocytes, are considered HCT/Ps: Human Cells, Tissues, and Cellular and Tissue-Based Products regulated by the FDA.[77] As such, they are subject to rules designed to prevent communicable diseases.[78] A key question is whether synthetic gametes should be

> regulated solely under 21 C.F.R. Part 1271, the regulations to prevent communicable disease transmission authorized by section 361 of the Public Health Service Act. . . . [or] as biological products, drugs, or devices under section 351 of the Public Health Service Act and/or the Food Drug and Cosmetic Act.[79]

Number of Embryos Transferred, 86 FERTILITY & STERILITY S51 (2006); *Preconception Gender Selection for Nonmedical Reasons*, 75 FERTILITY & STERILITY 861 (May 2001); ; *see also* Michael J. Malinowski, *Choosing the Genetic Makeup of Children: Our Eugenics Past – Present, and Future?*, 36 CONN. L. REV. 125, 185–87 (2003) (identifying additional professional guidelines).

[73] *See* 2004 PRESIDENT'S COUNCIL REPORT, *supra* note 39, at 175. *But see* LA. REV. STAT. ANN. § 9:128 (2008) (requiring clinics to adhere to professional guidelines).

[74] *See infra* Part III.B.2 (discussing the FDA's claim of regulatory authority over ooplasmic transfer).

[75] *See infra* Parts III.B.1, III.B.3 (discussing federal and state regulation of gametes).

[76] Yuen, *supra* note 14, at 554.

[77] Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing, 66 Fed. Reg. 5447, 5448 (Jan. 19, 2001) (to be codified at 21 C.F.R. pts. 207, 807, 1271).

[78] 21 C.F.R. § 1271.75 (2010). Sections 1271.85(a)–(c) of the regulations require anonymously donated gametes to be tested for the following diseases: human immunodeficiency virus, type 1; human immunodeficiency virus, type 2; hepatitis B virus; hepatitis C virus; *treponema pallidum*; human T-lymphotropic virus, type I; human T-lymphotropic virus, type II; cytomegalovirus ("CMV"); chlamydia trachomatis; and neisseria gonorrhea. 21 C.F.R. § 1271.85(a)–(c).

[79] *Letter to Sponsors/Researchers – Human Cells Used in Therapy Involving the Transfer of Genetic Material by Means Other Than the Union of Gamete Nuclei*, U.S. FOOD & DRUG ADMIN.

2. FDA Regulation of Oocytes

The FDA has asserted its jurisdiction to control research involving oocyte nuclear transfer and a related procedure, ooplasmic transfer. In 1998, researchers used oocyte nuclear transfer by

> removing the nucleus from a woman's egg and injecting it into a donor's egg, from which the nucleus had already been removed. The technique was meant to help older women whose infertility was believed linked to problems with the cytoplasm of her own eggs. The reconstructed egg was then fertilized with the father's sperm and implanted in the patient's womb. (This is not cloning, because an adult cell is not involved, but the nuclear transfer process is the same.)[80]

The researchers "gave their findings to doctors in China because regulations imposed by the [FDA] in 2001 made it too difficult to continue the research in the United States."[81]

Ooplasmic transfer was developed by Dr. Jacques Cohen of the Saint Barnabas Medical Center in New Jersey. Rather than transferring the nuclei of the intended mother into the denucleated donor egg, as in oocyte nuclear transfer, the ooplasm (or cytoplasm) from the donor egg is "injected into the ooplasm of another woman whose embryos previously failed to develop."[82] As with oocyte nuclear transfer, a child born using ooplasmic transfer has genetic material from three sources: the donor egg, the intended mother's egg, and the sperm.[83]

In July 2001, the FDA sent a letter to the New Jersey researchers regarding the ooplasmic transfer which stated the following:

(May 6, 2009), http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm105852.htm.

80 HENRY C. LEE & FRANK TIRNADY, BLOOD EVIDENCE: HOW DNA IS REVOLUTIONIZING THE WAY WE SOLVE CRIMES 318 (2003).

81 Denise Grady, *Pregnancy Created Using Egg Nucleus of Infertile Woman*, N.Y. TIMES, Oct. 14, 2003, at A22, http://query.nytimes.com/gst/fullpage.html?res=980DE4D7113FF937A25753C1A9659C8B63&pagewanted=all.

82 Anne Drapkin Lyerly, *Marking the Fine Line: Ethics and the Regulation of Innovative Technologies in Human Reproduction*, 11 MINN. J. L. SCI. & TECH. 685, 701 (2010). For additional information on ooplasm transfer, see also, BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMM., DEP'T OF HEALTH & HUMAN SERVS., BRIEFING DOCUMENT FOR DAY 1, MAY 9, 2002, OOPLASM TRANSFER AS METHOD TO TREAT FEMALE INFERTILITY, [hereinafter BRMAC, BRIEFING DOCUMENT], *available at* http://www.fda.gov/OHRMS/DOCKETS/ac/02/briefing/3855B1_01.pdf.

83 Javitt & Hudson, *supra* note 10, at 1226; *see also* LEE & TIRNADY, *supra* note 80, at 318.

> We want to advise you that the Food and Drug Administration (FDA) has jurisdiction over human cells used in therapy involving the transfer of genetic material by means other than the union of gamete nuclei.
>
> Examples of such genetic material include, but are not limited to:
>
> - cell nuclei (e.g., for cloning),
> - oocyte nuclei,
> - ooplasm, which contains mitochondrial genetic material, and
> - genetic material contained in a genetic vector, transferred into gametes or other cells.
>
> The use of such genetically manipulated cells (and/or their derivatives) in humans constitutes a clinical investigation and requires submission of an Investigational New Drug application (IND) to FDA. We wish to inform you of the FDA regulatory process governing clinical investigations, which includes requirements applicable to manufacturing processes, the study of the safety and efficacy of such cells, and the protection of human participants in such studies. We can advise you whether or not your activities require submission of an IND. If what you are doing or plan to do does require an IND, we would be pleased to provide you with information and guidance regarding filing such an application.[84]

Would a synthetic gamete constitute the "use of such genetically manipulated cells (and/or their derivatives) in humans"? Arguably not. Synthetic sperm or ova would contain chemically created DNA, not human DNA, and thus would be outside of the banned procedures cited in the letter. The use of a synthetic gamete avoids the problem of "heteroplasmy," that is, the mixing of ooplasm, and specifically mitochondria, from more than one individual:

> According to the FDA, "it is clear that stringent mechanisms have evolved to insure homogeneity of

[84] *See Letter to Sponsors/Researchers*, *supra* note 79.

> mitochondrial genotypes at the initiation of human development. The FDA has concerns about the safety of perturbing this process." Moreover, ooplasm transfer "changes the genetic makeup of the resulting offspring. Appropriate follow-up of children born after ooplasm transfer and their progeny must therefore be considered carefully."[85]

A broader reading of the FDA's regulations on HCT/Ps, however, might apply to research on synthetic gametes. The regulations at 21 C.F.R. § 1271.10 include a list of requirements for Public Health Service Act section 361 products, including gametes and embryos, which are to be subject to less stringent regulation (with no FDA pre-market review) *if* the HCT/P is "minimally manipulated."[86] Combining sperm with ova through intracytoplasmic sperm injection ("ICSI"),[87] for example, has fallen into this category requiring no review. In our case, using ICSI to inject synthetic sperm into a human ovum could be within the reach of section 361; the same would be true for injecting human sperm into a synthetic ovum.

Several articles have urged the FDA to expand the scope of their review to include assisted reproduction, especially IVF, but so far to no avail.[88] If the FDA disagreed and chose to categorize the synthetic gametes under section 351 of the Public Health Service Act, then the research would be treated as an investigational new drug and subject to the same extensive testing as a new pharmaceutical. Section 351 products are those that do not meet the Section 1271.10 requirements and are regulated like drugs and/or biological products, requiring FDA pre-market review and approval. They represent more risk and include gene therapy products, human cloning, and human cells used in therapy involving the transfer of genetic material. The synthetic cell could fit into this more regulated category, although it generally refers to somatic (i.e., non-gamete) cell therapies like cloning and gene therapy that typically involve replacing defective genes. Still, the argument can be made that the stringent regulations that apply when DNA is being manipulated demonstrate a risk-based intent and should therefore apply where DNA is being manufactured.

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85 Javitt & Hudson, *supra* note 10, at 1227 (footnotes omitted) (quoting BRMAC, BRIEFING DOCUMENT, *supra* note 10, at 4).

86 21 C.F.R. § 1271.10(a)(1) (2010).

87 Intracytoplasmic sperm injection, developed in the 1990s, involves inserting a single sperm into an egg and then implanting the resulting embryo.

88 *See, e.g.*, Baruch, *supra* note 42, at 262–63; King, *supra* note 38, at 288–89; Malinowski, *supra* note 74, at 219–20.

3. State Regulation of Gametes

State legislation on gametes is concerned largely with the sale of sperm or eggs for valuable consideration, ensuring informed consent before donation, and resolving issues of property ownership of deposited gametes. New York, for example, broadly prohibits the sale of tissue for valuable consideration.[89] Other states specifically ban the sale of human gametes for certain purposes,[90] while Florida permits only "reasonable compensation" for donation.[91] Some states have enacted laws requiring informed consent before gametes can be donated to research,[92] and some criminalize use that is inconsistent with the gamete provider's purpose.[93] Finally, some states address issues of parentage[94] or the disposition of gametes in the event of death or divorce.[95]

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89 N.Y. PUB. HEALTH LAW § 4364(5) (McKinney 2002) ("No bank or storage facility shall sell or otherwise transfer tissue for valuable consideration. Valuable consideration shall not include reasonable costs associated with the procurement, processing, storage and distribution of tissue.").

90 *See* CAL. HEALTH & SAFETY CODE § 125350 (West Supp. 2010) (prohibiting the sale of human oocytes "for the purposes of medical research or development of medical therapies"); CONN. GEN. STAT. ANN. § 19a-32d(c)(3) (West Supp. 2010) ("A person who elects to donate for stem cell research purposes any . . . unfertilized human eggs or human sperm . . . shall not receive direct or indirect payment for such . . . unfertilized human eggs or human sperm."); IND. CODE ANN. § 35-46-5-3(a) (West Supp. 2010) (criminalizing the purchase or sale of human ova); LA. REV. STAT. ANN. § 9:122 (2008) (prohibiting the sale of human ova).

91 FLA. STAT. ANN. § 742.14 (West 2010) ("Only reasonable compensation directly related to the donation of eggs, sperm, and preembryos shall be permitted.").

92 *See, e.g.*, CAL. HEALTH & SAFETY CODE § 125335(a) ("Prior to obtaining informed consent from a subject for [assisted oocyte production ("AOP")] or any alternative method of ovarian retrieval on a subject for the purpose of procuring oocytes for research or the development of medical therapies, a physician and surgeon shall provide to the subject a standardized medically accurate written summary of health and consumer issues associated with AOP and any alternative methods of oocyte retrieval."); CONN. GEN. STAT. ANN. § 19a-32d(c)(3) ("A person who elects to donate for stem cell research purposes any . . . unfertilized human eggs or human sperm shall provide written consent for that donation . . . .").

93 CAL. PENAL CODE 367g(a) (West 2010) ("It shall be unlawful for anyone to knowingly use sperm, ova, or embryos in assisted reproduction technology, for any purpose other than that indicated by the sperm, ova, or embryo provider's signature on a written consent form.").

94 *See, e.g.*, TEX. FAM. CODE ANN. § 160.706(a) (West 2008) ("If a marriage is dissolved before the placement of eggs, sperm, or embryos, the former spouse is not a parent of the resulting child unless the former spouse consented in a record . . . ."); *Id.* § 160.707 ("If a spouse dies before the placement of eggs, sperm, or embryos, the deceased spouse is not a parent of the resulting child unless the deceased spouse consented in a record . . . .").

95 FLA. STAT. ANN. § 742.17 ("A commissioning couple and the treating physician shall enter into a written agreement that provides for the disposition of the commissioning couple's eggs, sperm, and preembryos in the event of a divorce, the death of a spouse, or any other unforeseen circumstance.").

None of these statutes would limit creating synthetic gametes as long as researchers did not violate laws on informed consent or valuable consideration for the human gametes analyzed for their DNA sequences. As is the case with embryos, the professional societies' limitations on buying and selling gametes are voluntary and thus would be applicable only in cases where a state has mandated compliance with a professional society's guidelines.[96] The parentage statutes, however, may apply to the successful use of a synthetic gamete, an issue to which we now turn.

IV. PARENTAGE AND INHERITANCE FOR CHILDREN WITH SYNTHETIC GAMETES

Assuming that the practical and regulatory problems are resolved, and a child is created using synthetic gametes, who are the parents? Traditional notions of "genetic parents" and "birth mothers"[97] may break down once we have the ability to create sperm or ova entirely from chemicals.

The 2008 Uniform Probate Code ("UPC") sections on assisted reproduction answer the parentage questions fairly easily because the UPC looks at intended parents rather than genetic parents. First, consider three scenarios with two intended parents, both alive:

1. *Synthetic sperm and the ovum of the birth mother*: UPC section 2-120 declares that the birth mother is the child's mother,[98] as do most state statutes. The key question is, who is the father? If the birth mother is married, then her husband is presumed to have consented to be the father, a presumption that can be rebutted by clear and convincing evidence.[99] If the birth mother is not married, then consent to assisted reproduction with the intent to be the parent of the resulting child can be shown by a signed record or functioning as a parent no later than two years after the child's birth.[100]

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96 2004 PRESIDENT'S COUNCIL REPORT, *supra* note 39, at 178; *see, e.g.*, *2008 Guidelines for Gamete and Embryo Donation*, *supra* note 72, at S30.

97 "Birth mother" is defined as "a woman, other than a gestational carrier under Section 2-121, who gives birth to a child of assisted reproduction. The term is not limited to a woman who is the child's genetic mother." UNIF. PROBATE CODE § 2-120(a)(1) (amended 2008), 8 U.L.A. 58 (Supp. 2010).

98 *Id.* § 2-120(c).

99 *Id.* § 2-120(h)(1).

100 *Id.* § 2-120(f)(1), (f)(2)(A).

2. *Synthetic sperm and donated human ovum where the intended mother gives birth*: The UPC treats this scenario the same as the first, because the UPC looks at the intended parents rather than the genetic parents. The ovum donor is not a parent, so she is out of the equation.[101] A parent-child relationship exists with the birth mother and may exist with the birth mother's husband or partner as in scenario one. The problem is the existing statutes in many states that have not been updated to include ova donations. Some states have statutes modeled after the 1973 Parentage Act that stipulate that a donor who gives sperm to a licensed physician for use by a married woman is not the father of the resulting child.[102] In one of these states, the ovum "donor" might still be able to claim she is the child's mother because her donation did not comply with the statutory language.[103]

3. *Human sperm and synthetic ovum where the intended mother gives birth*: There are no complications here. The birth mother is presumed to have a parent-child relationship, which is what the parties intend. For the father, if he is married to the birth mother, he is the father because his sperm was used during his lifetime,[104] so long as the couple did not divorce before placement (implantation) of the sperm, eggs, or embryos, and he did not withdraw his consent, in writing, before the placement.[105] If the birth mother is single, the other intended parent must show his consent through the means detailed in scenario one.

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101 *Id.* § 2-120(b).

102 *See, e.g.*, MINN. STAT. ANN. § 257.56(2) (West 2007); MO. ANN. STAT. § 210.824 (West 2010); MONT. CODE ANN. § 40-6-106 (2009); NEV. REV. STAT. ANN. § 126.061 (LexisNexis 2010); WISC. STAT. ANN. § 891.40 (West 1997 & Supp. 2010).

103 *See, e.g.,* Jhordan C. v. Mary K., 179 Cal. App. 3d 386, 393 (1986) (noting that the California statute is limited "to instances in which the semen is provided to a licensed physician.... Accordingly, [the California statute] by its terms does not apply to the present case" in which sperm was provided directly to the woman, and thus the sperm "donor" was the legal father). *Accord*, Turchyn v. Cornelius, 1999 Ohio App. LEXIS 4129 (1999).

104 UNIF. PROBATE CODE § 2-120(d).

105 *Id.* § 2-120(i), (j).

The next scenario involves the use of a gestational carrier and so the intended mother is *not* the birth mother. Under the UPC, the gestational carrier is not a parent of the resulting child unless a court so orders, or in cases where the gestational carrier is the genetic mother *and* no one else has a parent-child relationship.[106]

> 4. *Gestational carrier is birth mother with synthetic sperm and/or ovum:* Because of cases such as *In re Baby M*,[107] gestational carriers are rarely genetically related to the child; either the intended mother's ovum or a donated ovum is implanted. In several states, the birth mother is conclusively presumed to be the child's mother, which is not what the parties intend. Statutes in two states that conclusively presumed the gestational carrier to be the child's mother have been struck down as unconstitutional.[108] If the gestational carrier is not the mother, then the UPC would treat the intended parents as the legal parents of the child, as in our previous scenarios.

Finally, we must consider the parentage issues if either the implantation of the embryo containing a synthetic gamete, or the gestational agreement concerning such an embryo, has occurred after one or both of the intended parents has died, commonly called postmortem conception ("PMC").

PMC is the subject of numerous court cases, statutes, and newspaper articles. Courts in at least nine jurisdictions have adjudicated cases

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106 *Id.* § 2-121(c).

107 *In re* Baby M., 537 A. 2d 1227 (1988) (surrogate Mary Beth Whitehead was also the genetic mother, *Id. at* 1234; New Jersey Supreme Court declared surrogate was the mother of the resulting child, *Id.* at 1234). *C.f.* Johnson v. Calvert, 851 P. 2d 776 (Cal. 1993) (surrogate was not the child's genetic mother, *Id. at* 778; court noted that "although the [Uniform Parentage] Act recognizes both genetic consanguinity and giving birth as means of establishing a mother and child relationship, when the two means do not coincide in one woman, she who intended to procreate the child--that is, she who intended to bring about the birth of a child that she intended to raise as her own--is the natural mother under California law. *Id.* at 782.

108 *See* J.R. v. Utah, 261 F. Supp. 2d 1268, 1289 (D. Utah 2002); Soos v. Superior Court of the State of Ariz., 897 P.2d 1356, 1361 (Ariz. Ct. App. 1994) (holding that the surrogate statute violated the Equal Protection Clause). In a third state, the court avoided the constitutional problem by extending its paternity statute to allow a gestational carrier to deny maternity. *In re* Roberto d.B., 923 A.2d 115, 124 (Md. 2007).

involving PMC children.[109] Several states have enacted statutes requiring written consent to be a parent of a PMC child;[110] two states have statutes that eliminate some or all claims of a PMC child.[111] If the decedent's gametic material is used to conceive the child, the usual issues of parentage and inheritance of a PMC child will come into play. The added complexity here occurs when the decedent is *not* the genetic parent. The consent issues can be analogized to a decedent's consent for assisted reproduction in which donated gametes are used, because in either case, synthetic gamete or donated gamete, the decedent has no biological tie to the child. The UPC provides that, in cases where no gestational carrier is used, the decedent's intent to be a parent can be shown by a signed record or by clear and convincing evidence of such intent.[112] If the birth mother is the decedent's surviving spouse and no divorce proceedings were pending at the time of the decedent's death, then the decedent is presumed to have consented to be a parent of the PMC child.[113] However, if a gestational carrier is used, UPC section 2-

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[109] Courts in New Jersey, Massachusetts, Arizona, and New York have held that state law allows a decedent to be named the parent of a PMC child if certain conditions are met. *See* Gillett-Netting v. Barnhart, 371 F.3d 593, 599 (9th Cir. 2004); Woodward v. Comm'r of Soc. Sec., 760 N.E.2d 257, 272 (Mass. 2002); *In re* Estate of Kolacy, 753 A.2d 1257, 1263-64 (N.J. Super. Ct. Ch. Div. 2000); *In re* Martin B., 841 N.Y.S. 2d 207, 211 (N.Y. Sur. Ct. 2007). Courts interpreting the state law of California, Arkansas, New Hampshire California and Virginia have held that a PMC child cannot inherit from a decedent. Vernoff v. Astrue, 568 F.3d 1102, 1112 (9th Cir. 2009); Finley v. Astrue, 270 S.W.3d 849, 850 (Ark. 2008); Khabbaz v. Comm'r of Soc. Sec., 930 A.2d 1180, 1182 (N.H. 2007); Schafer v. Astrue, 2011 U.S. App. LEXIS 7456 at 9 (4th Cir. 2011). Florida law states that a PMC child inherits only if provided for in the decedent's will, and one court has ruled that absent such testamentary provision a PMC child cannot inherit in intestacy and thus is ineligible for Social Security survivor benefits. Stephen v. Comm'r of Soc. Sec., 386 F. Supp. 2d 1257, 1265 (M.D. Fla. 2005); *c.f.* Capato v. Comm'r of Soc. Sec., 631 F.3d 626, 632 (3rd Cir. 2011) (PMC child who is undisputed biological child of decedent is his child for purposes of Social Security Act, notwithstanding Florida law).

[110] *See* ALA. CODE § 26-17-707 (LexisNexis 2009); CAL. PROB. CODE § 249.5 (West Supp. 2011); COLO. REV. STAT. ANN. § 19-4-106(8) (West 2005 & Supp. 2010); DEL. CODE ANN. tit. 13, § 8-707 (2009); FLA. STAT. ANN. § 742.17(4) (West 2010); LA. REV. STAT. ANN. § 9:391.1(A) (2008); N.M. STAT. ANN. § 40-11A-707 (LexisNexis Supp. 2010); N.D. CENT. CODE § 14-20-65 (2009); TEX. FAM. CODE ANN. § 160.707 (West 2008); UTAH CODE ANN. § 78B-15-707 (LexisNexis 2008); WASH. REV. CODE ANN. § 26.26.730 (West 2005); WYO. STAT. ANN. § 14-2-907 (2009).

[111] *See* N.Y. EST. POWERS & TRUSTS LAW § 5-3.2(b) (McKinney 1999 & Supp. 2011) (noting that a PMC child has no claim as a pretermitted heir, but may take in other circumstances); VA. CODE ANN. § 20-164 (2008) (stating that any child born more than ten months after the death of a parent is not recognized as the child of that parent and thus cannot inherit in intestacy or by will).

[112] UNIF. PROBATE CODE § 2-120(f).

[113] *Id.* § 2-120(h)(2).

121 requires that the decedent's sperm or eggs be used, and thus the decedent would *not* be a parent of the PMC child. [114]

The UPC, if enacted, would resolve the question of parenthood in favor of the intended parents, but to date only two states have enacted the UPC section on assisted reproduction.[115] Many states have not updated their statutes to address the donation of ova; others refuse to enforce gestational carrier agreements. In these states, the lack of a genetic parent due to the use of synthetic gametes may create problems for courts. Similarly, these states may declare the gestational carrier to be the mother of the child regardless of her genetic connection to the child.

V. CONCLUSION

In a paper published in 1971, seven years before he and a colleague successfully used in vitro fertilization for the first time to create a human child, Dr. Edwards warned of the possibility of the rise of gestational surrogacy, egg banks, gene splicing, sexing blastocysts, and artificial wombs.[116] We have yet to address all of Dr. Edwards' concerns over thirty years after Louise Brown was born in 1978. Now that Venter's announcement has opened the door to synthetic gametes, it is time to start thinking about both regulatory issues and parentage issues for synthetic sperm, ova, and embryos. Should existing regulations of gametes and embryos be updated to include those created chemically? We have at least three choices: we can allow researchers to proceed in the same manner as PGD and other techniques used in assisted reproduction with little regulation or oversight; we can analogize to oocyte transfer or cloning and stop all research until the safety issues have been resolved; or we can allow research with more oversight.

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[114] By the time we have successfully manufactured synthetic gametes, we may have also perfected an artificial womb and as a result have no need for a gestational carrier. *See* Gretchen Reynolds, *Artificial Wombs: Will We Grow Babies Outside Their Mothers' Bodies?*, POPULAR SCI. (Aug. 1, 2005, 2:00 pm), http://www.popsci.com/scitech/article/2005-08/artificial-wombs (quoting Hung-Ching Liu, the director of the Reproductive Endocrine Laboratory at the Center for Reproductive Medicine and Infertility at Cornell University, who said that an artificial human womb may be available in "'10 years, maybe, or a little more . . . . It could take as much as 50 years, but I'm very hopeful that this is possible.'").

[115] Uniform Probate Code § 2-120 (child conceived by assisted reproduction other than child born to gestational carrier) has been adopted in three states: Colorado, Minnesota and North Dakota. COLO. REV. STAT. 15-11-120; MINN. STAT. ANN. 524.2-120 (Subd. 7); N.D. CENT. CODE 30.1-04-19. Uniform Probate Code § 2-121 (child born to gestational carrier) has been adopted in Colorado and North Dakota. COLO. REV. STAT. 15-11-121; N.D. CENT. CODE 30.1-04-20.

[116] Robert G. Edwards & David J. Sharpe, *Social Values and Research in Human Embryology*, 231 NATURE 87, 87–91 (1971).

Choosing the first path may bring technologies into the marketplace before they are fully tested.[117] If we choose the second path, it is difficult to foresee how the safety concerns will be addressed. The traditional way is to do research on animals, but experience has shown us that humans do not react in precisely the same way as animals, and the outcomes can be unpredictable.[118] Scholarly discussion urging more regulation and oversight of ART could be applied to the issue of synthetic gametes to determine the appropriate level of oversight.[119]

There is a second critical issue: once a synthetic gamete has been created and used to create a living child, who are the child's parents? Should we move to a regime of intended parents for synthetic reproduction, as the UPC has already urged for children of assisted reproduction? Such a move would require a fundamental shift in the way states approach parentage, away from biological and genetic markers and toward intent (or consent) to be a parent of the resulting child. For reasons of public policy, consent to be a parent is presumed when one engages in coitus. Even if the child was conceived under criminal or fraudulent circumstances (for example, a false promise of infertility), the progenitors are still the parents of the resulting child.

In contrast, when a child is conceived using assisted reproduction, the public policy considerations are quite different, and consent (or

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[117] *See, e.g.*, Anne Adams Lang, *Doctors Are Second-Guessing The 'Miracle' of Multiple Births*, N.Y. TIMES, June 13, 1999, www.nytimes.com/1999/06/13/health/doctors-are-second-guessing-the-miracle-of-multiple-births.html?src=pm (noting that the incidence of multiple births has quadrupled since the mid-1980s, largely because of the use of ART, and that almost all are born premature with various physical problems and a highly increased mortality rate); Peres, *supra* note 32, at C1 (describing lawsuit against a medical center that claimed it could screen a woman's eggs for the genes that carry cystic fibrosis using PGD where the resulting child had cystic fibrosis); Gladys B. White, *A Devil's Bargain for the Infertile: Fertility Treatments Are Causing More Multiple Births, Leading To Risks to Mothers and Newborns*, CHI. TRIB., June 24, 2007, at C9 (stating the same).

[118] *See, e.g.*, Daniel G. Hackam & Donald A. Redelmeier, *Translation of Research Evidence From Animals to Humans*, 296 J. AM. MED. ASS'N 1731, 1732 (2006) ("Only about a third of highly cited animal research translated at the level of human randomized trials."). Trisha Gura states that

> many thousands of drugs have shown activity in either cell or animal models, but only 39 that are used exclusively for chemotherapy, as opposed to supportive care, have won approval from the U.S. Food and Drug Administration. "The fundamental problem in drug discovery for cancer is that the model systems are not predictive at all."

Trisha Gura, *Systems for Identifying New Drugs Are Often Faulty*, 278 SCI. 1041, 1041 (1997) (quoting Alan Oliff, the former executive director for cancer research at Merck Research Laboratories).

[119] *See, e.g.*, Baruch, *supra* note 42, at 267–70; King, *supra* note 38, at 288–89; Malinowski, *supra* note 72, at 197–222.

rather, *intent*) to be the parent needs to be established. In many instances involving assisted reproduction, the biological parent does not intend to be the parent of the child. Whenever donor sperm, ova, or embryos are used in assisted reproduction, the donor has usually agreed not to seek parentage rights in a resulting child. Similarly, with gestational carrier agreements, while the carrier is biologically connected to the child as the birth mother, she has usually agreed she will not claim to be the resulting child's mother (although her agreement may not be enforceable in all states). In addressing assisted reproduction with donor gametes or gestational carriers, the UPC attempts to determine the parents where too many possibilities abound; one California case identified six different possible parents of the resulting child.[120] With synthetic gametes, the problem may instead be too few possible human parents because at least one genetic parent will be out of the equation.

The two UPC sections on assisted reproduction have been adopted in only two states despite being promulgated in 2008.[121] Although some states may have hesitated because they do not enforce gestational carrier arrangements, this does not explain why they have failed to address the use of assisted reproduction in other ways, such as with donor gametes. As we move toward the possibility of synthetic gametes, the debate over genetic and biological parents versus intended parents will demand resolution.

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[120] Buzzanca v. Buzzanca, 72 Cal. Rptr. 2d. 280, 282-88 (gestational carrier and her husband, egg donor, sperm donor, and the genetically unrelated intended parents) (Cal. Ct. App. 1998).

[121] *Supra* note 115.