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BY KERRY LYNN MACINTOSH*

INTRODUCTION

All human beings have mitochondria within their cells that produce energy.[1] Most of us inherit healthy mitochondria through the eggs of our mothers,[2] but some of us are not so lucky. Mutations in mitochondrial DNA (mtDNA) can cause these tiny organelles to function improperly and disrupt tissues that require a lot of energy, like the brain, kidney, liver, heart, muscle, and central nervous system.[3] For example, a specific mtDNA mutation induces Leigh syndrome, a condition in which seizures and respiratory failure lead to decline in mental and motor skills, disability, and death.[4]

Mitochondrial replacement therapy (MRT) offers a solution to this problem. It replaces dysfunctional mitochondria with normal mitochondria in human eggs or embryos in order to produce a healthy child.[5] A female child will transmit normal mitochondria through her eggs to her descendants, who will also be free of disease.[6] In the United Kingdom, the Human Fertilisation and Embryology Authority (HFEA) has already

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1. Paula Amato et al., *Three-parent In Vitro Fertilization: Gene Replacement for the Prevention of Inherited Mitochondrial Diseases*, 101 FERTILITY & STERILITY 31, 31 (2014).

2. Jackie Leach Scully, *A Mitochondrial Story: Mitochondrial Replacement, Identity and Narrative*, 31 BIOETHICS 37, 37 (2017). Rarely, fathers can also transmit mitochondria to offspring via a molecular mechanism that remains unclear. Shiyu Luo et al., *Biparental Inheritance of Mitochondrial DNA in Humans*, 115 PNAS 13039 (2018).

3. Amato et al., *supra* note 1.

4. Luo et al., *supra* note 2.

5. Amato et al., *supra* note 1, at 32; Scully, *supra* note 2. Methods are discussed in Part I.B.

6. Amato et al., *supra* note 1, at 32.

granted fourteen applications to perform MRT on patients.[7] Unfortunately, American women who carry mitochondrial disease and wish to save their children from sickness and death are unable to access MRT because the law currently stands in their way.[8]

The U.S. Congress has placed a federal moratorium on heritable germline modification,[9] including MRT.[10] Some observers argue that MRT should be exempt from the federal moratorium because it does not actually alter the nuclear genome.[11] However, even if the U.S. Congress were to heed this advice, and the U.S. Food and Drug Administration (FDA) were to authorize clinical trials, another serious legal roadblock looms on the horizon because many prolife advocates claim that MRT is a form of human cloning.[12]

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7. Emily Mullin, *Patient Advocates and Scientists Launch Push to Lift Ban on "Three-parent IVF"*, STAT (Apr. 16, 2019), https://www.statnews.com/2019/04/16/mitochondrial-replacement-three-parent-ivf-ban/ [hereinafter Mullin, *Patient Advocates*].

8. *See id.* (citing an estimate by the United Mitochondrial Disease Foundation that a dozen women per year would be interested and eligible to undergo MRT).

9. Since 2016, the U.S. Congress has tacked a rider onto the annual appropriations legislation for the U.S. Department of Health and Human Services (DHHS). The rider prevents the FDA from acknowledging receipt of applications to conduct clinical trials of heritable germline modification in humans. By tying the hands of the responsible federal agency, the rider places such clinical trials out of reach. KERRY L. MACINTOSH, *The Regulation of Human Germline Genome Modification in the United States,* in HUMAN GERMLINE GENOME MODIFICATION AND THE RIGHT TO SCIENCE: A COMPARATIVE STUDY OF NATIONAL LAWS AND POLICIES 110–11 (Andrea Boggio, Cesare P.R. Romano, & Jessica Almqvist eds., 2019); Andrea Boggio et al., *The Human Right to Science and the Regulation of Human Germline Engineering*, 2 CRISPR J. 134, 138 (2019). Congress has enacted the same rider for the past four years. Consolidated Appropriations Act, 2016, 114 Pub. L. No. 113, Div. A, tit. 7, § 749, 129 Stat. 2242, 2283 (2015); Consolidated Appropriations Act, 2017, 115 Pub. L. No. 31, Div. A, tit. 7, § 736, 131 Stat. 135, 173 (2017); Consolidated Appropriations Act of 2018, 115 Pub. L. No. 141, tit. 7, § 734, 132 Stat. 348, 389 (2018); Consolidated Appropriations Act of 2019, 116 Pub. L. No. 6, tit. 6, § 731, 133 Stat. 13, 81 (2019). Most recently, the House of Representatives defeated an attempt to remove the rider from the 2020 appropriations bill. Jocelyn Kaiser, *Update: House Spending Panel Restores U.S. Ban on Gene-edited Babies*, SCIENCE (June 4, 2019, 1:45 PM), https://www.sciencemag.org/news/2019/06/update-house-spending-panel-restores-us-ban-gene-edited-babies.

10. The FDA believes that MRT falls within the scope of the rider and cannot be performed legally in the United States. *Advisory on Legal Restrictions on the Use of Mitochondrial Replacement Techniques to Introduce Donor Mitochondria into Reproductive Cells Intended for Transfer into a Human Recipient*, U.S. FOOD AND DRUG ADMIN. (Mar. 16, 2018), https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/advisory-legal-restrictions-use-mitochondrial-replacement-techniques-introduce-donor-mitochondria?source=govdelivery [hereinafter *Advisory on Legal Restrictions on the Use of Mitochondrial Replacement Techniques*].

11. Eli Y. Adashi et al., *In Support of Mitochondrial Replacement Therapy*, 25 NATURE MED. 870, 870 (June 3, 2019), https://doi.org/10.1038/s41591-019-0477-4; Eli Y. Adashi & I. Glenn Cohen, *Preventing Mitochondrial Disease: A Path Forward*, 131 OBSTETRICS & GYNECOLOGY 553, 553–54 (2018).

12. For example, David Prentice, the vice-president of the prolife group, Charlotte Lozier Institute, claims that MRT is a form of human cloning because it involves nuclear transfer. Mullin, *Patient Advocates*, *supra* note 7. Similarly, Arina Grossu, who directs the Center for Human

Do state laws banning human cloning pose a legal risk to scientists who conduct MRT research and/or medical providers and patients who use MRT to produce children? This article seeks to answer that question. Part I describes and compares human cloning and MRT methods in biological terms. Part II reviews state laws that prohibit human cloning. Part III analyzes these laws in more detail and discusses whether they are applicable to common MRT methods. Finally, Part IV concludes that states should amend their anti-cloning laws to exclude MRT methods.

I. BACKGROUND

This Part begins by explaining how scientists clone animals and human embryos. Next, it describes two common MRT methods: maternal spindle transfer and pronuclear transfer. Last, it compares human cloning with these MRT methods and ultimately finds that while they are supported by different goals, they have very similar processes.

A. The Science of Cloning

Ordinarily, an animal reproduces through sexual reproduction, wherein a sperm and an egg combine to produce an embryo capable of developing into a member of the animal's species.[13] When born, an animal carries nuclear DNA inherited from both of its parents and mtDNA inherited from its mother.[14]

Cloning, however, is a form of asexual reproduction. The experiment that created Dolly the sheep offers one example of how cloning works. That experiment began after a sheep of the Finn Dorset breed died, leaving behind stored mammary tissue.[15] This tissue was composed of somatic cells, a biological term that refers to cells other than germ cells, germ cell precursors, or stem cells.[16] Each somatic cell had a nucleus which stored the chromosomes of the dead sheep.[17] Ian Wilmut and his associates accessed the stored tissue, culled donor cells from it, and

Dignity at the Family Research Council in Washington, D.C., states that certain MRT methods, including pronuclear transfer, involve human cloning. Arina O. Grossu, *Three-Parent Embryo Creation*, 40 ETHICS & MEDICS 1, 2 (2015).

13. HENRY T. GREELY, THE END OF SEX AND THE FUTURE OF HUMAN REPRODUCTION 28–29 (2016).

14. KERRY LYNN MACINTOSH, HUMAN CLONING: FOUR FALLACIES AND THEIR LEGAL CONSEQUENCES 28 (2013) [hereinafter MACINTOSH, HUMAN CLONING].

15. IAN WILMUT & ROGER HIGHFIELD, AFTER DOLLY: THE USES AND MISUSES OF HUMAN CLONING 114 (2006).

16. *Somatic cells*, BIOLOGY-ONLINE DICTIONARY, https://www.biology-online.org/dictionary/Somatic_cells (last visited June 22, 2008).

17. MACINTOSH, HUMAN CLONING, *supra* note 14, at 1.

starved the cells into a dormant state.[18] They also obtained donor eggs from other sheep and removed the chromosomes in a process known as enucleation.[19] They injected one donor cell into each egg and used electricity to fuse the pair and nudge them into becoming embryos.[20] Of the two hundred seventy-seven fused products, twenty-nine successfully became embryos and were transferred to a surrogate sheep of the Scottish Blackface breed.[21] One sheep became pregnant and delivered Dolly, a healthy lamb.[22]

Dolly carried the nuclear DNA of her Finn Dorset cell donor.[23] Thus, an observer might conclude she had only one genetic parent, but that conclusion would be incorrect. Dolly also received mtDNA from the Scottish Blackface sheep that donated the egg for the cloning procedure and thus she was not entirely genetically identical to her Finn Dorset predecessor.[24]

Since Dolly was born, scientists have cloned animals using a variety of cloning techniques.[25] Some have fused entire donor cells to eggs, while others have removed and injected the nuclei from donor cells into eggs.[26] Scientists may accomplish activation through chemical agents rather than electricity.[27] Regardless of technique, most embryos created through cloning do not come to term.[28] However, once born, animal clones can mature into healthy and ordinary members of their species.[29] Moreover, thanks to genetic mutations in the donor cell, epigenetic variation, and environmental influences, animal clones have their own unique physical attributes and personalities.[30] Contrary to popular belief, they are not copies of their cell donors.

18. *See* WILMUT & HIGHFIELD, *supra* note 15, at 112–16 (describing the selection of tissue and culturing of donor cells).

19. *See id.* at 107–13 (detailing the process of retrieving sheep eggs and removing chromosomes from them). In fact, the eggs used for cloning are at a point in their development where the nuclear membrane has dissolved and the chromosomes float free, so the term "enucleation" is an approximation. *Id.* at 95.

20. *See id.* at 116–19 (discussing the fusion and activation process).

21. *Id.* at 124.

22. *Id.* at 124–25.

23. *Id.* at 243.

24. *Id.* at 243–45.

25. *See* MACINTOSH, HUMAN CLONING, *supra* note 14, at 9–15 (surveying experimental elements and techniques).

26. *Id.* at 11.

27. *Id.*

28. *See id.* at 9–15 (discussing efficiency of animal cloning).

29. *See id.* at 19–24 (discussing experiments that produced healthy animal clones).

30. *See id.* at 33–37 (describing experiments that produced unique animal clones).

Turning to human beings, scientists have cloned blastocysts—that is, embryos that are five to six days old[31]—and derived stem cell lines from them.[32] However, such research is controversial. Some critics believe human life begins at conception and consider research that harms or kills human embryos to be immoral,[33] even if those embryos are clones.[34]

Scientists have not yet cloned human babies.[35] Even so, human embryos implant in the uterus at the blastocyst stage,[36] so the successful cloning of human blastocysts suggests that births may be just a uterine transfer away.[37] Like Dolly, a human child born through cloning will inherit her nuclear DNA from her somatic cell donor, and her mtDNA from her egg donor.[38]

B. The Science of MRT

MRT can be performed in various ways, but this article focuses on maternal spindle transfer and pronuclear transfer, the two most-studied methods.[39] In both methods, three adults must contribute gametes. A man (the partner) must contribute sperm to fertilize eggs. A woman with dysfunctional mitochondria (the patient) must contribute eggs containing her nuclear DNA. Lastly, a woman with healthy mitochondria must donate

31. SHERMAN J. SILBER, HOW TO GET PREGNANT 25 (2007).

32. *See* Masahito Tachibana et al., *Human Embryonic Stem Cells Derived by Somatic Cell Nuclear Transfer*, 153 CELL 1228, 1230–31 (2013). Such lines inherit healthy mitochondria from the donor eggs used in the procedure and may provide cell therapies for patients with mitochondrial disease. *Id.* at 1236.

33. *See e.g.*, Congregation for the Doctrine of the Faith, *Instruction Dignitas Personae on Certain Bioethical Questions*, VATICAN CITY ¶ 32 (Sep. 8, 2008), http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html (decreeing that stem cell derivation that kills an embryo is illicit).

34. *See id.* at 30 (stating that cloning embryos to produce stem cells to heal the sick is immoral); PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY 152–54, 157–58 (1st ed. 2002) (explaining why some members of the Council opposed cloning for biomedical research).

35. *See* KERRY LYNN MACINTOSH, ILLEGAL BEINGS: HUMAN CLONES AND THE LAW 127 (2005) [hereinafter MACINTOSH, ILLEGAL BEINGS] (explaining that most people have concluded that the Raelian claim to have cloned a human baby was a hoax).

36. SILBER, *supra* note 31.

37. MACINTOSH, HUMAN CLONING, *supra* note 14, at 47.

38. *Id.* at 47–50.

39. Lyndsey Craven et al., *Novel Reproductive Technologies to Prevent Mitochondrial Disease*, 23 HUM. REPROD. UPDATE 501, 505 (2017). Potentially, MRT could also be accomplished through germinal vesicle nuclear transfer (transfer of an immature egg nucleus into an enucleated donor egg followed by maturation and fertilization of the reconstructed egg) or polar body transfer (transfer of the first polar body of an egg into an enucleated donor egg followed by fertilization of the reconstructed egg). *Id.* at 509–10.

her eggs (the egg donor). Observers often describe MRT as "three-parent in vitro fertilization"[40] or "three-parent IVF."[41]

1. Maternal Spindle Transfer

Suppose a patient generates eggs with dysfunctional mitochondria. Each egg has a maternal spindle—that is, a cellular structure to which chromosomes are attached.[42] To perform maternal spindle transfer, a technician takes the spindle out of that egg.[43] He inserts the spindle into an enucleated donor egg which has cytoplasm and healthy mitochondria but no spindle or chromosomes.[44] He then fuses the transferred spindle to the donor egg with electricity or an inactivated virus.[45] Sperm from the patient's partner is used to fertilize the reconstructed egg.[46] If the fertilization results in an embryo, the embryo can be transferred to the patient for gestation. A child born through this process inherits nuclear DNA from the patient and her partner and healthy mitochondria from the egg donor.[47] The child also gets some of the patient's mitochondria along with the spindle, but hopefully too few to cause disease.[48]

Dr. John Zhang was the first to successfully use maternal spindle transfer to avoid mitochondrial disease, but he transferred the embryo to his patient in Mexico to circumvent FDA regulation.[49] After a healthy baby boy was born in 2016,[50] Dr. Zhang requested a meeting with the FDA to discuss the prospect of clinical trials of MRT in the United States.[51] The Center for Biologics Evaluation and Research (CBER), a

40. Amato et al., *supra* note 1.

41. Mullin, *Patient Advocates*, *supra* note 7.

42. Craven et al., *supra* note 39, at 511.

43. *Id*.

44. *Id*. at 507.

45. Lynsey Cree & Pasqualino Loi, *Mitochondrial Replacement: from Basic Research to Assisted Reproductive Technology Portfolio Tool—Technicalities and Possible Risks*, 21 MOLECULAR HUM. REPROD. 3, 6 (2015).

46. Craven et al., *supra* note 39, at 507.

47. Amato et al., *supra* note 1, at 32.

48. *Id.* at 32–33.

49. Mullin, *Patient Advocates*, *supra* note 7. *See* John Zhang et al., *Live Birth Derived from Oocyte Spindle Transfer to Prevent Mitochondrial Disease*, 34 REPROD. BIOMEDICINE ONLINE 361 (2017).

50. Jessica Hamzelou, *Exclusive: World's First Baby Born with New "3 Parent" Technique*, NEW SCIENTIST, Sept. 27, 2016, https://www.newscientist.com/article/2107219-exclusive-worlds-first-baby-born-with-new-3-parent-technique.

51. Emily Mullin, *Pregnancy Reported in the First Known Trial of "Three-person IVF" for Infertility*, STAT (Jan. 24, 2019), https://www.statnews.com/2019/01/24/first-trial-of-three-person-ivf-for-infertility/ [hereinafter Mullin, *Pregnancy Reported*]; Letter from Mary A. Malarkey, Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, to John Zhang, Chief Executive Officer, Darwin Life, Inc. and New Hope Fertility Center

subunit of the FDA, sent him a letter declining to meet due to the federal moratorium referenced in the introduction.[52] The CBER castigated him for marketing MRT online without a license, claimed he had violated federal law by exporting the embryo to Mexico without a license, and asked him to identify steps he would take to avoid further violations.[53] Thus, until the moratorium is eliminated and the FDA approves clinical trials, Americans who are carriers of mitochondrial disease must travel to a foreign country and undergo the entire maternal spindle transfer procedure there.

Maternal spindle transfer may also be able to help infertile women who have suboptimal mitochondria.[54] In 2019, a Greek woman who had failed at IVF four times due to poor egg quality underwent maternal spindle transfer and gave birth to a healthy baby.[55] If maternal spindle transfer can help infertile women, demand for it will increase.

2. Pronuclear Transfer

Pronuclear transfer is an alternative process. To illustrate, suppose a patient generates eggs which carry dysfunctional mitochondria. Her eggs are retrieved and fertilized with sperm from her partner. Each fertilized egg contains a female pronucleus (from the egg) and a male pronucleus (from the sperm).[56] Each pronucleus holds twenty-three chromosomes and a small amount of cytoplasm within a membrane.[57] Jointly, the two pronuclei contain the forty-six chromosomes needed for the proper development of a human being.[58]

A technician removes the two pronuclei from the patient's fertilized egg and transfers them into a fertilized donor egg from which the pronuclei have been removed.[59] Then, the technician fuses the transplanted pronuclei to the donor egg with electricity or an inactivated virus.[60] If this

(Aug. 4, 2017), https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/Enforcement/UntitledLetters/UCM570225.pdf.

52. Letter from Mary A. Malarkey to John Zhang, *supra* note 51.

53. *Id.*

54. Mullin, *Pregnancy Reported, supra* note 51.

55. Catherine Heffner, *First Baby Born in Mitochondrial Donation for Infertility Trial*, BIONEWS (Apr. 15, 2019), https://www.bionews.org.uk/page_142476; Helen Thomson, *First 3-parent Baby Born in Clinical Trial to Treat Infertility*, NEW SCIENTIST (Apr. 11, 2019), https://www.newscientist.com/article/2199441-first-3-parent-baby-born-in-clinical-trial-to-treat-infertility.

56. Cree & Loi, *supra* note 45.

57. Craven et al., *supra* note 39, at 506–07.

58. A human being has forty-six chromosomes arrayed in twenty-three pairs. *See* SILBER, *supra* note 31, at 291.

59. Craven et al., *supra* note 39, at 506 fig.3(A).

60. Cree & Loi, *supra* note 45.

process results in an embryo, the embryo can be transferred to the woman's uterus for gestation. A child born through this process inherits nuclear DNA from the patient and her male partner and healthy mitochondria from the egg donor.[61] The child also receives some mitochondria that carry mutations via the cytoplasm harbored within the patient's pronucleus, but the percentage will likely be too low to cause disease.[62]

In the United Kingdom, both pronuclear transfer and maternal spindle transfer are permitted to avoid transmitting mitochondrial disease. However, only the Newcastle Fertility Centre at Life is currently licensed to provide these services, and it must first obtain HFEA permission for each case.[63] In Ukraine, a fertility clinic has employed pronuclear transfer to help several infertile women have babies.[64] Again, if these procedures can help infertile women, demand for them will increase.

C. Comparison

As the foregoing discussion shows, maternal spindle transfer and pronuclear transfer use different processes. Thus, this article compares each method to human cloning separately.

1. Maternal Spindle Transfer

As Part I.A explained, the key step in creation of a cloned human embryo is the transfer of a somatic cell, or its nucleus, into an unfertilized, enucleated egg. If that embryo is transferred to a woman for gestation, it may develop into a baby who has the same forty-six chromosomes as the somatic cell donor. The baby inherits mtDNA from the egg donor. Significantly, this process does not require any sperm; thus, cloning is asexual reproduction.

By contrast, maternal spindle transfer is a technology that facilitates sexual reproduction. The patient's unfertilized egg cell has a spindle with forty-six chromosomes attached. Transferring that spindle into an enucleated donor egg yields a reconstructed egg that cannot become an embryo on its own. The patient's male partner must contribute a spermatozoon to fertilize the reconstructed egg, whereupon the egg extrudes half of its chromosomes as a polar body, leaving it with only twenty-three

61. Amato et al., *supra* note 1, at 32.

62. *Id.* at 33.

63. Human Fertilisation and Embryology Authority, *Mitochondrial Donation Treatment*, HUM. FERTILISATION & EMBRYOLOGY AUTH., https://www.hfea.gov.uk/treatments/embryo-testing-and-treatments-for-disease/mitochondrial-donation-treatment (last updated Feb. 13, 2021).

64. Rob Stein, *Clinic Claims Success in Making Babies with 3 Parents" DNA*, NPR (June 6, 2018, 5:11 AM), https://www.npr.org/sections/health-shots/2018/06/06/615909572/inside-the-ukrainian-clinic-making-3-parent-babies-for-women-who-are-infertile.

chromosomes.[65] The spermatozoon provides the other twenty-three chromosomes necessary to create an embryo. If the embryo is transferred to the patient for gestation, it may develop into a baby with a nuclear genome that has never existed before. Again, the baby inherits mtDNA from the egg donor.

Despite this distinction between asexual and sexual reproduction, human cloning and maternal spindle transfer have features in common: both procedures transfer nuclear material from one cell to another; both depend on an egg donor who contributes mtDNA; and neither destroy a human embryo (see table 1a). These technologies sacrifice somatic cells and unfertilized eggs, but those items are not potential human life in and of themselves. In fact, the woman in Dr. Zhang's experiment selected maternal spindle transfer over pronuclear transfer because she did not want to kill an embryo.[66]

Table 1a: Human cloning compared with maternal spindle transfer

Human Cloning	**Maternal Spindle Transfer**
Asexual Reproduction	Sexual Reproduction
One man or one woman contributes nuclear DNA	One man and one woman contribute nuclear DNA
Egg donor contributes mtDNA	Egg donor contributes mtDNA
No sperm required	Sperm required
Human embryos not destroyed	Human embryos not destroyed

2. Pronuclear Transfer

Pronuclear transfer begins with sexual reproduction: the patient's egg and the donor egg are fertilized with sperm. Next, two pronuclei that jointly contain forty-six chromosomes are transferred from the patient's fertilized egg into a fertilized donor egg from which the pronuclei have been removed. If an embryo results and is transferred to the patient for gestation, it may develop into a baby which will have the same nuclear genome as the original fertilized egg. The baby inherits mtDNA from the egg donor.

Pronuclear transfer resembles human cloning in its second step: the shift of chromosomes from one fertilized egg to another is an asexual

65. SILBER, *supra* note 31, at 23–24.
66. Zhang et al., *supra* note 49, at 363.

process, and it creates an entity that can become a baby (see table 1b). Indeed, some prolife advocates see little distinction between pronuclear transfer and human cloning. In their view, the patient's fertilized egg, an individual worthy of respect, is destroyed in the cloning process, along with the individual who was once embodied in the fertilized donor egg.[67] Reproductive cloning seems merciful by contrast, because it does not destroy fertilized eggs or embryos capable of becoming a baby.

Table 1b: Human cloning compared with pronuclear transfer

Human Cloning	**Pronuclear Transfer**
Asexual Reproduction	Sexual and Asexual Reproduction
One man or one woman contributes nuclear DNA	One man and one woman contribute nuclear DNA, creating a fertilized egg that contributes pronuclei
Egg donor contributes mtDNA	Egg donor contributes mtDNA
No sperm required	Sperm required
Human embryos not destroyed	Fertilized eggs destroyed

II. STATE ANTI-CLONING LAWS: AN OVERVIEW

Seventeen of fifty states have laws that prohibit human cloning.[68] Seven states ban all human cloning, including cloning human embryos for research in the lab: Arizona, Arkansas, Indiana, Michigan, North Dakota, Oklahoma, and South Dakota.[69] Another ten states allow scientists to clone human embryos for research, but forbid anyone to clone a baby: California, Connecticut, Illinois, Iowa, Maryland, Massachusetts, Missouri, Montana, New Jersey, and Virginia.[70]

States phrase their bans in different ways. Some states say that no person may clone a human being.[71] Other states assert that no person may

67. *See, e.g.*, Grossu, *supra* note 12, at 1, 2 (claiming that pronuclear transfer creates three individuals and kills two for their parts).

68. KERRY LYNN MACINTOSH, ENHANCED BEINGS: HUMAN GERMLINE MODIFICATION AND THE LAW 134 (2018) [hereinafter MACINTOSH, ENHANCED BEINGS].

69. MACINTOSH, HUMAN CLONING, *supra* note 14, at 209.

70. *Id.*

71. CAL. HEALTH & SAFETY CODE § 24185(a) (West, Westlaw through Ch. 3 of 2020 Reg. Sess.); ILL. COMP. STAT. ANN. 110/40(a) (West, Westlaw through P.A. 101-629); MO. ANN. STAT. CONST. ART. 3, § 38(d).2(1) (West, Westlaw current through Nov. 6, 2018 General Election).

engage,[72] conduct,[73] perform,[74] or participate[75] in human cloning. States may also prohibit various activities involving cloned human embryos, including their creation,[76] implantation into a uterus or similar environment,[77] or use in aid of human reproduction.[78] Many states also bar attempts to commit these proscribed acts.[79]

72. CAL. HEALTH & SAFETY CODE § 24185(a); CONN. GEN. STAT. ANN. § 32-41jj(b)(1) (West, Westlaw through Nov. 6, 2018 General Election); MASS. GEN. LAWS ANN. ch. 111L, § 8(a) (West, Westlaw through Ch. 30 of the 2020 Ann. Sess.); MICH. COMP. LAWS. ANN. §§ 333.16275(1), 750.430a(1) (West, Westlaw current through P.A. 2020, No. 62, of the 2020 Reg. Sess., 100th Legis.); N.J. STAT. ANN. § 2C:11A-1 (West, Westlaw through L.2019, c. 469 and J.R. No. 22).

73. MD. CODE ANN., ECON. DEV. § 10-440(a) (West 2008).

74. ARK. CODE ANN. § 20-16-1002(a)(1) (2003); IOWA CODE ANN. § 707C.4.1.a (2008); MONT. CODE ANN. § 50-11-102(1)(a) (2009); N.D. CENT. CODE ANN. § 12.1-39-02.1.a (West 2020); OKLA. STAT. ANN. tit. 63, § 1-727.B.1 (West 2019); S.D. CODIFIED LAWS § 34-14-27(1) (2019); VA. CODE ANN. § 32.1-162.22.A(i) (West 2019).

75. IND. CODE ANN. § 35-46-5-2(c)(1) (West 2019). It is illegal to participate in performing and/or attempt to perform human cloning in Arkansas, Iowa, Montana, North Dakota, Oklahoma, and South Dakota. ARK. CODE ANN., § 20-16-1002(a)(2); IOWA CODE, § 707C.4.1.b; MONT. CODE ANN. § 50-11-102(1)(b); N.D. CENT. CODE ANN. § 12.1-39-02.1.b; OKLA. STAT. ANN. § 1-727.B.2; S.D. CODIFIED LAWS § 34-14-27(2).

76. ARIZ. REV. STAT. ANN. § 36-2312.A (West 2010).

77. CONN. GEN. STAT. ANN. § 32-41jj(b)(2); IND. CODE ANN. § 35-46-5-2(c)(2); VA. CODE ANN. § 32.1-162.22.A(ii).

78. CONN. GEN. STAT. ANN. § 32-41jj(b)(3).

79. ARIZ. REV. STAT. ANN. § 36-2312.A; ARK. CODE ANN., § 20-16-1002(a)(1),(2); CAL. HEALTH & SAFETY CODE § 24185(c)(1); ILL. COMP. STAT. ANN. 110/40(a); IND. CODE ANN. § 35-46-5-2(c)(2); IOWA CODE, § 707C.4.1.a,b; MD. CODE ANN., ECON. DEV. § 10-440(a); MASS. GEN. LAWS ANN. ch. 111L, § 8(a); MICH. COMP. LAWS. ANN. §§ 333.16275(1), 750.430a(1); MO. ANN. STAT. CONST. ART. 3, § 38(d).2(1); MONT. CODE ANN. § 50-11-102(1)(a),(b); N.D. CENT. CODE ANN. § 12.1-39-02.1.a,b; OKLA. STAT. ANN. § 1-727.B.1,2; S.D. CODIFIED LAWS § 34-14-27(1),(2); VA. CODE ANN. § 32.1-162.22.A(ii).

Table 2 describes the crimes,[80] prison sentences,[81] and/or fines[82] that states impose on scientists, medical providers, patients, and other participants who run afoul of their laws. California and Virginia do not criminalize human cloning but do impose hefty civil penalties.

80. ARIZ. REV. STAT. ANN. § 36-2312.D (Class 1 misdemeanor); ARK. CODE ANN., § 20-16-1002(b) (Class C felony); CONN. GEN. STAT. ANN. § 32-41jj(b) (offense); ILL. COMP. STAT. ANN. 110/40(b) (Class 1 felony); IND. CODE ANN. § 35-46-5-2(c) (Level 6 felony); IOWA CODE, § 707C.4.2 (Class C felony); MD. CODE ANN., ECON. DEV. § 10-440(b) (felony); MASS. GEN. LAWS ANN. ch. 111L, § 8(d) (unspecified); MICH. COMP. LAWS. ANN. § 750.430a(3) (felony); MO. ANN. STAT. CONST. ART. 3, § 38(d).3 (crime); MONT. CODE ANN. § 50-11-102(2) (felony); N.J. STAT. ANN. § 2C:11A-1 (crime of the first degree); N.D. CENT. CODE ANN. § 12.1-39-02.3 (Class C felony); OKLA. STAT. ANN. § 1-727.D (misdemeanor); S.D. CODIFIED LAWS § 34-14-27 (Class 6 felony).

81. Five states specify prison terms for violation: CONN. GEN. STAT. ANN. § 32-41jj(b) (up to ten years); MD. CODE ANN., ECON. DEV. § 10-440(b) (up to ten years); MASS. GEN. LAWS ANN. ch. 111L, § 8(d) (five to ten years); MICH. COMP. LAWS. ANN. § 750.430a(3) (up to ten years); MO. ANN. STAT. CONST. ART. 3, § 38(d).3 (up to fifteen years). In the other states that consider human cloning a crime, one must consult additional laws to determine the possible prison sentence. For example, New Jersey declares that human cloning is a crime of the first degree but does not specify the sentence. However, its code of criminal justice provides that a person convicted of a crime in the first degree can be sentenced to prison for ten to twenty years. N.J. STAT. ANN. §§ 2C:11A-1, 2C:43-6.a(1).

82. ARK. CODE ANN., § 20-16-1002(d)(1) (civil fine of $250,000 or twice the pecuniary gain, whichever is greater); CAL. HEALTH & SAFETY CODE § 24187(a),(b) (civil fine up to $250,000 for an individual or up to $1,000,000 for an entity, or twice the pecuniary gain, whichever is greater); CONN. GEN. STAT. ANN. § 32-41jj(b) (criminal fine up to $100,000); IOWA CODE, § 707C.4.3 (civil penalty of twice the pecuniary gain); MD. CODE ANN., ECON. DEV. § 10-440(b) (criminal fine up to $200,000); MASS. GEN. LAWS ANN. ch. 111L, § 8(d) (criminal penalty up to $1,000,000 plus collection of profit made as damages); MICH. COMP. LAWS. ANN. § 333.16275(3) (civil fine of $10,000,000), § 750.430a(3) (criminal fine up to $10,000,000); MO. ANN. STAT. CONST. ART. 3, § 38(d).3 (criminal fine up to $250,000 and civil penalty up to $50,000 plus forfeiture of profit); MONT. CODE ANN. § 50-11-102(4) (unspecified fines); S.D. CODIFIED LAWS § 34-14-27 (civil fine of $2,000 or twice the pecuniary gain); VA. CODE ANN. § 32.1-162.22.C (civil penalty up to $50,000).

Table 2: Human Cloning Laws

State	Criminal Offense	Prison Sentence Stated in Law	Maximum Criminal or Civil Fine Stated in Law
Bans All Human Cloning			
Arizona	Class 1 Misdemeanor		
Arkansas	Class C Felony		$250,000 or twice gain
Indiana	Level 6 Felony		
Michigan	Felony	Up to 10 years	$10,000,000
North Dakota	Class C Felony		
Oklahoma	Misdemeanor		
South Dakota	Class 6 Felony		$2,000 or twice gain
Bans Cloning Babies			
California	None		$250,000 (individual) or $1,000,000 (firm) or twice gain
Connecticut	Offense	Up to 10 years	$100,000
Illinois	Class 1 Felony		
Iowa	Class C Felony		Twice gain
Maryland	Felony	Up to 10 years	$200,000
Massachusetts	Not Described	Up to 10 years	$1,000,000 + profit
Missouri	Crime	Up to 15 years	$250,000 and civil fine of $50,000 + profit
Montana	Felony		Unspecified fines
New Jersey	Crime of first degree		
Virginia	None		$50,000
Total	**15**	**5**	**11**

States may also forbid ancillary activities, including the shipment,[83] transfer or receipt,[84] possession,[85] or importation[86] of the products of human cloning. Some states also prohibit the purchase or sale,[87] shipment,[88] or transfer or receipt[89] of such items as somatic cells, eggs, embryos, or fetuses for the purpose of human cloning. Such prohibitions may ensnare egg donors, lab technicians, or even delivery personnel who deliver packages. However, depending on the state, such offenses may be considered misdemeanors rather than felonies.[90]

The state of mind required for criminal conviction varies. For example, Michigan provides that one may not intentionally engage in human cloning.[91] Arizona prohibits the intentional or knowing creation of a human embryo by a method other than fertilization.[92] South Dakota requires only that a person knowingly or recklessly violate its cloning law.[93] Illinois, Maryland, and Oklahoma do not specify a state of mind, despite their imposition of criminal penalties.[94]

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83. ARK. CODE ANN., § 20-16-1002(a)(3); IND. CODE ANN. § 35-46-5-2(c)(3); MONT. CODE ANN. § 50-11-102(1)(c); OKLA. STAT. ANN. § 1-727.B.3; VA. CODE ANN. § 32.1-162.22.A(iv).

84. ARK. CODE ANN., § 20-16-1002(a)(3); IND. CODE ANN. § 35-46-5-2(c)(3); IOWA CODE, § 707C.4.1.c; MONT. CODE ANN. § 50-11-102(1)(c),(d); N.D. CENT. CODE ANN. § 12.1-39-02.1.c; OKLA. STAT. ANN. § 1-727.B.3; S.D. CODIFIED LAWS § 34-14-27(3); VA. CODE ANN. § 32.1-162.22.A.(iv).

85. VA. CODE ANN. § 32.1-162.22.A.(iii).

86. OKLA. STAT. ANN. § 1-727.B.4.

87. CAL. HEALTH & SAFETY CODE § 24185(b); MASS. GEN. LAWS ANN. ch. 111L, § 8(a).

88. ARK. CODE ANN., § 20-16-1002(a)(4); MONT. CODE ANN. 50-11-102(1)(d).

89. ARK. CODE ANN., § 20-16-1002(a)(4); MASS. GEN. LAWS ANN. ch. 111L, § 8(a); MONT. CODE ANN. § 50-11-102(1)(d); N.D. CENT. CODE ANN. § 12.1-39-02.1.d; S.D. CODIFIED LAWS § 34-14-27(4).

90. ARK. CODE ANN., § 20-16-1002(c); IOWA CODE, § 707C.4.2.b; N.D. CENT. CODE ANN. § 12.1-39-02.3; MONT. CODE ANN. § 50-11-102(3); OKLA. STAT. ANN. § 1-727.D; *but see* S.D. CODIFIED LAWS § 34-14-27 (deeming all violations to be felonies).

91. MICH. COMP. LAWS. ANN. § 750.430a(1).

92. ARIZ. REV. STAT. ANN. § 36-2312.A; *accord* ARK. CODE ANN., § 20-16-1002(a)(1),(2); IND. CODE ANN. § 35-46-5-2(a),(c)(1); IOWA CODE, § 707C.4.1.a,b; N.D. CENT. CODE ANN. § 12.1-39-02.1.a,b (making it illegal to intentionally or knowingly perform or participate in human cloning); MO. ANN. STAT. CONST. ART. 3, § 38(d).3 (imposing criminal penalties for knowing or willful violations); *see also* CONN. GEN. STAT. ANN. § 32-41jj(b); MASS. GEN. LAWS ANN. ch. 111L, § 8(a); MONT. CODE ANN. § 50-11-102(1)(a),(b); N.J. STAT. ANN. § 2C:11A-1 (applying penalties to those who knowingly violate the law).

93. S.D. CODIFIED LAWS § 34-14-27.

94. ILL. COMP. STAT. ANN. 110/40(a),(b); MD. CODE ANN., ECON. DEV. § 10-440(a),(b); OKLA. STAT. ANN. § 1-727.B.1,2,D. The laws in California and Virginia impose only civil penalties and thus require no state of mind. CAL. HEALTH & SAFETY CODE §§ 24185(a), 24187; VA. CODE ANN. § 32.1-162.22.A,C.

III. DO STATE ANTI-CLONING LAWS PROHIBIT MRT?

Maternal spindle transfer and pronuclear transfer are not human cloning.[95] However, a broad or vague anti-cloning law may nevertheless include these MRT methods within its scope. Thus, before commencing experiments, scientists must determine which states may view them as criminals and punish their research with prison sentences. Likewise, medical providers must identify states that may punish them for helping women get pregnant through MRT. Patients must also be careful, lest they be prosecuted for having children in the wrong way.

Before analysis begins, two points deserve mention. First, because anti-cloning laws have not been interpreted by appellate courts,[96] their application cannot be predicted with certainty and political factors must be considered. Second, this article adopts dictionary meanings for two undefined terms that appear in anti-cloning laws: human being and organism. "Human being" will be taken to mean a person,[97] that is, a man, woman, or child.[98] "Organism" will be considered to refer to a "single living plant, animal, or other living thing."[99] A human embryo is a human organism in its earliest phase.[100] Although a fertilized egg is not an embryo in a strict biological sense,[101] it is alive and can become a zygote and ultimately a baby. Thus, this article assumes that the term organism could encompass a fertilized egg as well.

Table 3 illustrates which MRT methods may violate anti-cloning laws in various states.

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95. Craven et al., *supra* note 39, at 507.

96. A Westlaw search of state annotated codes conducted on June 7, 2019 returned no such cases.

97. Cambridge Dictionary, *human being*, https://dictionary.cambridge.org/us/dictionary/english/human-being (last visited June 1, 2019).

98. Cambridge Dictionary, *person*, https://dictionary.cambridge.org/us/dictionary/english/person (last visited June 1, 2019). Similarly, the Oxford Dictionaries describe a human being as "[a] man, woman, or child of the species Homo sapiens, distinguished from other animals by superior mental development, power of articulate speech, and upright stance."
Oxford Dictionaries, *human being*, https://en.oxforddictionaries.com/definition/human_being (last visited June 1, 2019).

99. Cambridge Dictionary, *organism*, https://dictionary.cambridge.org/us/dictionary/english/organism (last visited June 10, 2019).

100. Cambridge Dictionary, *embryo*, https://dictionary.cambridge.org/us/dictionary/english/embryo (last visited June 10, 2019).

101. Katerina Georgadaki et al., *The Molecular Basis of Fertilization (Review)*, 38 INT'L J. MOLECULAR MED. 979, 984 (2016) (The pronuclei must move toward each other and their membranes must rupture before their nuclear material can form a zygote, the first cell of an embryo.).

Table 3: MRT Methods that May Violate Anti-Cloning Laws

State	Maternal Spindle Transfer	Pronuclear Transfer
Bans All Human Cloning		
Arizona	x	x
Arkansas		x
Indiana		x
Michigan		x
North Dakota		x
Oklahoma		x
South Dakota		x
Bans Cloning Babies		
California		x
Connecticut		x
Illinois	x	x
Iowa		x
Maryland		
Massachusetts		
Missouri	x	x
Montana		x
New Jersey		
Virginia		x
Total	**3**	**14**

Because statutory language varies from state to state, the analysis is quite complex. To simplify, this Part groups states together according to common statutory elements. States with laws that are relatively easy to analyze are presented before states with more complex laws. A few states prohibit more than one type of conduct and are therefore discussed in more than one Part.

A. Creating an Embryo by a Method Other Than Fertilization

Arizona prohibits creation of an in vitro human embryo by any method other than fertilizing a human egg with human sperm.[102] In this manner, it excludes human cloning for research and reproduction. Illinois and Missouri adopt a similar approach, forbidding the transfer of "anything other than the product of fertilization of an egg of a human female by a sperm of a human male" to start a pregnancy that may lead to a fetus or child.[103] Their laws do not affect lab research, but do block reproductive cloning.

At first glance, these laws may not seem to affect maternal spindle transfer and pronuclear transfer because these methods involve the fertilization of eggs with sperm.[104] However, this impression may be deceiving. Maternal spindle transfer merges two eggs before fertilization and pronuclear transfer reorganizes two eggs into one after fertilization.[105] Because these methods entail more than simple fertilization, scientists who use them to create human embryos in Arizona are at serious risk. In addition, medical providers and patients who use these methods to achieve pregnancies likely violate the law in all three states.

Additionally, political factors increase the risk that these state authorities will clamp down on MRT. Pronuclear transfer will offend prolife advocates because it destroys fertilized eggs, and these advocates can mount a successful attack on pronuclear transfer in Arizona, where the ban on the creation of in vitro embryos evinces a respect for nascent human life. Although maternal spindle transfer does not destroy fertilized eggs, conservatives may argue that it produces children who will be confused by having two mothers and a father.[106] This argument will be potent in Illinois and Missouri, where laws describe fertilization as a process involving the egg of *one* female and the sperm of *one* male.[107] Patient advocates will counter that MRT spares children from suffering and death, but local prosecutors may not heed them.

B. Replicating Genetic Material, Human Beings, or Human Individuals

States can also foil human cloning by describing it in terms of replication. Human cloning cannot copy anyone,[108] but it does transmit

102. ARIZ. REV. STAT. ANN. § 36-2312.A.
103. ILL. COMP. STAT. ANN. 110/40(a); MO. ANN. STAT. CONST. ART. 3, § 38(d).6(2).
104. Cree & Loi, *supra* note 45.
105. *Id.*
106. Grossu, *supra* note 12.
107. ILL. COMP. STAT. ANN. 110/40(a); MO. ANN. STAT. CONST. ART. 3, § 38(d).6(4).
108. MACINTOSH, ILLEGAL BEINGS, *supra* note 35, at 22–23.

nuclear DNA from one entity to another. Connecticut, Maryland, and New Jersey bar replication of a "living human being's complete set of genetic material,"[109] a "human being,"[110] or a "human individual,"[111] respectively. The laws are worded to ban reproductive cloning while sparing lab research on cloned embryos.[112]

Connecticut and Maryland do not define "human being." That term generally refers to a man, woman, or child.[113] "Human individual" must have a similar meaning in New Jersey, because its law not only forbids replication of a human individual, but also specifies that a cell must not be cultivated "through the egg, embryo, fetal, and newborn stages *into a new human individual.*"[114]

Even if maternal spindle transfer "replicates" one egg by transferring its spindle and chromosomes into another, an egg is not a human being or individual. Fertilization of the reconstructed egg ensures that if a human being or individual does result, he or she will have his or her own unique nuclear DNA. Similarly, even if pronuclear transfer "replicates" one fertilized egg by shifting its pronuclei into another, a fertilized egg is not a human being or individual. If the fertilized egg is transferred to a woman and a child results, the child will have his or her own unique nuclear DNA. Therefore, the laws discussed in this Part do not extend to either technology. However, medical providers and patients located in Connecticut may still be at risk for the reasons given in Part III.D below.

C. Creating an Entity That is Genetically Identical to Its Predecessor

Similarly, states can thwart human cloning by prohibiting the creation of an embryo, fetus, or human being that is genetically identical to its predecessor. California, Indiana, and Montana employ this approach.[115] Indiana prohibits all human cloning, including cloning

109. CONN. GEN. STAT. ANN. § 32-41jj(a)(2). Interestingly, Connecticut bars replicating a human being's "*complete* set of genetic material." *Id.* (emphasis added). However, human cloning replicates only the nuclear DNA of the cell donor; mtDNA comes from the woman who donates the egg for the procedure. MACINTOSH, ILLEGAL BEINGS, *supra* note 35, at 24. Thus, despite the use of "complete," Connecticut must intend its law to operate where there is replication of nuclear DNA but not mtDNA.

110. MD. CODE ANN., ECON. DEV. §§ 10-429(f), 10-440(a).

111. N.J. STAT. ANN. § 2C:11A-1.

112. *See* CONN. GEN. STAT. ANN. § 32-41jj(b),(d) (prohibiting development after gastrulation begins); MD. CODE ANN., ECON. DEV. §§ 10-429(f), 10-440(a) (making it illegal to create a new human being or permit development beyond an embryo); N.J. STAT. ANN. § 2C:11A-1 (prohibiting cultivation through the egg, embryo, fetal, and newborn stages).

113. *See supra* notes 97–98 and accompanying text.

114. N.J. STAT. ANN. § 2C:11A-1 (emphasis added).

115. CAL. HEALTH & SAFETY CODE § 24185(a),(c)(3); IND. CODE ANN. §§ 16-18-2-56.5(a), 35-46-5-2(c)(1); MONT. CODE ANN. §§ 50-11-102(1)(a),(b), 50-11-103(2). California requires

embryos for research,[116] while California and Montana prohibit reproductive cloning only.[117]

Maternal spindle transfer yields a reconstructed egg with the same spindle and chromosomes as the patient's original egg. However, these states do not prohibit creation of an egg that is genetically identical to a prior egg. Moreover, once a sperm fertilizes the reconstructed egg, any resulting embryo, fetus or child will have its own unique nuclear DNA. Thus, maternal spindle transfer does not violate the anti-cloning laws in these three states.

In comparison, pronuclear transfer shifts the pronuclei of the patient's fertilized egg into another fertilized egg from which the pronuclei have been removed. If an embryo results and is transferred to a woman, the eventual fetus will have the same nuclear DNA as the patient's fertilized egg. California prohibits human reproductive cloning, defined as "the creation of a human fetus that is substantially genetically identical to a *previously born human being.*"[118] The patient's fertilized egg is not a previously born human being; ergo, pronuclear transfer does not qualify as human reproductive cloning in California. However, readers should note that the Golden State also forbids nuclear transfer, as discussed in Part III.D below.

In Indiana, cloning occurs when asexual reproduction creates a human embryo from the cell or cells of a genetically identical human.[119] Pursuant to that definition, pronuclear transfer creates an embryo that is "genetically identical" because it has the same nuclear DNA as the patient's fertilized egg.[120] Thus, the key question is whether that egg is a "human." Indiana does not define the term. However, its decision to ban

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that the predecessor be only *substantially* genetically identical, thereby recognizing that a human clone inherits nuclear DNA from her cell donor but mtDNA from her egg donor. Indiana and Montana do not add the word substantially; presumably, however, their laws are intended to outlaw processes that result in an entity whose nuclear DNA matches that of a predecessor.

116. *See* IND. CODE ANN. §§ 16-18-2-56.5(a), 35-46-5-2(c)(1) (barring cloning, defined as the creation of a human embryo), and § 35-46-5-2(c)(2) (forbidding the implantation of a cloned human embryo in order to initiate a pregnancy).

117. *See* CAL. HEALTH & SAFETY CODE § 24185(a),(c)(3) (referring to human reproductive cloning as creation of a human fetus); MONT. CODE ANN. §§ 50-11-101(4), 50-11-102(1)(a),(b) (referring to reproductive human cloning as gestation or birth of a child).

118. CAL. HEALTH & SAFETY CODE § 24185(a),(c)(3) (emphasis added).

119. IND. CODE ANN. § 16-18-2-56.5(a). As Part I.C.2 clarified, the first step in pronuclear transfer is sexual reproduction, which occurs when sperm fertilizes eggs. Yet one can argue that the patient's fertilized egg reproduces asexually in the second step, when the technician shifts its pronuclei and chromosomes to the emptied donor egg and creates a new embryo. *See supra* Part I.C.2. This point is developed further in Part III.E.1.

120. Indiana must consider an embryo to be "genetically identical" when it shares nuclear DNA with a predecessor because a human clone inherits nuclear DNA from a somatic cell donor but mtDNA from an egg donor. *See supra* note 109.

all human cloning reflects a desire to protect embryonic human life. If a prosecutor decides that fertilized eggs qualify as humans, he may prosecute scientists who create embryos through pronuclear transfer, as well as medical providers and patients who put those embryos to reproductive use.[121]

In Montana, reproductive human cloning is "human cloning intended to result in the gestation or birth of a child who is genetically identical to another conceptus, embryo, fetus, or human being, living or dead."[122] An embryo is "an organism of the species Homo sapiens from the single cell stage to 8 weeks of development."[123] Accordingly, the patient's fertilized egg qualifies as an embryo: it has a single cell, belongs to our species, and is an organism.[124] When this embryo's pronuclei are transferred into another fertilized egg, the embryo is cloned, and any resulting fetus or child is "genetically identical" to it.[125] Thus, pronuclear transfer violates Montana law when used as reproductive technology.[126]

D. Engaging in Nuclear Transfer

States can also bar human cloning by prohibiting nuclear transfer. Three states adopt this approach: California, Connecticut, and Virginia.[127] (California and Connecticut, which were discussed in Parts III.B and C, prohibit more than one type of activity.). To generalize, these states construe nuclear transfer as shifting a nucleus from any human cell into an enucleated egg, but only when the objective is to achieve pregnancy or

121. Indiana law exempts "a treatment or procedure to enhance human reproductive capability through the manipulation of human oocytes or embryos," including IVF. IND. CODE ANN. § 16-18-2-56.5(b)(1)(A). One can argue that this exemption applies when pronuclei are manipulated as part of an IVF process, but there is no guarantee courts will embrace this interpretation.

122. MONT. CODE ANN. § 50-11-101(4).

123. *Id.* § 50-11-101(1).

124. *See supra* notes 99–100 and accompanying text.

125. Montana's law must mean that an embryo is genetically identical when it shares nuclear DNA with a predecessor since a human clone only inherits nuclear DNA from her somatic cell donor. *See supra* note 109.

126. Montana exempts IVF or other medical procedures that helps women get pregnant "if the procedure is not specifically intended to result in the gestation or birth of a child who is genetically identical to another conceptus, embryo, fetus, or human being, living or dead." MONT. CODE ANN. § 50-11-103(2). Unfortunately, as explained in the text, pronuclear transfer does produce a child who is genetically identical to the patient's original fertilized egg, but for the difference in mtDNA. Thus, medical providers and patients cannot rely on this exception to protect them.

127. CAL. HEALTH & SAFETY CODE § 24185(a),(c)(1); CONN. GEN. STAT. ANN. § 32-41jj(b); VA. CODE ANN. § 32.1-162.22.A.

create a human being.[128] In other words, the laws forbid nuclear transfer used for reproduction.

Maternal spindle transfer moves a spindle with chromosomes from one egg to another, but this transfer does not create an embryo or human being. Instead, it creates a reconstructed egg that must be fertilized with sperm to produce an embryo for uterine transfer. Laws that conceptualize nuclear transfer as the key reproductive event will not reach this process.

By contrast, pronuclear transfer shifts two pronuclei from the patient's fertilized egg into a fertilized donor egg that has had its own pronuclei removed. This process creates an embryo that can be transferred to the patient to initiate a pregnancy. Therefore, pronuclear transfer qualifies as nuclear transfer if two pronuclei are the legal equivalent of a nucleus.

Virginia defines "nucleus" as "the cell structure that houses the chromosomes and, thus, the genes."[129] California and Connecticut do not define "nucleus," but the biological meaning of the term is consistent with the Virginia definition.[130] A pronucleus is a cell structure that houses chromosomes and genes. Moreover, as explained in Part I.B.2, two pronuclei are the functional equivalent of a single nucleus because they jointly possess forty-six chromosomes and can drive the development of a baby. Hence, pronuclear transfer may indeed qualify as nuclear transfer in these three states. Nevertheless, California and Connecticut embrace embryonic stem cell research[131] and may lack the political will to punish medical providers and patients who destroy fertilized eggs in the course of pronuclear transfer.

E. Using Somatic Cell Nuclear Transfer

Finally, states can halt human cloning by prohibiting somatic cell nuclear transfer. Eight states adopt this strategy in whole or in part: Arkansas, Iowa, Massachusetts, Michigan, North Dakota, Oklahoma, South Dakota, and Virginia. This section groups states by similar provisions and generalizes where possible. It concludes that Arkansas, Iowa, Michigan,

128. *See* CAL. HEALTH & SAFETY CODE § 24185(c)(1); CONN. GEN. STAT. ANN. § 32-41jj(b); VA. CODE ANN. § 32.1-162.22.A.

129. VA. CODE ANN. § 32.1-162.21.

130. *See* Biology Online, *nucleus*, https://www.biology-online.org/dictionary/Nucleus (last visited Dec. 18, 2019) (describing a cell nucleus as a membrane-surrounded organelle that contains chromosomes).

131. In California, pluripotent stem cell research, including derivation of stem cells from IVF embryos or cloned human embryos, is a state constitutional right. CAL. CONST. art. XXXV, § 5. Connecticut also authorizes embryonic stem cell research. CONN. GEN. STAT. ANN. § 32-41jj(d).

North Dakota, Oklahoma, and South Dakota may consider pronuclear transfer to be illicit human cloning.

1. Arkansas, Iowa, North Dakota, Oklahoma, and South Dakota

Arkansas, Iowa, North Dakota, Oklahoma, and South Dakota have very similar anti-cloning laws.[132] These states view human cloning as human asexual reproduction. A scientist moves the genetic material (Arkansas, North Dakota), nuclear material (Oklahoma, South Dakota), or nucleus (Iowa) of a human somatic cell into a fertilized or unfertilized egg from which the scientist has removed or inactivated the nuclear material (Arkansas) or nucleus (Iowa, North Dakota, Oklahoma, South Dakota).[133] In Arkansas, Oklahoma, North Dakota, and South Dakota, human asexual reproduction must produce a living organism with a human (or predominantly human) genetic constitution to be within the scope of their laws.[134] As Part III mentioned at its outset, a human embryo is a living organism;[135] ergo, these four states forbid all human cloning including lab research. Iowa, on the other hand, bans only human reproductive cloning, i.e., somatic cell nuclear transfer for implantation into a uterus or substitute.[136]

Whether these laws extend to maternal spindle transfer or pronuclear transfer depends on the answers to several questions: first, what constitutes a human somatic cell; second, what constitutes asexual reproduction; third, do pronuclei qualify as a "nucleus" of a somatic cell or recipient egg; and fourth, what is a living organism? This section considers each of these questions in turn.

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132. ARK. CODE ANN., § 20-16-1002(a)(1); IOWA CODE, § 707C.4.1.a; N.D. CENT. CODE ANN. § 12.1-39-02.1.a; OKLA. STAT. ANN. § 1-727.B.1; S.D. CODIFIED LAWS § 34-14-27(1).

133. ARK. CODE ANN., § 20-16-1001(4); IOWA CODE, § 707C.3.4; N.D. CENT. CODE ANN. § 12.1-39-01.2; OKLA. STAT. ANN. § 1-727.A.1; S.D. CODIFIED LAWS § 34-14-26(1).

134. ARK. CODE ANN., § 20-16-1001(4) (human); N.D. CENT. CODE ANN. § 12.1-39-01.2 (human or predominantly human); OKLA. STAT. ANN. § 1-727.A.1 (human); S.D. CODIFIED LAWS § 34-14-26(1) (human or predominantly human). In Arkansas, the living organism must be "genetically virtually identical to an existing or previously existing human organism." ARK. CODE ANN., § 20-16-1001(4). The use of the word "virtually" seems to acknowledge that a human clone inherits mtDNA from an egg donor and is not entirely genetically identical to her cell donor. MACINTOSH, ILLEGAL BEINGS, *supra* note 35, at 23–24.

135. The Arkansas, Oklahoma, and South Dakota laws strengthen this conclusion by emphasizing that the organism can be at any stage of development. ARK. CODE ANN., § 20-16-1001(4); OKLA. STAT. ANN. § 1-727.A.1; S.D. CODIFIED LAWS § 34-14-26(1).

136. IOWA CODE, §§ 707C.3.1, 707C.4.1.a,b,c.

a. Human Somatic Cell

Arkansas, Iowa, Oklahoma, North Dakota, and South Dakota define a human "somatic cell" as a diploid cell with a complete set of chromosomes obtained or derived from a living or dead human body (or organism, in North Dakota) at any stage of development.[137] An unfertilized egg is a cell with a complete set of chromosomes until a spermatozoon penetrates it and it expels half of its chromosomes in a polar body.[138] However, a court probably would not interpret this definition to include an unfertilized egg; doing so would conflict with fundamental biological principles, which hold that somatic cells are all cells *other than* sperm and eggs, their precursors, and stem cells.[139] Because maternal spindle involves only unfertilized eggs, anti-cloning laws in these states should not reach maternal spindle transfer. Thus, the rest of this section concentrates on pronuclear transfer.

Pronuclear transfer is legally riskier because it employs *fertilized* eggs. As Part I.B.2 explained, the fertilized egg is a cell with pronuclei that jointly contain the complete set of chromosomes needed to develop a human being. But is this cell obtained or derived from a living or deceased human body or organism at any stage of development, as the legal definition of "somatic cell" requires? The answer may be yes, for the fertilized egg *itself* is alive and represents the human body or organism in its *earliest* stage of development. In that regard, a fertilized egg differs biologically from an unfertilized egg, which is not a somatic cell. Accordingly, as strange as it may seem, there is a risk that the law recognizes a fertilized egg as a somatic cell in these five states.

b. Human Asexual Reproduction

Arkansas, Iowa, Oklahoma, North Dakota, and South Dakota all require "human asexual reproduction" before labeling an activity as human cloning.[140] Pronuclear transfer may not seem to be asexual because it

137. ARK. CODE ANN., § 20-16-1001(6); IOWA CODE, § 707C.2; OKLA. STAT. ANN. § 1-727.A.2; N.D. CENT. CODE ANN. § 12.1-39-01.4; S.D. CODIFIED LAWS § 34-14-26(2). North Dakota omits the term "diploid," which is redundant because it ordinarily refers to a cell that has a complete set of chromosomes, half inherited from the mother and the other from the father. Biology Online, *diploid*, https://www.biology-online.org/dictionary/Diploid (last visited Dec. 18, 2019).

138. SILBER, *supra* note 31, at 23–24.

139. *See supra* note 16 and accompanying text.

140. ARK. CODE ANN., § 20-16-1001(4); IOWA CODE, § 707C.3.1; OKLA. STAT. ANN. § 1-727.A.1; N.D. CENT. CODE ANN. § 12.1-39-01.2; S.D. CODIFIED LAWS § 34-14-26(1).

begins when sperm fertilizes eggs,[141] yet pronuclear transfer also entails the transfer of female and male pronuclei from the patient's fertilized egg to the fertilized egg of the donor. From a pro-life perspective, the patient's fertilized egg reproduces asexually through this second step.[142]

c. Nucleus

As Part I explained, in cloning, a technician transfers a somatic cell or its nucleus into a donor egg from which the nucleus has been removed. In pronuclear transfer, a technician transfers the pronuclei of the patient's fertilized egg into a fertilized donor egg from which the pronuclei have been removed. The two processes are similar, but cloning involves nuclei and pronuclear transfer involves pronuclei. Thus, the next question is whether the laws in these states are worded broadly enough to include pronuclei.

Arkansas, North Dakota, Oklahoma, and South Dakota define human cloning in terms of transferring genetic or nuclear material,[143] both of which could encompass pronuclei. However, Iowa refers specifically to transferring the "nucleus" of a human somatic cell.[144] Similarly, although Arkansas refers to removing nuclear material—a term that could include pronuclei—from the donor egg,[145] Iowa, North Dakota, Oklahoma, and South Dakota refer specifically to removing a "nucleus" from the donor egg.[146]

Iowa and North Dakota do not define "nucleus," but Oklahoma and South Dakota do, referring to "the cell structure that houses the chromosomes, and thus the genes."[147] As Part I.C.2 mentioned, two pronuclei house the same forty-six chromosomes as a single nucleus.[148] Moreover, Iowa, North Dakota, Oklahoma, and South Dakota speak of removing a nucleus from a *fertilized* or unfertilized egg[149]and a fertilized egg can only

141. Arkansas defines human asexual reproduction as *not* initiated by the union of egg and sperm. ARK. CODE ANN., § 20-16-1001(1),(4). Arguably, pronuclear transfer falls within this definition because it is a form of reproduction that is not initiated by the union of a *single* egg with sperm.

142. *See supra* Part I.C.2 (explaining why pro-life advocates view pronuclear transfer as cloning).

143. *See* ARK. CODE ANN., § 20-16-1001(4); N.D. CENT. CODE ANN. § 12.1-39-01.2; OKLA. STAT. ANN. § 1-727.A.1; S.D. CODIFIED LAWS § 34-14-26(1).

144. IOWA CODE, § 707C.3.4.

145. ARK. CODE ANN., § 20-16-1001(4).

146. IOWA CODE, § 707C.3.4; N.D. CENT. CODE ANN. § 12.1-39-01.2; OKLA. STAT. ANN. § 1-727.A.1; S.D. CODIFIED LAWS § 34-14-26(1).

147. OKLA. STAT. ANN. § 1-727.A.3; S.D. CODIFIED LAWS § 34-14-26(4).

148. *See supra* Part I.C.2.

149. IOWA CODE, § 707C.3.4; N.D. CENT. CODE ANN. § 12.1-39-01.2; OKLA. STAT. ANN. § 1-727.A.1; S.D. CODIFIED LAWS § 34-14-26(1) (emphasis added).

have pronuclei. Thus, from a risk management standpoint, one should anticipate that these states may treat two pronuclei as the legal equivalent of a single nucleus.

d. Living Organism

Finally, in Arkansas, North Dakota, Oklahoma and South Dakota, human cloning requires creation of a living organism with a human or predominantly human genetic constitution.[150] A human embryo created via pronuclear transfer easily meets that description. To be sure, Arkansas also requires that this embryo be "genetically virtually identical to an existing or previously existing human organism."[151] This requirement is satisfied because the embryo has the same nuclear DNA as the patient's fertilized egg and differs only in mtDNA.

To summarize this section, laws in these five states may be read broadly to reach pronuclear transfer, and political factors reinforce this conclusion. Arkansas, Oklahoma, North Dakota, and South Dakota ban all human cloning, including the cloning of embryos for research. In a state where even cloned embryos are cherished, scientists who experiment with pronuclear transfer may be perceived as murderers. Meanwhile, in Iowa, the specter of babies with three parents may convince prosecutors to crack down on medical providers and patients who use pronuclear transfer for reproduction.

2. Massachusetts, Michigan, and Virginia

Massachusetts, Michigan, and Virginia also ban human cloning, including somatic cell nuclear transfer.[152] Michigan law forbids all human cloning and non-therapeutic research.[153] Massachusetts bans any cloning intended to create a human fetus or child.[154] Virginia bars initiating a pregnancy by implanting into a uterine environment the product of somatic cell nuclear transfer.[155]

150. ARK. CODE ANN., § 20-16-1001(4); N.D. CENT. CODE ANN. § 12.1-39-01.2; OKLA. STAT. ANN. § 1-727.A.1; S.D. CODIFIED LAWS § 34-14-26(1). The North and South Dakota laws add the reference to a predominantly human constitution to ensure that scientists cannot clone human beings using human DNA and animal eggs.

151. ARK. CODE ANN., § 20-16-1001(4).

152. MASS. GEN. LAWS ANN. ch. 111L, §§ 2, 8(a); MICH. COMP. LAWS. ANN. §§ 333.16274(1),(5)(a), 333.16275(1), 750.430a(1); VA. CODE ANN. § 32.1-162.22.A(i),(ii).

153. MICH. COMP. LAWS. ANN. §§ 333.16274(1),(5)(a), 333.16275(1), 750.430a(1) (referring to production of a human embryo).

154. MASS. GEN. LAWS ANN. ch. 111L, §§ 2, 8(a) (specifying creation of human fetus or child).

155. VA. CODE ANN. § 32.1-162.22.A(ii).

In Michigan, human somatic cell nuclear transfer entails "transferring the nucleus of a human somatic cell into an egg cell from which the nucleus has been removed or rendered inert."[156] A human somatic cell is "a cell of a developing or fully developed human being *that is not and will not become a sperm or egg cell*."[157] Thus, an unfertilized egg is not a human somatic cell, and maternal spindle transfer is legal. However, a *fertilized* egg may qualify as a somatic cell because it is the first cell of a developing human being. Further, its two pronuclei are the functional equivalent of a nucleus. Shifting them from one fertilized egg into another may constitute human cloning, so even lab experiments are risky in Michigan.

Massachusetts describes somatic cell nuclear transfer as "the technique in which the nucleus of an oocyte is replaced with the nucleus of a somatic cell."[158] Somatic cell is defined narrowly as "a *nongamete cell* obtained from a living or deceased *human being*."[159] This narrow definition spares both maternal spindle transfer and pronuclear transfer from categorization as human cloning. The spindle and chromosomes that are transferred in maternal spindle transfer come from the patient's unfertilized egg, which is a gamete and thus not a somatic cell.[160] The pronuclei that are transferred in pronuclear transfer come from the patient's fertilized egg, which is the first cell in a new organism, but not a human being, i.e., a man, woman, or child.[161]

Virginia defines somatic cell nuclear transfer as "transferring the nucleus of a somatic cell of an existing or deceased human into an oocyte from which the chromosomes are removed or rendered inert."[162] A somatic cell is "a *mature* diploid cell, i.e., a cell having a complete set of chromosomes."[163] The dictionary meaning of "mature" is fully grown.[164] Fertilized or unfertilized egg cells are not fully grown in the usual sense because they are capable of further development. As such, it seems unlikely that Virginia would deem maternal spindle transfer and pronuclear transfer to be somatic cell nuclear transfer. Nevertheless, as Part III.D

156. MICH. COMP. LAWS. ANN. § 333.16274(5)(d).
157. *Id.* § 333.16274(5)(c) (emphasis added).
158. MASS. GEN. LAWS ANN. ch. 111L, § 2.
159. *Id.* (emphasis added).
160. *Id*.
161. *See supra* notes 97–98 and accompanying text.
162. VA. CODE ANN. § 32.1-162.21.
163. *Id.* (emphasis added).
164. Cambridge Dictionary, *mature*, https://dictionary.cambridge.org/us/dictionary/english/mature (last visited June 4, 2019).

noted, Virginia's anti-cloning law also bans nuclear transfer, so pronuclear transfer may still be illegal there.[165]

IV. CONCLUSION

To summarize the foregoing analysis, maternal spindle transfer does not constitute unlawful human cloning in these states: Arkansas, California, Connecticut, Indiana, Iowa, Maryland, Massachusetts, Michigan, Montana, New Jersey, North Dakota, Oklahoma, South Dakota, and Virginia. However, Arizona, Illinois, and Missouri have broadly worded laws that could be interpreted to bar maternal spindle transfer. In Arizona, even lab experiments involving this method may be illegal if the sperm is used to fertilize reconstructed eggs, resulting in embryos. In Illinois and Missouri, lab research is safe, but the use of maternal spindle transfer to help women get pregnant may not be.

Pronuclear transfer faces a more complicated legal landscape. Its use in research and reproduction does not constitute illegal human cloning in Maryland, Massachusetts, and New Jersey. Even so, it may qualify as unlawful human cloning in another fourteen states due to vague statutory language and political factors. Those who employ pronuclear transfer in research or reproduction are at risk in Arizona, Arkansas, Indiana, Oklahoma, Michigan, North Dakota, and South Dakota. Those who use it in reproduction are at jeopardy in California, Connecticut, Illinois, Iowa, Missouri, Montana, and Virginia.

To be sure, if charges of human cloning are filed, a defendant can assert the rule of lenity, meaning that when a criminal law is ambiguous, a court should resolve doubts in favor of the defendant.[166] The rule serves two purposes: it ensures that the public has fair warning of prohibited conduct; and it places the responsibility for defining prohibited conduct squarely with legislatures and not courts.[167] Although the rule may rescue an individual defendant, it does not solve a more fundamental problem. State anti-cloning laws threaten to chill MRT lab research and clinical treatments. To put it bluntly, scientists, medical providers, and patients do not want to be charged with crimes only to raise the rule of lenity at the last minute in a desperate attempt to avoid conviction. They would much rather conduct research, help patients, or conceive healthy children without having to place their liberty and assets at risk.

Nor can scientists, medical providers, and patients solve this problem simply by switching from pronuclear transfer to maternal spindle

165. VA. CODE ANN. § 32.1-162.22.A(ii).
166. United States v. Bass, 404 U.S. 336, 347 (1971).
167. *Id.* at 348.

transfer. Although some scientists believe there is no reason to prefer one over the other,[168] these methods are not interchangeable. Maternal spindle transfer reduces the carryover of mitochondria from the patient, while pronuclear transfer creates embryos that are developmentally more competent.[169] Scientists should be free to conduct research that may reveal further comparative advantages or disadvantages. Likewise, medical providers and patients should have the ability to choose the method that best suits their particular needs. And in any event, even maternal spindle transfer appears to be illegal in Arizona, Illinois, and Missouri.

State legislatures can resolve this problem by amending anti-cloning laws to expressly exempt MRT in research and reproduction. For example, they could add the following provision: "This law does not apply to scientific research or assisted reproduction involving maternal spindle transfer, pronuclear transfer, or any similar method that supplies a human egg or embryo with donor mitochondria."

Alternatively, state legislatures can delegate the authority to issue clarifying regulations to state health departments or other relevant agencies. For example, California already delegates to the State Department of Health Services the power to "adopt, interpret, and update regulations, as necessary, for purposes of more precisely defining the procedures that constitute human reproductive cloning."[170] California could improve its law by adding the qualifying words "do or do not" before the word "constitute." It should also delegate to the Department the power to determine what does and does not fall within the scope of the term "clone."

Regardless of how states choose to resolve this discrepancy, the time to implement legislative fixes is now. Anti-cloning laws were meant to prevent cloning experiments in humans but they should not stand in the way of research or treatments that may help carriers of mitochondrial disease have healthy children.

168. Craven et al., *supra* note 39, at 506.
169. Cree & Loi, *supra* note 45, at 7.
170. CAL. HEALTH & SAFETY CODE § 24185(c)(3).