GOVERNING THE WILD WEST: DIAGNOSING & TREATING THE LACK OF REGULATIONS SURROUNDING ASSISTED REPRODUCTIVE TECHNOLOGIES

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INTRODUCTION

According to the Centers for Disease Control and Prevention (CDC), infertility is defined as "not being able to get pregnant (conceive) after one year (or longer) of unprotected sex."[1] Approximately 12% of American women aged 14 to 44 have difficulty getting pregnant or carrying a pregnancy to term.[2] As infertility is such a common problem, the medical field has gone to great lengths over the last half-century to alleviate the burden of reproductive challenges on individuals and families. Assisted Reproductive Technologies (ARTs) are one means to this end. This article will explore the nature of the governing regulatory scheme—or lack thereof—surrounding ARTs in the United States and the consequences that follow from an underregulated legal climate. More pointedly, I aim to expose how the absence of ART specific language from the regulatory scheme impacts the consumers of the infertility industry in America.

First, I will briefly outline the biological process of human conception and establish a working definition of infertility. Second, I will explicate potential medical treatments for the condition of infertility with a special emphasis on in vitro fertilization (IVF). From there, I will provide a brief overview of the history of IVF and its regulation at both the federal and state level. Fourth, I will highlight some gaps in the oversight of IVF practice and insurance coverage; I will also delineate some of the negative consequences that follow from these gaps. Fifth, I will provide possible alternative causes for the shortcomings in regulation. Finally, I posit that the current failures of the ART and IVF regulatory scheme can be boiled down to a lack of communication between the medical sciences and the law. Specifically, this manifests through an issue called the law-science lag in which science advances at a pace faster than the law or regulation can maintain. This lag leads to significant deference to the sciences, regulatory gaps, and piecemeal governance over the application of scientific development. In this note, I argue that the lack of a medically informed regulatory scheme significantly

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[1] DIV. REPROD. HEALTH, NAT'L CTR. FOR CHRONIC DISEASE PREVENTION & HEALTH PROMOTION, *Infertility: Frequently Asked Questions*, CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 16, 2019), https://www.cdc.gov/reproductivehealth/infertility/index.htm.

[2] *Id.*

diminishes the effectiveness of any oversight of the IVF industry. Ineffective oversight, in turn, creates a hotbed for detrimental consequences to ART market consumers and American society as a whole.

I. THE SCIENCE ITSELF

A. Reproduction & The Need for ARTs

Pregnancy is a precarious occurrence.[3] A woman's body releases an egg from one of her ovaries during ovulation; a man's sperm joins with the egg through the process of fertilization; the fertilized egg moves through the fallopian tube toward the uterus, or the womb, where it attaches to the inside of the uterus in the final stage of the process, called implantation.[4] Infertility can result from a failure of one, more than one, or none of these steps.[5]

According to the CDC, infertility affects approximately 12% of American women aged 15 to 44.[6] When a couple has difficulty conceiving, there is approximately a 50% chance that the male partner is the cause of the infertility.[7] All in all, recent developments in fertility studies have shown that "[g]etting pregnant, if at all possible, is a lot harder than most people think."[8] In fact, one in every eight couples struggles with fertility issues.[9]

Identifiable causes of male-factor infertility, or when the male partner is the cause of the infertility, include problems in the testes, a blockage in the pathway that allows sperm to exit the testes during ejaculation, or problems in the pituitary or hypothalamus.[10] This can result in the semen containing too few sperm, no sperm at all, abnormally shaped sperm, and/or sperm with poor motility.[11] Factors contributing to infertility for the female partner can include "ovulation dysfunction, anatomical problems, endometriosis, uterine defects, infection, immunological problems, or

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[3] *Id.* (emphasizing that pregnancy only happens when a range of factors align within a process that has many steps).

[4] *Id.*

[5] *Id.* (arguing that not only is the reproductive process sensitive, but there are outside factors–like age of the parties–that can impact the potential outcome of the procreative process).

[6] *Id.*

[7] AM. SOC'Y FOR REPROD. MED., *Diagnostic Testing for Male Factor Infertility*, REPRODUCTIVEFACTS.ORG, https://www.reproductivefacts.org/news-and-publications/patient-fact-sheets-and-booklets/documents/fact-sheets-and-info-booklets/diagnostic-testing-for-male-factor-infertility/ (last visited Nov. 6, 2020). Male factor infertility may come in the form of producing too few sperm to fertilize an egg, making sperm that are not shaped properly or that do not move the way they should, or having a blockage in the reproductive tract that prevents proper movement of sperm.

[8] Sahaj Kohli, *12 Mind-Blowing Stats Everyone Should Know About Infertility: It Affects Men and Women Equally*, HUFFINGTON POST (Oct. 11, 2017), https://www.huffpost.com/entry/infertility-statistics-stats-about-infertility_n_571f8c0ce4b0f309baee9bde.

[9] *Id.*

[10] *Male Factor Infertility*, COLUMBIA UNIV. IRVING MED. CTR., https://www.columbiadoctors.org/treatments-conditions/male-factor-infertility (last visited Jan. 6, 2022) [hereinafter *Male Factor Infertility*].

[11] *Id*.

unknown causes."[12] Different treatments may be used depending on the cause of the infertility.

B. Infertility Treatments & Technologies

As infertility is such a common problem, the medical field has gone to great lengths over the last half-century to alleviate the burden of reproductive challenges on individuals and families. ARTs are one means to this end. According to the CDC, ARTs "includes all fertility treatments in which both eggs and embryos are handled."[13]

There are a range of fertility treatments available that vary in invasiveness.[14] While many of the different ARTs are controversial, couples resorting to medical intervention to become pregnant has become increasingly more common over the last fifty years.[15] As of April 2017, over one million babies born in the United States (and abroad) were conceived via some kind of ART.[16] It is becoming more and more common for people to seek medical intervention to have children over the last fifty years. The increase in ART sought has been met with pushback and controversy in various forms. On the one hand, there is an argument that ARTs present moral bioethical issues because they involve the "instrumental manipulation

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[12] *Female Infertility*, COLUMBIA UNIV. FERTILITY CTR., https://www.columbiaobgyn.org/patient-care/our-centers/columbia-university-fertility-center/conditions-and-treatments/female-infertility (last visited Jan. 6, 2022). Ovulation dysfunction means that a woman's reproductive system does not produce the "proper amounts of hormones necessary to develop, mature, and release a healthy egg." *Id*. Blocked fallopian tubes—caused by previous surgery, pelvic infections, or endometriosis—are the most common reason sperm is unable to reach the egg. Endometriosis is a condition where the tissue that lines the uterus develops outside the uterus; consequently, the menstrual cycle results in internal bleeding which can cause scar tissue and inflammation that affects how the reproductive organs function.

[13] *Assisted Reproductive Technology (ART): What is Assisted Reproductive Technology?*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 8, 2019), https://www.cdc.gov/art/whatis.html (last visited Sept. 9, 2020).

[14] *Types of Assisted Reproductive Treatment*, VICTORIAN ASSISTED REPROD. TREATMENT AUTH., https://www.varta.org.au/information-support/assisted-reproductive-treatment/types-assisted-reproductive-treatment [hereinafter VARTA].

[15] *See generally* John Collins Harvey, *Ethical Issues and Controversies in Assisted Reproductive Technologies*, 4 CURRENT OP. OBSTETRICS & GYNECOLOGY 750 (1992); World Health Organization [WHO] Report by Effy Vayena et. al., Practices and Controversies in Assisted Reproduction (2001): Report of a meeting on Medical, Ethical and Social Aspects of Assisted Reproduction, WHO Doc. WQ 208 (Sept. 17–21, 2001) http://apps.who.int/iris/bitstream/handle/10665/42576/9241590300.pdf;jsessionid=494FA41FE751CCD30AB866928C483C70?sequence=1; Gerardo Vela et al., *Advances and Controversies in Assisted Reproductive Technology*, 76 MOUNT SINAI J. MED. 506 (2009); Rebecca Buckwalter-Poza, *The Frozen Children: The Rise—And Complications—of Embryo Adoption in the U.S.*, PAC. STANDARD (May 3, 2017), https://psmag.com/news/frozen-children-rise-complications-embryo-adoption-u-s-80754; Wes Judd, *The Messy, Complicated Nature of Assisted Reproductive Technology*, PAC. STANDARD (May 3, 2017) https://psmag.com/news/the-messy-complicated-nature-of-assisted-reproductive-technology; Michael White, *Designer Babies Aren't Coming Anytime Soon*, PAC. STANDARD (June 14, 2017), https://psmag.com/environment/designer-babies-arent-coming-anytime-soon; Michael Morrison & Stevienna de Saille, *CRISPR in Context: Towards a Socially Responsible Debate on Embryo Editing*, 5 PALGRAVE COMMC'NS 1 (Sept. 24, 2019).

[16] Maggie Fox, *A Million Babies Have Been Born in the U.S. with Fertility Help*, NBC NEWS: HEALTH (Apr. 28, 2017, 12:08 PM), https://www.nbcnews.com/health/health-news/million-babies-have-been-born-u-s-fertility-help-n752506.

of fertilization, disregarding its natural environment, the sexual act, and the implications that arise from this."[17] There is also a position that ARTs pose ethical problems related to the specific medical aspects of the techniques used, including—but not limited to—the loss of embryos, embryo selection, the right to privacy during gamete donation, and the misuse of techniques for social purposes.[18] These moral and ethical controversies are combatted by the desire of individuals and couples to have children—an objective good.[19]

ARTs include ovulation induction (OI), ratification insemination or intrauterine insemination (IUI), intracytoplasmic sperm injection (ICSI), intracytoplasmic morphologically selected sperm injection (IMSI), donor conception, preimplantation genetic test (PGT), surrogacy, and in vitro fertilization (IVF).[20] IVF, intrauterine insemination,[21] and testicular extraction of sperm (TESE) are used to address male-factor infertility.[22] For female-factor infertility, there are a wider range of treatment options because there are a larger set of possible causes. Various fertility drugs are available for women who are infertile due to ovulation disorders.[23] Surgeries—though rare because of the success of other treatments—are used to correct problems or improve female infertility.[24] The most common forms of reproductive assistance for female-factor infertility include IUI and IVF.[25] Since the delivery of the first American IVF baby in 1981, there has been extensive development in medical technology surrounding reproduction in the United States.[26] IVF will be the main focus of this paper.

At its most basic level, IVF refers to the process whereby doctors retrieve one or more ova from a woman's body, fertilized in a lab, and then implanted back in the uterus in hopes of resulting in a pregnancy. In detail the process is as follows: the woman has hormone injections to stimulate her

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[17] Justo Aznar & Julio Tudela, *Bioethics of Assisted Reproductive Technology*, *in* INNOVATIONS IN ASSISTED REPRODUCTION TECHNOLOGY 2 (Nidhi Sharma et al. eds., 2020).

[18] *Id.*

[19] *Id. See generally* Harvey, *supra* note 15; Vayena et. al., *supra* note 15; Paul R. Brezina & Yulian Zhao, *The Ethical, Legal, and Social Issues Impacted by Modern Assisted Reproductive Technologies*, 2012 OBSTETRICS & GYNECOLOGY INT'L 1 (2012); Adrienne Asch & Rebecca Marmor, *Assisted Reproduction*, HASTINGS CTR. BIOETHICS BRIEFINGS (Sept. 17, 2015), https://www.thehastingscenter.org/briefingbook/assisted-reproduction/; Fiona C. Ross & Tessa Moll, *Assisted Reproduction: Politics, Ethics, and Anthropological Futures*, 39 MED. ANTHROPOLOGY: CROSS-CULTURE STUDS. HEALTH & ILLNESS 553 (2020).

[20] VARTA, *supra* note 14.

[21] This is the best treatment for sperm motility or concentration issues; intrauterine insemination can be combined with or used without treatment for the female partner. *Male Factor Infertility*, *supra* note 10.

[22] *Id.*

[23] Fertility drugs generally work like natural hormones—follicle-stimulating hormone and luteinizing hormone—to trigger ovulation. *Female Infertility*, MAYO CLINIC (Aug. 27, 2021), https://www.mayoclinic.org/diseases-conditions/female-infertility/diagnosis-treatment/drc-20354313.

[24] *Id.*

[25] *Id.*

[26] Craig Niederberger & Antonio Pellicer, *40 Years of IVF*, 110 FERTILITY & STERILITY 185, 188 (2018); Fox, *supra* note 16. This is not just a development in the United States, ARTs have been developed worldwide.

ovaries to produce multiple eggs.[27] Once the eggs have matured, they are retrieved from the woman's body.[28] The egg extraction procedure takes place while the woman is under a light anesthetic with the guidance of an ultrasound.[29] If the woman's own eggs are not viable for use in the IVF process, she can use eggs from a donor.[30] The eggs and sperm—from the male partner or a donor—are then placed into a culture dish in a laboratory to allow the eggs to fertilize, and develop into embryos.[31] Three to five days later, if embryos have formed, one or more is placed into the woman's uterus during the embryo transfer procedure.[32] If there are embryos remaining after the embryo transfer procedure, they can be frozen and used later if the first transfer is not successful or if the couple so desires.[33] Approximately six to seven weeks after the embryo transfer, a pregnancy can be verified using ultrasound technology.[34]

In the early years of IVF, it was performed with sperm and egg from members of a heterosexual marriage; but IVF evolved to include more options that make use of donor gametes. Current options for IVF include the following: traditional IVF, donor IVF (i.e., egg and sperm donation for transfer into another woman), IVF through the use of a surrogate, and egg donation to a laboratory for research, destruction, or cryopreservation (freezing).[35] IVF is a common treatment for male tubal blockage and unexplained infertility.[36] Other techniques, like intrauterine insemination and testicular extraction of sperm, are frequently used for other types of male-factor infertility.[37]

II. A BRIEF HISTORY OF THE LAW SURROUNDING IVF

The first IVF baby was born in the United States in the early 1980s. Since that time, both the regulatory scheme and medical innovations have continued to evolve. This section will briefly explore the historical trajectory of ART development leading to the current state of the law.

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[27] VARTA, *supra* note 14.

[28] *Id.*

[29] *Id.*

[30] Rachel Gurevich, *Having a Child with Egg Donor IVF: The Egg Donor IVF Process, Costs, and Success Rates*, VERYWELL FAM. (Sept. 12, 2020), https://www.verywellfamily.com/egg-donor-ivf-basics-4114768.

[31] VARTA, *supra* note 14.

[32] *Id.*

[33] *Id.*

[34] *Id.* "Couple" is the language most often used by the field; however, it is becoming increasingly common that more than just couples are involved in the ART process.

[35] Phyllis Griffin Epps, *The Entwined Destinies of Roe v. Wade and Assisted Reproductive Technology*, UNIV. HOUS. L. CTR. (Sept. 6, 2000), https://www.law.uh.edu/healthlaw/perspectives/Reproductive/000906Entwined.html.

[36] Male Factor Infertility, supra note 10.

[37] *Id*.

A. Federalism & Federal Laws

1. Early IVF Research and Development

Early on in IVF research, the Institutional Review Board (IRB) system, which is used to regulate research on human subjects, did not exist.[38] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (The Committee) was founded in 1973.[39] It endeavored to create ethical guidelines and rules for all biomedical research. In the ART specific environment, it governed "for research projects on embryos or fetuses submitted for consideration for federal funding."[40] The Committee recommended an Ethics Advisory Board oversee project approval regarding laboratory conception to receive federal funding;[41] however, the Ethics Advisory Board was not established until 1977 by which time IVF research was well under way, though no live births had yet been achieved anywhere.[42] At this time, the Ethics Advisory Board weighed in on IVF and asserted that, "the procedure was 'ethically defensible, though still legitimately controverted' and that 'there were compelling reasons to proceed with it under limited circumstances.'"[43] This publicized response by the Ethics Advisory Board postponed any funding decisions because of the legitimacy the publicity gave the controversy.[44] There was an initial move toward—not regulation—but internal governance; however, it ultimately did not manifest that way.

In the same decade, the 1970s, the decade of *Roe v. Wade* and the championing of women's reproductive freedom in relation to the pro-life-pro-choice debate,[45] IVF faced many regulatory challenges that mirrored the early development of abortion practices.[46] The medical practices involved

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[38] Milana Bochkur Dratver, *Comparative Study of IVF Policy and Practice in the United States and Israel*, THE SCOPE: BLOG YALE SCI. MAG. (Feb. 16, 2017), https://medium.com/the-scope-yale-scientific-magazines-online-blog/comparative-study-of-ivf-policy-and-practice-in-the-united-states-and-israel-b3f4da2e9695.

[39] *Id.*

[40] *Id.*

[41] *Id.*

[42] *Id.*

[43] *Id.*

[44] *Id*.

[45] Roe v. Wade, 410 U.S. 113 (1973) (holding that abortion was within the scope of the personal liberty guaranteed by the Due Process Clause, though the right was not absolute).

[46] Epps, *supra* note 35; Dratver, *supra* note 38. For a compelling account of the early development of IVF regulation parrallels the evolution abortion regulation, *see* Stephanie K. Boys & Evan M. Harris, *IVF and the Anti-Abortion Movement: Considerations for Advocacy Against Overturning* Roe v. Wade, 19 ADVANCES IN SOCIAL WORK 518 (2019); Jennifer Wright, *Why Anti-Choice People Are Okay With IVF*, HARPER'S BAZAAR (June 14, 2019), https://www.harpersbazaar.com/culture/politics/a27888471/why-anti-choice-people-against-abortion-are-okay-with-ivf/; Margaret Marsh & Wanda Ronner, *Why new anti-abortion laws may make it harder to conceive*, WASH. POST (Aug. 15, 2019), https://www.washingtonpost.com/outlook/2019/08/15/why-new-anti-abortion-laws-may-make-it-harder-conceive/; Alexandra Hutzler, *Anti-Abortion Groups Take On IVF, Fertility Clinics Over Unused Embryos: 'They Are Still Alive'*, NEWSWEEK (Oct. 8, 2019 9:56 AM), https://www.newsweek.com/anti-abortion-groups-take-ivf-1463839.

in IVF and ARTs themselves are regulated individually, and with much variation, state-by-state.[47] At the federal level, ARTs are governed by the Fertility Clinic Success Rate and Certification Act 1992 (the Wyden Law), Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Centers for Medicare and Medicaid Services.[48] These federal laws and agency laws govern reporting practices, diagnoses, and human tissues; however, they do not go into most ART issues. A prime example of this is the Wyden Law.

2. The Wyden Law

The Wyden Law was designed to create transparency around the clinical success rates of fertility treatments in the United States.[49] The Wyden Law places requirements on the CDC that mandate annual reporting of ART data from all facilities providing ART services, including success rates, number of cycles, number of singleton live births, etc.[50] The Wyden Law also provides States with a model embryology laboratory certification process;[51] however, these model processes are not accompanied by any implementation requirements at the state level.[52] In other words, while the Wyden Law offers an example of the ideal conditions for an embryology lab, there are no enforcement mechanisms to insure those standards are being met. Additionally, because the procedures at embryology labs are not deemed "diagnostic," they fall outside the confines of the Clinical Laboratory Improvement Act (CLIA) under which compliance is mandatory.[53]

3. CLIA

CLIA applies where the clinical practice of ART is deemed diagnostic.[54] In these circumstances, CLIA mandates certain standards for the condition of andrology laboratories and the practices involved in providing ART services.[55] There have been very few changes in federal legislation since the Wyden Law's enactment in 1992.[56]

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[47] Lucy Frith & Eric Blyth, *Assisted Reproductive Technology in the USA: Is More Regulation Needed?*, 29 REPROD. BIOMED. ONLINE 516, 517 (2014).

[48] *Id.*

[49] *Id.*

[50] Frith & Blyth, *supra* note 47, at 517; *Assisted Reproductive Technology (ART): Policy Documents*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 8, 2018), https://www.cdc.gov/art/nass/policy.html [hereinafter *ART Policy Docs*].

[51] Frith & Blyth, *supra* note 47, at 518; *ART Policy Docs*, *supra* note 50.

[52] Frith & Blyth, *supra* note 47, at 518.

[53] *Id.*

[54] David Adamson, *Regulation of Assisted Reproductive Technologies in the United States*, 78 FERTILITY & STERILITY 932, 932 (2002).

[55] *Id.*

[56] Dratver, *supra* note 38.

All in all, there is little oversight from the federal government or internal professional agencies over ARTs. In fact, no federal organization oversees the number of children conceived by a single patient, the types of medical information or updates supplied by donors, which genetic tests may be performed on embryos, how many fertilized eggs may be placed into a woman, or age limitations on donors.[57]

4. The FDA

The little, non-ART specific regulation that is in place can most aptly be said to derive from the FDA. The FDA oversees the standards set for screening and testing donors for human tissue and tissue-based products.[58] The regulations requiring the FDA to conduct this oversight were not designed with ARTs in mind and, consequently, do not incorporate language specific to genetic testing of prospective donors and other concerns unique to ARTs.[59] Moreover, only "small sections of the Good Tissue Practice regulations apply to most reproductive establishments."[60] In other words, the FDA has little governing power in the arena of ARTs.

B. Agency Regulation

1. ASRM

Regarding the implementation of federal laws in the ART context, there have been federal agency regulations—outside the FDA—governing IVF practices. Most guidance for the practices of IVF related procedures and ARTs is provided by the American Society of Reproductive Medicine (ASRM).[61] ASRM and the Society for Assisted Reproductive Technology (SART) supply guidelines and codes of conduct for fertility clinics and their staffs at a national level.[62] Much like the model embryology laboratory certification process outlined by the Wyden Law, the guidelines provided by the ASRM are not mandatory and the ASRM does not punish clinics, banks, or other institutions who deviate from the guidelines.[63] There is a lack of consistency in the practices and standards between clinics providing ART

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[57] *Id.*

[58] *Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products*, U.S. FOOD & DRUG ADMIN. (2007), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/eligibility-determination-donors-human-cells-tissues-and-cellular-and-tissue-based-products.

[59] Frith & Blyth, *supra* note 47, at 518.

[60] *Id.* (quoting Brooks A. Keel & Tammie K. Schalue, *Reproductive Laboratory Regulations, Certifications and Reporting Systems*, *in* REPRODUCTIVE ENDOCRINOLOGY & INFERTILITY: INTEGRATING MODERN CLINICAL & LABORATORY PRACTICE 55, 56 (Douglas T. Carrell & C. Matthew Peterson eds., 2010)).

[61] Dratver, *supra* note 38.

[62] Frith & Blyth, *supra* note 47, at 517. There is a significant difference in the oversight between academic clinics and private practice; academic clinics are governed by the institution's regulations and policies, while private practice is a standalone for-profit institution.

[63] Dratver, *supra* note 38.

services (like IVF).[64] This dramatic variation in practices and standards from one clinic to the next is a direct result of the absence of ARSM—or other governing body—enforcement mechanisms.[65]

C. State Regulation

Outside of the limited federal regulatory structure of ARTs, states have the ability to pass legislation governing this area; however, many have failed to do so.[66] At the state level, a license to practice medicine is required to offer IVF and other ART services.[67] It is important to note that certification through the American Board of Obstetrics and Gynecology or the Reproductive Endocrinology Subspecialty Board are not required to offer IVF or other ART services.[68] There are additional state licensing and inspection standards that must be met for facilities in which IVF and ARTs are offered.[69] The aforementioned state standards and requirements do not regulate the practice of administering ARTs or IVF itself; rather, they govern the physicians and facilities that conduct the practice. With the advent of IVF came the potential for left over embryos and other gametes, so there was a need for legislative response. By 2007, legislation on embryo and gamete disposition was enacted in sixteen states.[70] Now, at least one state has banned embryo destruction, and others have limited disposition choices through judicial determinations.[71] The actual state regulation of the practice of IVF and IVF related techniques vary drastically from state to state[72] if it is present at all.[73]

The regulation of insurance coverage of IVF and IVF related care is another issue. Like ARTs and the administration of IVF services, federal legislation has not set requirements for coverage of these infertility treatments; therefore, States are responsible to govern any standards related to insurance coverage in this area. As of 2017, only five states instituted

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[64] Frith & Blyth, *supra* note 47, at 518.

[65] *Id.*

[66] *Id.*

[67] Adamson, *supra* note 54, at 933.

[68] *Id.*

[69] *Id.*

[70] Frith & Blyth, *supra* note 47, at 518.

[71] Lisa A. Rinehart, *Storage, Transport, and Disposition of Gametes and Embryos: Legal Issues and Practical Considerations*, 115 FERTILITY & STERILITY 274, 278 (2021).

[72] As of August 2020, nineteen states have passed infertility insurance laws, thirteen of those include IVF coverage, and ten states have fertility preservation laws for iatrogenic (medically-induced) infertility—including Connecticut. *Infertility Coverage by State*, RESOLVE: THE NAT'L INFERTILITY ASS'N, https://resolve.org/what-are-my-options/insurance-coverage/infertility-coverage-state/ (last visited Dec. 14, 2020); CONN. GEN. STAT. § 52-190a (2019).

[73] Dratver, *supra* note 38. *See generally* NAT'L INFERTILITY ASS'N, *How Does Your State Do When It Comes to Access to Care and Support for Infertility?*, STATE FERTILITY SCORECARD: RESOLVE, http://familybuilding.resolve.org/fertility-scorecard/ (last visited Dec. 14, 2020) [hereinafter NAT'L INFERTILITY ASS'N]. There are no regulations in any state that determine a legal time limit on the storage of frozen eggs or embryos. Richard Vaughn, *Uniform Laws Needed to Regulate Abandoned Embryos*, INT'L FERTILITY L. GROUP (Aug. 26, 2019), https://www.iflg.net/laws-needed-abandoned-embryos/.

unique insurance policies that increase access to IVF procedures by requiring mandatory insurance coverage.[74] In other words, insurance companies in all but five states could refuse to provide IVF health insurance coverage.

There is limited federal oversight, directed more toward reporting; patchwork of state laws focusing on general medical care and insurance. This account of the law governing ARTs and IVF related technologies does not fully explore all the language, expectations, or idiosyncrasies of state and individual institutional oversight. Given the variation between jurisdictions and between stand-alone facilities administering ART services, it is impossible to offer an exhaustive discussion of the current regulations in every nook and cranny of the infertility industry. This patchwork regulatory structure is illustrative of the discontinuity and inconsistency that exists in the policies governing ARTs.

III. CONSEQUENCES OF LACK OF GOVERNING LAW

The loose legal oversight creates a market for ARTs where there are significant variations between the availability of insurance coverage and the administration of infertility treatments not only from state to state and clinic to clinic, but sometimes from one physician to another within individual clinics.[75] Some observable consequences for American society and individuals that result from this variation include: the commodification of reproductive markets, a trend toward medical tourism, and increased frequency of disputes over embryos and parental rights.

A. Commodification of Reproductive Markets

Without universalized standards in place for the insurance coverage of IVF and IVF related treatments, the lack of federal funding has created a burgeoning for-profit infertility market. Individuals facing infertility, who choose to enter the ART market, can purchase lawful reproductive services from willing providers.[76] By 2019, the last year for which there is preliminary ART national summary data reported by the CDC, there were over 440 ART clinics in the United States.[77] That year, there were 293,672 total cycles of ART treatments performed.[78] They resulted in over 28,000

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[74] NAT'L INFERTILITY ASS'N, *supra* note 73 (describing insurance requirements in Connecticut, Illinois, Massachusetts, New Jersey, and Rhode Island).

[75] Claudia Geib, *Advanced Reproductive Technology is Here. But Who Decides Who Gets Access?*, FUTURISM (Feb. 2, 2018), https://futurism.com/gatekeepers-future-reproductive-technology.

[76] Judith F. Daar, *Accessing Reproductive Technologies: Invisible Barriers, Indelible Harms*, 23 BERKELEY J. GENDER L. & JUST. 18, 35 (2008).

[77] *Assisted Reproductive Technology (ART): National ART Surveillance*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 7, 2019), https://www.cdc.gov/art/nass/index.html.

[78] *Final National Summary Report for 2019*, SOC'Y FOR ASSISTED REPROD. TECH.'S NAT'L SUMMARY REP. (2021), https://www.sartcorsonline.com/rptCSR_PublicMultYear.aspx?reportingYear=2018# (last visited Jan. 8, 2022) (contributing to the summary are the following cycle types: minimal stimulation, natural cycle,

singleton live births.[79] In the United States in 2019, there were 3,745,540 live births;[80] therefore, between .75-1% of children born in the United States in 2019 were born via ART.[81] These numbers illustrate the significant demand for very expensive infertility treatments in the United States.[82]

One of the two most prominent barriers posed by the ART market to potential consumers is the high cost of services.[83] In 2012, the average cost per IVF cycle in the United States was $9,266.[84] As of March 2020, the average cost per IVF cycle in the United States rose to over $12,000 excluding the cost of medications, which can be upwards of $3,000 per cycle.[85] What this translates to, in terms of accessibility to IVF as a treatment option with limited-to-no insurance coverage,[86] is an exacerbation of the already established healthcare disparity in the United States.[87] In a 2016

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conventional stimulation, in vitro maturation; also contributing to the data summary are the following technologies: First IVF, Elective single-embryo transfer (eSET), Preimplantation genetic testing (PGT), Day 5/6 transfer, Frozen egg, Frozen embryo, Gestational carriers, intracytoplasmic sperm injection (ICSI), Intravaginal culture (IVC). From these categories, the only ART not considered to be IVF related technology is IVC) [hereinafter SART]. The Society for Assisted Reproductive Technologies noted that the COVID-19 pandemic caused some embryo transfers to be delayed, thus a higher number of cycles occurred without a transfer during the twelve months after the retrieval cycle. This impacted the overall live birth success rates per cycle by making them statistically significantly lower than the previous reporting year in 2018.

[79] *Id.*

[80] Brady E. Hamilton et al., *Births: Provisional Data for 2019*, CTRS. FOR DISEASE CONTROL & PREVENTION (2020), https://www.cdc.gov/nchs/data/vsrr/vsrr-8-508.pdf.

[81] SART, *supra* note 78 (noting that this figure is lower than in previous years due to the COVID-19 pandemic, for example live singleton births resulting from ARTs made up 1.5-2% of all live births in the United States in 2018).

[82] Charis Thompson, *IVF Global Histories, USA: Between Rock and a Marketplace*, 2 REPROD. BIOMED. & SOC'Y ONLINE 128, 132 (2016).

[83] Daar, *supra* note 76, at 35.

[84] Brezina & Zhao, *supra* note 19, at 3.

[85] Rachel Gurevich, *How Much Does IVF Really Cost?*, VERYWELL FAM. (Mar. 5, 2020), https://www.verywellfamily.com/how-much-does-ivf-cost-1960212. Beyond economic status impacting only accessibility to infertility treatments, studies have shown that the socioeconomic divide amongst IVF consumers can also affect the likelihood of the success of their IVF; women with a household income of $100,000 are twice as likely to achieve success when undergoing IVF than women from households making under $100,000 ($p < .05$), even after accounting for variables such as cycle volume, age, race, level of education, and geography. *Money, Occupation and IVF Success Rates*, FERTILITY IQ, https://www.fertilityiq.com/topics/ivf/money-occupation-and-ivf-success-rates (last visited Dec. 14, 2020). In 2019 the fertility clinics and infertility services industry in the United States was worth $6 billion. John LaRosa, *Steady Growth of U.S. Fertility Clinics Industry Halted by COVID-19*, MKT. RSCH. BLOG (May 13, 2020), https://blog.marketresearch.com/steady-growth-of-u.s.-fertility-clinics-industry-halted-by-covid-19#:~:text=The%20%246%20billion%20fertility%20clinics,rates%2C%20a%20strong%20economy%2C%20and. More pointedly, the average salary of a fertility specialist in 2020 in the United States was $273,602. *Fertility Specialist Salary*, ECON. RES. INST. (Dec. 14, 2020), https://www.erieri.com/salary/job/fertility-specialist/united-states.

[86] Thompson, *supra* note 82, at 132 (describing the context where some fertility procedures are covered if you have "the right health insurance and have opted into the right benefits" in fifteen states: Arkansas, California, Connecticut, Hawaii, Illinois, Louisiana, Maryland, Massachusetts, Montana, New Jersey, New York, Ohio, Rhode Island, Montana, and West Virginia).

[87] *Id.* at 130. The median household income was $68,703 in the United States in 2019. Jessica Semega et al., *Income and Poverty in the United States: 2019*, U.S. CENSUS BUREAU (Sept. 15, 2020), https://www.census.gov/library/publications/2020/demo/p60-270.html. According to a study that spanned from 2013 to 2016, "[j]ust a third of those making less than $25,000 a year sought treatment for

article, Thompson argues that United States residents' "access to IVF has been stratified from the start by ability to pay" deriving from the lack of funding for embryonic research that followed the ruling of *Roe v. Wade*.[88]

The second barrier that consumers seeking to enter the fertility treatment market face, according to Daar's 2008 article, is the providers' discretion in deciding whom to treat.[89] As one scholar argued, in the United States there is a "paradoxical nexus: Pretty much any fertility treatment is available if you can pay for it, yet you can still be refused if a clinician does not agree with your lifestyle."[90] In addition to the socioeconomic and racial barriers that all individuals seeking access to the ART market face, single women and same-sex couples encounter "reduced access from at least two additional sources: provider discrimination against single and lesbian women [and gay men], and legislative efforts to ban access to unmarried individuals."[91] Most disturbingly, it has been argued that even if providers are not explicit in their discriminatory motivations for refusal of treatment, because medical ethics allows providers to refuse treatment based on their own "clinical discretion"—physicians can refuse treatment for any or no reason at all.[92] While some states have medical antidiscrimination laws with respect to marital status or sexual orientation, states without protection for these individuals may pose insurmountable barriers to local access to ARTs and IVF related technology.[93]

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infertility, compared with two thirds of those making $100,000 or more." Lisa Rapaport, *U.S. Women with Less Income, Education Often Lack Access to Infertility Care*, REUTERS: HEALTHCARE & PHARMA (July 17, 2019, 3:19 PM), https://www.reuters.com/article/us-health-infertility-disparities/u-s-women-with-less-income-education-often-lack-access-to-infertility-care-idUSKCN1UC2GB; *see* Adrienne L. Riegle, *Income Disparities in Medical Helpseeking for Infertility*, POPULATION ASS'N AM. 2012 ANN. MEETING (2012), https://paa2012.princeton.edu/papers/122270. Health disparities are "preventable circumstances relating to individuals' health status based on social factors such as income, ethnicity, education, age and gender. These factors can result in circumstances such as a lack of access to proper health care resources (including insurance) or decreased life expectancy rates." *6 Examples of Health Disparities and Solutions*, USCPRICE SOL PRICE SCH. OF PUB. POL'Y: EXEC. MENTAL HEALTH ADMIN. BLOG, https://healthadministrationdegree.usc.edu/blog/examples-of-health-disparities/ (last visited Jan. 6, 2022). There is a well-established health care disparity in the United States on racial, ethnic, geographical, and socioeconomic grounds. *See Reducing disparities in health care*, AM. MED. ASS'N: PATIENT SUPPORT & ADVOC., https://www.ama-assn.org/delivering-care/patient-support-advocacy/reducing-disparities-health-care (last visited Jan. 6, 2022); Nambi Ndugga & Samantha Artiga, *Disparities in Health and Health Care: 5 Key Questions and Answers*, KAISER FAM. FOUND. (May 11, 2021), https://www.kff.org/racial-equity-and-health-policy/issue-brief/disparities-in-health-and-health-care-5-key-question-and-answers/; Sofia Carratala & Connor Maxwell, *Health Disparities by Race and Ethnicity*, CTR. FOR AM. PROGRESS (May 7, 2020), https://www.americanprogress.org/article/health-disparities-race-ethnicity/; U.S. DEP'T OF HEALTH & HUM. SERVS., *CDC Health Disparities and Inequalities Report – United States, 2013*, 62 MORBIDITY & MORTALITY WKLY. REP. (Nov. 22, 2013), cdc.gov/mmwr/pdf/other/su6203.pdf.

[88] Thompson, *supra* note 82, at 130.

[89] Daar, *supra* note 76, at 35–36.

[90] Geib, *supra* note 75.

[91] Daar, *supra* note 76, at 43; *see also* Geib, *supra* note 75.

[92] Daar, *supra* note 76, at 65 ("Proponents of physician autonomy in the provision of ART services might look to a companion area of the law, which permits doctors to refuse to provide certain types of health care services on moral or ethical grounds.").

[93] *Id.* at 44. This topic has gained additional attention since the Trump administration's attempt to expand the so-called conscience rule for health care workers that was overturned in late 2019; there has

Even in the states in which medical anti-discrimination legislation does exist, the consensus among the courts is that infertility is a "'medical illness' but it does not necessarily follow that its treatment will always be considered a medical service."[94] Due to this, "a person's chance of accessing IVF as a form of reproductive assistance in the United States correlates with their race, class, disability, and citizenship status, as well as with where they live and their age."[95]

B. Cross-Border Reproduction & Medical Tourism

Diminished access to reproductive assistance is not the only consequence of a commodified reproductive field. In a market whose "growth of IVF in the USA [is] marked as much by exclusion as by its inclusivity,"[96] another downstream effect of the cost prohibitive nature of IVF technology is the push towards finding more cost-effective alternatives.[97] One method is the practice of medical tourism which is defined as the growing number of United States and other Western citizens who travel abroad to less developed countries such as India, Thailand, Malaysia with the primary purpose of receiving medical treatment, like ARTs.[98] Medical tourism promises *significant* cost savings for United States patients.[99] This is the case because the funding structure for IVF technologies and ARTs is "highly variable" between different nations.[100]

Beyond the international dimension of medical tourism, domestic medical tourism exists within the United States. Unlike international medical tourism, domestic medical tourism is often motivated by the inaccessibility to local IVF technology and ARTs because consumers are denied treatment for one reason or another (e.g., marital status, sexual orientation, race, etc.).[101] Domestic medical tourism may also be motivated by financial concerns over the exorbitant cost of ART services. Conversely, domestic medical tourism may create even more harmful consequences than

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been a reinvigoration of the view that religious refusal of treatment by physicians is unethical. Sarah C. Hull, *Not So Conscientious Objection: When Can Doctors Refuse to Treat?*, STAT NEWS (Nov. 8, 2019), https://www.statnews.com/2019/11/08/conscientious-objection-doctors-refuse-treatment/.

[94] Daar, *supra* note 76, at 44, n.40. *Compare* Egert v. Conn. Gen. Life Ins. Co., 900 F.2d 1032 (7th Cir. 1990) (rejecting insurance company claim that it does not consider infertility to be an illness where internal company memoranda refer expressly to the "illness of infertility," company ordered to reimburse for infertility treatments) *with* Kinzie v. Physician's Liab. Ins. Co., 750 P.2d 1140 (Okla. Civ. App. 1987) (while plaintiff's infertility was considered a medical condition, she was still denied insurance coverage for treatment because conceiving a child was not considered medically necessary to her physical health).

[95] Thompson, *supra* note 82, at 130.

[96] *Id.* at 134.

[97] I. Glenn Cohen, *Protecting Patients with Passports: Medical Tourism and the Patient-Protective Argument*, 95 IOWA L. REV. 1467, 1471–72 (2010).

[98] *Id.* at 1471, 1476–77 (noting that this is distinguishable from incidental medical tourism where travels received care from foreign providers that is "ancillary to another reason for travel, such as pleasure tourism or business travel, as well as care for expatriates living abroad full-time.").

[99] *Id.* at 1472.

[100] Brezina & Zhao, *supra* note 19, at 3.

[101] Daar, *supra* note 76, at 55.

mere economic burden—including psychological and emotional costs results from leaving one's home, job, partner, and family in pursuit of access to infertility treatments.[102] Barriers to local access can place additional obstacles in peoples' way giving rise to particular psychological and emotional costs.

C. Disputes over Embryos

Overcoming the discrimination, financial barriers, and successfully completing the IVF process does not indicate the exhaustion of possible legal issues. What happens if all the embryos are not used at the time of embryo transfer? They can be discarded or frozen.[103] Freezing embryos, however, can lead to other legal complications. Due to the lack of regulation surrounding freezing embryos, conflict can ensue about the plans for frozen embryos if they are abandoned, if the couple can no longer pay for their storage, if a partner dies, or if the couple decides to separate.[104] There are a few options for the fate of the embryo in these situations: the embryo is stored indefinitely, the embryo is thawed and disposed of, the embryo is given to one party or the other, the embryo is donated to another individual or couple, donated to research, or the embryo is disposed of using a method that is clearly stated in an agreement between the parties and the storage facility.[105] The problem exposes itself when the involved parties disagree on the desired outcome.

This is another area that is left up to the states to regulate.[106] Few states have any statutes regarding the disposition of embryos, but those that do are generally "vague and, therefore, do nothing to prevent litigation."[107] Since most state statutes are unhelpful, if they exist at all, there is a large potential for litigation over these matters. Different jurisdictions have asserted different approaches to deal with these disputes.[108] Nonetheless, no matter

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[102] *Id.* Infertility has been reported to cause various psychological-emotional disorders including "turmoil, frustration, depression, anxiety, hopelessness, guilt, and feelings of worthlessness in life. . . . The overall prevalence of psychological problems of the infertile couples is estimated to be 25-60%, which is caused by a complexity of factors such as gender, the cause and duration of infertility, treatment methods, and culture." Seyede Batool Hasanpoor-Azghdy et al., *The Emotional-Psychological Consequences of Infertility Among Infertile Women Seeking Treatment: Results of a Qualitative Study*, 12 IRAN J. REPROD. MED. 131, 132 (2014).

[103] VARTA, *supra* note 14.

[104] Melanie J. Wender, *Embryo Disputes Becoming More Common in Family Law Practice*, THE LEGAL INTELLIGENCER (July 10, 2020, 4:15 PM), https://www.law.com/thelegalintelligencer/2020/07/10/embryo-disputes-becoming-more-common-in-family-law-practice/?slreturn=20201111110334.

[105] *Id.*; Brezina & Zhao, *supra* note 19, at 4.

[106] Wender, *supra* note 104.

[107] *Id.* (contrasting the state legislation in California, Florida, and North Dakota with the only state that has explicit legislation related to the condition of embryos: Louisiana).

[108] *Id.* (describing the different approaches to embryo disputes used in different jurisdictions, namely: (1) the contracts-based approach, *see* Kass v. Kass, 91 N.Y.2d 554 (N.Y. 1998), (2) the balancing approach, *see* A.Z. v. B.Z., 725 N.E.2d 1051 (Mass. 2000), (3) the contemporaneous mutual assent approach); *see also* ALL. FOR FERTILITY PRES., *Supreme Court Refuses to Hear Illinois Disputed Embryos Case*, THE ALL. BLOG (Mar. 8, 2016),

the approach utilized, the litigation and conflicts that occur are economically demanding from all parties, the legal system, and emotionally taxing. Beyond that, the cost is high for the fertility industry to store and maintain frozen embryos. A 2012 article asserted that, "In the United States alone, it is estimated that over 400,000 embryos are currently cryopreserved, many of which will not be used by their genetic parents."[109] By 2020, the number of cryopreserved embryos in the United States reached 620,000.[110]

D. Parental Disputes

In addition to the potential for discrimination and the disputes over embryos, lack of clear regulation in this area can—and has—led to confusion and conflicts over parental roles after the birth of the child. The loose legal environment can lead to disputes over who is the legal parent of children produced from gamete donation, embryo donation, or both.[111] This has created particular uncertainty for same-sex couples and single women regarding parental rights over children.[112] This matter is complicated further when gestational surrogates and gamete donors are used in IVF practices. Gamete donors, the men and women who donate sperm and eggs, "are now an integral part of the ART world."[113] In 2008, donor eggs were routinely used in almost one of every eight ART cycles.[114]

Beyond the complications within the relationships among the parties involved in conception, the potential for human error via the clinics renders the lack of universal legal definitions—like "parenthood," "biological," etc.—deeply concerning. For example, the case of a young couple who gave birth to twins in New York in 2019.[115] The catch? Due to the error by the clinic of mixing up the embryos, the twins were not related to the couple that carried the children, nor to each other.[116] The twisted saga only got more convoluted when one set of the genetic parents were notified, in Los Angeles, that their son had just been born 3,000 miles away.[117] It suffices to say that a custody battle followed where the court was put in the position, without guidance from statute, to decide who was entitled the presumption of parental rights.[118] While this particular instance is unique, it is illustrative

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https://www.allianceforfertilitypreservation.org/blog/supreme-court-refuses-to-hear-illinois-disputed-embryos-case.

[109] Brezina & Zhao, *supra* note 19, at 4.

[110] Anna Hecker, *What Should I Do with my Unused Embryos?*, N.Y. TIMES (Apr. 15, 2020), https://www.nytimes.com/2020/04/15/parenting/fertility/ivf-unused-frozen-eggs.html.

[111] Frith & Blyth, *supra* note 47, at 519.

[112] *Id.*

[113] Daar, *supra* note 76, at 33.

[114] *Id.* at 34, n.55.

[115] Sarah Zhang, *IVF Mix-Ups Have Broken the Definition of Parenthood*, THE ATLANTIC (July 11, 2019, 2:23 PM), https://www.theatlantic.com/science/archive/2019/07/ivf-embryo-mix-up-parenthood/593725/.

[116] *Id.*

[117] *Id.*

[118] *Id.*

of some of the complications and conflict that follow from a lack of structure, clarity, and consistency in a regulatory scheme governing IVF and ARTs.

IV. POSSIBLE ALTERNATIVE CAUSES

The present regulatory structure surrounding ARTs has resulted in additional complications: the commodification of reproductive markets, a trend toward medical tourism, and increased frequency of disputes over embryos and parental rights. The task of the following section will be to explore possible forces that could explain the policy's evolutionary trajectory that resulted in this irregular and gap-ridden regulatory system.

A. It is "a business, not a research enterprise"[119]

One argument for the piecemeal regulation scheme governing ARTs and IVF is that state and local governments should be able to legislate for themselves and "in accordance with local values."[120] Beyond that, it is argued that the ART industry has "grown up" beyond the auspices of medical research.[121] Instead, ARTs and IVF have evolved as a business and the market has been commodified.[122] According to Sean Tipton, the chief lobbyist for the ASRM in 2015, the business orientation of the ART market does not mean that the market is "un-regulated."[123] There are the loose regulations and guidelines provided by the FDA and ASRM which are sufficiently supplemented by extensive "professional self-regulation"[124] that make up the difference from the absence of universal standards within the practices and administering of ART services.[125]

I posit that this business-minded alternative explanation for the current regulatory regime governing ARTs and IVF technologies fails to address, or even acknowledge, the gaps in the oversight that do exist. Moreover, the negative consequences that follow from the piecemeal regulatory structure seem to be written off as an acceptable result of the capitalist practices involved.[126] Beyond these problems, this approach also removes the fertility

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[119] Michael Ollove, *Lightly Regulated In Vitro Fertilization Yields Thousands of Babies Annually*, WASH. POST (Apr. 13, 2015), https://www.washingtonpost.com/national/health-science/lightly-regulated-in-vitro-fertilization-yields-thousands-of-babies-annually/2015/04/13/f1f3fa36-d8a2-11e4-8103-fa84725dbf9d_story.html (quoting Arthur Caplan, director of the division of medical ethics at New York University's School of Medicine).

[120] Frith & Blyth, *supra* note 47, at 519.

[121] Ollove, *supra* note 119 (quoting Debra Mathews of the Johns Hopkins Berman Institute of Bioethics).

[122] *Id.*

[123] *Id.*

[124] *Id.*

[125] *Id.*

[126] These capitalist practices—which are excessively intertwined with profit—are not limited to the fertility industry; this is a critique that has been made more broadly of the biosciences and medicine in general. *See generally* Martin McKee & David Stuckler, *The Crisis of Capitalism and the Marketisation of Health Care: the Implications for Public Health Professionals*, 1 J PUB. HEALTH RES. 236 (2012);

industry from the realm of medical sciences. By commodifying the industry and transplanting it into the capitalist market, it further obfuscates the deeply personal essence of ARTs and IVF practices.

B. Religious and Moral Concerns

Another alternative explanation emerges from the extensive scholarly work addressing the parallels between the abortion debate and IVF evolution in the United States.[127] Social and religious ideologies have influenced the debates around related practices in similar ways.[128] Despite the secularity of many patients and practitioners, religion is commonly evident in IVF clinics in the United States through "its shaping of the abortion debate, but also in the values and practices patients and physicians bring to their treatment."[129] The influence of religion in this context can be reduced down to the dispute over when life begins.[130] The exact point of the beginning of life varies depending on the religious—and sometimes political—affiliation.[131] This dispute over the start of life is also what makes the abortion debate controversial: at what point in the pregnancy is aborting the fetus considered murder? One aspect of why this start-of-life dispute is so influential is because, for abortion as well as some practices and procedures related to IVF and its research, embryos can be discarded and destroyed which has been vocally opposed by Protestant Evangelicals and some Republican politicians over the years.[132]

I assert that this alternative argument for the current regulatory structure is also insufficient. There is, undoubtedly, a deep and intrinsic connection between the debate over abortion and ART; however, this theory alone cannot explain the lack of universal regulation surrounding ARTs because abortion practices are more highly regulated with clearly defined state requirements than ART services, including IVF.[133]

John Launer, *Medicine Under Capitalism*, 32 POSTGRADUATE MED. J. (2015); Anthony Oakland, *Why capitalism is stunting science*, SOCIALIST APPEAL (July 23, 2019), https://www.socialist.net/why-capitalism-is-stunting-science.htm; Christy Ford Chapin, *What Historians of Medicine Can Learn from Historians of Capitalism*, 94 BULLETIN HIST. MED. 319 (2020).

[127] *See, e.g.*, Brezina & Zhao, *supra* note 19, at 5; Judith Daar & Kimberly Mutcherson, *Intersections in Reproduction: Perspectives on Abortion and Assisted Reproductive Technologies*, 43 J.L., MED. & ETHICS 174 (2015); Thompson, *supra* note 82, at 131; Epps, *supra* note 35.

[128] Thompson, *supra* note 82, at 130.

[129] *Id.*

[130] *Id.* (describing the relationship of various religious sects to beliefs about the moment when life begins; specifically, Catholics and Evangelical Protestants are associated with the belief that life begins at conception while many Anglicans, Muslims, Mormons, Jews, and secular Americans are affiliated with life beginning post-conception based on various things like implantation, fetal ability to suffer, viability, the development of the primitive streak, quickening, survival out of the womb, etc.).

[131] *Id.*

[132] *Id.* at 131.

[133] *An Overview of Abortion Laws*, GUTTMACHER INST. (Oct. 1, 2021), https://www.guttmacher.org/state-policy/explore/overview-abortion-laws.

C. Lack of Scientific Consensus

A final alternative argument for the piecemeal, or absence of, regulation over ARTs and IVF is two-fold: there is a perception that science and medicine do not have a clear consensus on some of the chief issues facing the ART industry.[134] Without a clear consensus agreed upon within the medical community—the community that is supposed to be providing information to the law regarding its practices—it could be asked, how could the law create a reasonable set of standards? While this is a reasonable question, I pose that this lack of clear consensus is not unique to the medical area of ARTs.[135] This lack of consensus has not limited other areas of medicine from being regulated; thus, to argue that a lack of consensus among ART physicians and researchers should reduce the amount of oversight is contrary to this theory's core assumption of the parallels between ARTs and other areas of medicine.

V. SCIENCE VS. THE LAW

None of the three alternative explanations for the absence of, or piecemeal compilation of, ART regulation has proven to be sufficiently vindicatory in nature to account for both the current state of regulation as well as the downstream side effects. I propose a final, two-part theory as an explanation the present situation. I contend that the interplay of a phenomenon called "the science lag" combined with a lack of communication between the medical sciences and the law is to blame for the current regulatory scheme.

It has been acknowledged by legal scholars for nearly a century that there is an extensive delay in the legal community's acknowledgement of any shift in understanding following scientific innovation.[136] In the years since the *Daubert* decision,[137] the thought that "[l]aw lags science; it does

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[134] *See* Richard J. Paulson, *The Unscientific Nature of the Concept that "Human Life Begins at Fertilization," and Why It Matters*, 107 FERTILITY & STERILITY 566 (2017), https://www.fertstert.org/article/S0015-0282(17)30036-5/fulltext; *but see Life Begins at Fertilization*, PRINCETON PROFILES, https://www.princeton.edu/~prolife/articles/embryoquotes2.html (last visited Dec. 12, 2020).

[135] *See, e.g.*, UNIV. PA. SCH. MED., *Lack of Consensus Among Health Care Providers in Identifying Sepsis Poses Threat to Treatment*, SCI. DAILY (Apr. 16, 2013), https://www.sciencedaily.com/releases/2013/04/130416102325.htm; Monika Hermann et al., *Lack of Consensus in the Choice of Termination of Pregnancy for Turner Syndrome in France*, 19 BMC HEALTH SERVS. RSCH. 1 (2019); Pamela S. Roberts et al., *The Lack of a Consensus Definition for Mild Stroke Impacts Health Services for Patients*, NEURODIEM (Feb. 12, 2020), https://www.neurodiem.ca/news/the-lack-of-a-consensus-definition-for-mild-stroke-impacts-health-services-3NXTOHGEMzvCZ93pa6boHP.

[136] Frederick K. Beutel, *The Lag Between Scientific Discoveries and Legal Procedures*, 33 NEB. L. REV. 1 (1953), https://digitalcommons.unl.edu/nlr/vol33/iss1/3/ ("It is a generally recognized fact that law and legal procedures lag far behind any type of social change. This is true even in matters of change in social custom, religion, and habits of the people. But it seems to be far more marked when one approaches the problem of picking up scientific developments and transposing them to be used as tools in legal and governmental procedures.").

[137] Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993); *see Law Lags Science? Not in The Ninth Circuit*, APP. STRATEGIST DRUG & DEVICE BLOG (May 15, 2014),

not lead it,"[138] as well as the subsequent academic acknowledgement of the law's failure to abandon "junk science" in criminal cases have been hot button issues.[139] In a field of medical science that is moving as fast as ARTs, it is not difficult to conclude that even if the law was receptive to the sciences, the law would be behind the times.

I contend that a lack of communication between the medical sciences and the law is an equal contributor to inefficient and ineffective regulation. Clark C. Havighurst gained prominence by promoting these ideas; I draw from his work in the creation of a forum. In an article from 2020, Havighurst argues that the American health care industry resides in a "legal environment featuring irrational rules and doctrines, conflicting paradigms, multiple policy-making authorities, and inconsistent public policies."[140] This has evolved historically, over the last fifty years, through several significant events involving legal change, where some "important implications of the legal changes were not recognized by the observant public, industry insiders, or even decisionmakers themselves."[141] Contrary to the idea that health care law has developed on a streamline or logical path, Havighurst argues that the health care industry has evolved due to a surprising degree of chance.[142] A similar underlying conclusion, that there is a "substantial gulf between the scientific and legal disciplines," was articulated by Harold Green almost thirty years ago.[143]

VI. HOW SHOULD WE REGULATE?

My suggestions for the path forward in ART regulation informed my theory of why ART regulation evolved to its current state: the dual problem of the science lag and the lack of communication between science and the law. By ameliorating these two problems, I assert that a path towards better regulation of ARTs is possible.

Two scholars' works have inspired my suggested reform: Steven Goldberg and Clark C. Havighurst. First, in the early 1990s, Goldberg emerged as a leading scholar in the law-science field.[144] He identified that

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https://www.appellatestrategist.com/2014/05/articles/drug-device/law-lags-science-not-in-the-ninth-circuit/.

[138] Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996).

[139] Jim Hilbert, *The Disappointing History of Science in the Courtroom: Frye, Daubert, and the Ongoing Crisis of "Junk Science" in Criminal Trials*, 71 OKLA. L. REV. 759 (2019).

[140] Clark C. Havighurst, *American Health Care and The Law — We Need to Talk!*, 19 HEALTH AFFS. 84, 84 (2020).

[141] *Id.* at 86.

[142] *Id.* While this argument poses broad sweeping conclusions about the American health care system as a whole, one underlying conclusion that can reasonably be extracted from this argument is that the regulation currently in place is not a function of successful dialogue between the medical and legal fields.

[143] Harold P. Green, *The Law-Science Interface in Public Policy Decision making*, 51 OH. ST. L.J. 375, 405 (1990); Micah L. Berman & Annice E. Kim, *Bridging the Gap Between Science and Law: The Example of Tobacco Regulatory Science*, 43 J.L. MED. ETHICS 95, 95 (2015).

[144] Green, *supra* note 143, at 376.

the point where tensions between law and science increase is when scientific research advances from basic research to its technological applications.[145] At the basic research level, the law has a "remarkable degree of deference to the scientific community" because research, alone, has little direct potential to cause injury.[146] When research evolves into technology, legal control takes over which results in a "'regulatory gap' between research and application with 'enormous practical consequences.'"[147] One way to narrow the regulatory gap, Goldberg argues, is by having scientists step into the role of "science counselor" who would help "shape science to meet regulatory constraints."[148]

Second, Havighurst has called for the creation of a permanent, professionally staffed Forum on Legal Issues in Health Care within the Institute of Medicine (IOM).[149] Havighurst's Forum would focus on the legal issues in health care, like the financing, delivery, and quality of personal health services rather than the general law affecting individual or public health or regulating biomedical research or biotechnology as such.[150]

My proposition would be a Goldberg-Havighurst hybrid approach at the micro-level—in the singular area of ART services. This would be in the form of a National Forum of individuals on both sides of the law-science gulf.

I assert that these initial regulatory reform Forum meetings should occur on a regular and frequent basis to catalyze policy change.[151] After initial regulatory reform is established, the Forum will transition to an upkeep or maintenance mission. The dialogue of information would be a permanent staple of the Forum, integral to the maintenance of the policy surrounding the ever-evolving field of ARTs.

From the medical arena would be science counselors: obstetricians, reproductive endocrinologists, psychologists, public health officials, PhD researchers specializing in fertility, ART directors and clinic directors, etc. From the legal field: public representatives or legislators, staffers, attorneys, etc. This Forum would, ideally, address the federal "regulatory gap" that currently exists by initially identifying the failures of the current regulatory scheme at both the state and federal level.[152] This evaluation would practically resemble the exchange and translation of information. The

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[145] *Id.* at 377; Steven Goldberg, *The Reluctant Embrace: Law and Science in America*, 75 GEO. L.J. 1341, 1352 (1987).

[146] Green, *supra* note 143, at 377; Goldberg, *supra* note 127, at 1352.

[147] Green, *supra* note 143, at 378; Goldberg, *supra* note 127, at 1368.

[148] Green, *supra* note 143, at 378; Goldberg, *supra* note 127, at 1379.

[149] Havighurst, *supra* note 140, at 103.

[150] *Id.*

[151] Perhaps these meetings need to be held as frequently as multiple times a month over the duration of a year, or more.

[152] The exact process of appointment or selection for Forum representatives is not outlined in this note. This topic would require more extensive discussion than is possible in this context, as any appointment like this would be inherently politicized leading to the potential for bias and disruption of the objectivity of the Forum.

scientific representatives would present information regarding the current state of the ART itself, upcoming technological advancements, and areas of concern—from the medical and public health perspective—for increased likelihood of litigation resulting from practices or methodologies within the fertility industry. Next, the legal representatives could explore the condition state of the law and observable legal consequences that result from the present legal framework (including ongoing disputes in court, concerns raised by constituents, and interpretational challenges that triers of fact face in litigation when addressing issues pertinent to ART legislation and regulation). In the initial attempts to understand the need for reform, there would ideally be an opportunity for public comment so that constituents and general members of the public could express existing concerns related to ART services and the fertility industry.[153]

The establishment of the Goldberg-Havighurst hybrid forum would increase the communication between the law and this specialized area of medical sciences through the occurrence of the Forum meetings, alone. The nature of the informational exchange allows both sides of the law-science divide to acquire information possessed by the other. This informational exchange is vital to mitigate the science lag. In the long term, the ongoing meetings of the Forum ensure the ART policies continue to accurately address the needs and concerns of the fertility industry. By continuing the channel of communication between the science counselors and the policy makers, the legal representatives in the Forum will have first-hand access to scientific innovation, thus significantly diminishing the temporal delay that creates the scientific lag.

The forum would have the potential to greatly mitigate the negative downstream consequences that accompany the loose legal climate that governs ARTs. After initial regulatory reform is made, this would—ideally—establish a universal set of standards and practices to govern the fertility industry. The creation of uniform national standards alone would significantly the potential for domestic medical tourism because the regulations would not vary geographically. Beyond resolving the jurisdictional inconsistencies, a set of uniform national standards from an initial regulatory reform would allow for better understanding of the need for subsequent reform that would best alleviate the occurrence of gaps in insurance coverage that make IVF cost prohibitive. Beyond these effects, by establishing clear and definitive expectations of the physicians and the outcomes of the ART procedures, it could: (1) reduce the leeway affording providers discretion that allows for discrimination, (2) establish explicit standards for pre-ART consent and contracting to curtail disputes over embryos, and (3) positively delimit the boundaries of parenthood and rights of the various parties involved in ARTs.

[153] Perhaps this could even take the form of something like an amicus brief.

According to Berman and Kim, regulatory reform that only focuses on increased communication between the sciences and the law does not go far enough to actually effect the regulatory scheme.[154] They posit that, to actually facilitate the development of policy-relevant research to impact the regulatory structure there must be funding mechanisms and professional incentives for scientists and policy decisionmakers that encourage collaboration.[155] While these concerns about the extent of progress achievable through merely "increased communication" are valid, my approach is a slight variation on the criticized regulatory reform. Instead of having reform that only focuses on increased communication (meaning increased communication is the product of reform), I propose that increased communication inform and instruct the trajectory of policy change (using the increased communication as the means to the ends of regulatory reform). While the exact progress possible at the hands of the Forum is not entirely clear, there is significant potential for improving multiple areas of administering ARTs and patient care. Specifically, the Forum could guide policy reform in a direction to insure better access, provide more equitable patient care, and even establish fertility services an essential health service under the Affordable Care Act—diminishing the economic impact on individuals. In this way, my proposed Forum circumvents the concerns of this objection and, without further concerns, poses to be a viable method of establishing a new regulatory structure in this niche medical field.

CONCLUSION

Over the last forty years, the popularity of seeking ART treatments has continued to burgeon. To be frank, the science has grown beyond its britches. Since the infertility industry grew so rapidly, individual scientists and institutions have turned their focus to the immediate issues at hand as opposed to maintaining an eye for the big picture and its long-term efficiencies. A medical procedure that has a strong foothold in the capitalist market is not new or uncharted territory. What makes infertility different from other capitalist medical subspecialities, such as cosmetic surgery, is the inherent ethical treatment and recognition of an additional "life."

My proposed Forum provides a pathway toward efficiency and unification through a marriage of science and the law. By diminishing the science lag and increasing communication between science and the law, the regulatory reform has the potential to greatly improve consumption of fertility treatments across a wide socioeconomic and cultural community in the United States.

The current self-regulation of the infertility industry has shown to be insufficient. Yet, any reform will invariably be met with resistance. Neoclassicism assumes that individuals will act in ways that maximize

[154] Berman & Kim, *supra* note 143, at 98.
[155] *Id.*

utility and in accordance with rationally upholding their long-term best interests.[156] Many philosophers and legal scholars have shown that these neoclassical assumptions fail in the setting of economics.[157] The failure of the ART industry to self-regulate in accordance with its best interest is another example of neoclassical assumptions falling short. The evolution of ART has been over several decades and the solution will not be instantaneous; yet every attempt to create a more comprehensive and universal set of guidelines will be progress in the right direction.

[156] Christine Jolls et al., *A Behavioral Approach to Law and Economics*, 50 STAN. L. REV. 1471 (1997).

[157] *Id.*