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Regulating Devices that Create Life

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In vitro fertilization (IVF) led to approximately 74,590 births in 2018.[1] IVF success rates have increased roughly three-fold since the first live birth in 1978. Yet today the chance of giving birth using IVF is barely better than a coin toss, even for the youngest, healthiest patients.[2] Scientists and industry are pursuing methods to improve IVF success rates. However, many clinics seem unconcerned with the effectiveness of new methods. Marketing of these methods, so-called IVF "add-ons," to vulnerable patients seeking to start a family has led to calls for greater regulatory scrutiny.[3]

Add-ons include methods such as selecting the "best" sperm in a semen sample, or artificially "activating" eggs to prepare embryos for transfer to a uterus.[4] They run from a couple hundred dollars to more than ten thousand dollars. Data on their utilization is limited, but one estimate suggests that 74 percent of fertility patients used at least one add-on.[5]

Most notoriously, the practice of preimplantation genetic screening or preimplantation genetic testing for aneuploidies (PGS or PGT-A) is used to identify (and usually discard) embryos that show an abnormal number of chromosomes.[6] Mounting evidence illustrates that the $6,000–$12,000 test is not a good predictor of whether an embryo will develop into a healthy baby; one estimate suggests that approximately 40 percent of healthy embryos may have been unnecessarily discarded based on PGS results.[7] While the test may accurately identify cells exhibiting

[1] Society for Assisted Reproductive Technologies, National Summary Report 2018, www.sartcorsonline.com/rptCSR_PublicMultYear.aspx?reportingYear=2018#.

[2] Society for Assisted Reproductive Technologies, National Summary Report 2017, www.sartcorsonline.com/rptCSR_PublicMultYear.aspx?ClinicPKID=0#patient-cumulative.

[3] Pamela Mahoney Tsigdinos, The Big IVF Add-On Racket, N.Y. Times (Dec. 12, 2019).

[4] Alessandra Alteri et al., The IVF Shopping List: To Tick or Not to Tick, 4 EMJ 14 (2019).

[5] Human Fertilisation and Embryology Authority, Treatment add-ons (2019), www.hfea.gov.uk/treatments/explore-all-treatments/treatment-add-ons/.

[6] Stephen S. Hall, Tens of Thousands of Women Thought They Couldn't Have Babies. But What If They Could, N.Y. Mag. (Sept. 18, 2017).

[7] Richard J. Paulson, Preimplantation Genetic Screening: What Is the Clinical Efficacy? 8 Fert. Steril. 228 (2017).

aneuploidies, many questions remain regarding whether and how those results predict the health of a child resulting from the embryos tested. This means that many patients' hopes at biological parenthood may have been squandered due to their reliance on an expensive, erroneous test. To date, there has been no regulatory activity in the United States to stop clinics from making claims about, providing, or charging for PGS testing.

This chapter describes the genesis of the direct-to-consumer nature of the US fertility services market that makes consumers uniquely susceptible to offers of unproven technologies in hopes of increasing their likelihood of pregnancy success. It explores the many modes of regulation in the United States and their shortcomings as well as the limits of the Food and Drug Administration's (FDA's) lack of jurisdiction over embryos and the tests used to select and modify them. In light of these limitations, the chapter concludes by posing a two-pronged path forward to address the most pressing concerns about add-ons: 1) amendments to existing federal law to require fertility clinics and labs to report a list of all services they offer patients and tie their utilization to rates of success and 2) Federal Trade Commission enforcement action against clinics who make deceptive and/or unsupported claims about add-ons and other technologies.

15.1 FERTILITY SERVICES DIRECT-TO-CONSUMER MARKET

Modern assisted reproduction in the United States is a health care anomaly. First, fertility treatments are not consistently covered by private or public insurance, although coverage has increased in recent years. Consumer patients are cost-sensitive and will select providers based upon particular services offered.[8] Patients do not benefit from signals of necessity or quality from insurance companies' coverage decisions. People seeking fertility treatments rely heavily on the Internet and fertility center websites to inform their choices.[9] The resulting direct-to-consumer fertility markets makes the veracity of claims made by clinics critical to ensure consumers make informed choices. Yet, most fertility clinic websites do not comply with the guidelines outlined by the American Medical Association or the industry's own self-regulatory body.[10]

[8] Debora L. Sparr, The Baby Business: How Money, Science, and Politics Drive the Commerce of Conception (2006).

[9] Huang et al., Internet Use by Patients Seeking Fertility Treatment, 83 Int. J. Gynecol. Obstet. 83 (2003); EC Haagen et al., Current Internet Use and Preferences of IVF and ICSI Patients, 18 Hum. Rep. 2073 (2003).

[10] Robert Klitzman et al., Preimplantation Genetic Diagnosis (PGD) on In-Vitro Fertilization Websites: Presentations of Risks, Benefits, and Other Information, 92 Fert. Steril. 1276 (2009); Mary E. Abusief et al., Assessment of United States Fertility Clinic Websites According to the American Society for Reproductive Medicine (ASRM)/Society for Assisted Reproductive Technology (SART) Guidelines, 87 Fert. Steril. 88 (2007).

The medical component of the fertility industry does not act alone. Physician-run clinics interact with other for-profit players including multi-million-dollar sperm banks and agencies that broker provision of sperm, eggs, embryos, and surrogacy services. These transactions take place outside the context of any physician-patient relationship and contribute to the transactional atmosphere of fertility services. The market creates competition for patients and an incentive for providers to distinguish themselves by offering services that could improve patient consumers' likelihood of success.

Second, fertility innovation has been left to rely on private funds due to a ban on government funding.[11] Public funding triggers ethical obligations in developing new technologies, including informed consent requirements. Without public funding, fertility innovation occurs free from restrictions placed on most biomedical research. Coupled with its transactional nature, it is no surprise that fertility clinics offer and sell unproven add-ons in order to attract patients. At best, this means that empowered consumers are knowingly subsidizing the development of unproven technologies in hopes they might be lucky. At worst, vulnerable consumers are being exploited to spend significant funds for futile or harmful services they believe increase their odds of success.

The dangers of add-ons seem to be precisely the type of threat to public health that state medical boards and the FDA are designed to address – to eliminate unsafe or unproven medical interventions from the market or to "assur[e] the safety, effectiveness, quality, and security"[12] of medical interventions. Could the FDA not regulate these new technologies as medical devices applied to the earliest forms of human life? These questions are addressed in the following sections.

15.2 THE US FRAGMENTED PATCHWORK OF ART REGULATION

Federal oversight over the Assisted Reproductive Technology (ART) industry is well discussed within the academic literature and the popular press. Many have called the United States the "wild west";[13] however, as one of the editors of this volume points out, a number of mechanisms moderate behavior in US ART markets, resulting in a fragmented patchwork of regulation.[14] In fact, the American Society for Reproductive Medicine (ASRM) claims that "Assisted Reproductive Technologies are among the most regulated medical procedures in the United States."[15]

[11] Omnibus Appropriations Act of 2009, Pub. L. No. 111–118, § 509(a)(2).

[12] US Food & Drug Admin., FDA Fundamentals, www.fda.gov/about-fda/fda-basics/fda-fundamentals.

[13] Judith Daar, Federalizing Embryo Transfers: Taming the Wild West of Reproductive Medicine?, 23 Colum. J. Gender & L. 257 (2012).

[14] I. Glenn Cohen, The Right to Procreate in Assisted Reproductive Technologies in the United States, in Oxford Handbook of Comparative Health Law (Tamara K. Hervey & David Orentlicher eds., forthcoming).

[15] American Society for Reproductive Medicine, Oversight of Assisted Reproductive Technology (2010), www.asrm.org/globalassets/asrm/asrm-content/about-us/pdfs/oversiteofart.pdf.

If the United States is the "wild west" of ART, it is not because there are no sheriffs in town. There are multiple sheriffs, mayors, and informally deputized leaders each trying to address their own overlapping concerns. Some of these regulations and private law controls are discussed in this section.

15.2.1 *Federal Regulation of Fertility Industry & Reproductive Medicine*

Within the federal government, four agencies regulate ART: the FDA, the Centers for Medicare and Medicaid Services (CMS), the Department of Health and Human Services, through the Centers for Disease Control (CDC), and the Federal Trade Commission (FTC). The FDA regulates the approval of fertility drugs and requires gamete screening to prevent transmission of communicable diseases. The future of the role of the FDA and FTC will be further discussed in Sections 15.3 and 15.4 respectively.

CMS regulates laboratories through the Clinical Laboratory Improvement Amendment of 1988 (CLIA).[16] However, CLIA applies to tests connected with human diagnoses, such as testing blood or semen for fertility-related issues; it does not extend to testing on embryos.

The Department of Health and Human Services (through the CDC) is explicitly charged with oversight of ART. The Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA) requires fertility clinics to report their success rates and ART data.[17] The FCSRCA was passed in light of public concern with fertility clinics overstating the likelihood of success to prospective patients. FCSRCA also attempts to step in where CLIA leaves off by issuing model guidance for embryology laboratory certification. However, there is no enforcement mechanism to compel clinics to comply, and the model recommendations create no legal obligation for labs to adopt them.[18]

Finally, the FTC has broad authority to prohibit "unfair or deceptive acts or practices affecting commerce."[19] The billion-dollar fertility industry clearly affects commerce and falls under FTC control. In contrast to FCSRCA, the FTC Act includes enforcement power. The FTC previously exercised its authority in fertility services when it filed charges for deceptive practices against five clinics for misrepresenting their success rates in October 1992.[20] Additionally in July 1995, the FTC authored an editorial in the leading journal of reproductive medicine in which it described its "concerns with advertising pregnancy success rates."[21]

[16] 42 U.S.C. § 263a (2019).
[17] Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102–493, 106 Stat. 3146.
[18] 64 Fed. Reg. 39,374.
[19] 15 U.S.C. § 45 (2019).
[20] Robert Pear, Fertility Clinics Face Crackdown, N.Y. Times (Oct. 26, 1992).
[21] Michael A. Katz, Federal Trade Commission Staff Concerns with Assisted Reproductive Technology Advertising, 64 Fert. Ster. 10 (1995).

15.2.2 *State Regulation of Fertility Industry and Reproductive Medicine*

State practice of medicine laws, including licensing of medical professionals, facilities, laboratories, and pharmacies, apply to ART. State medical boards could act to suspend or revoke licenses if clinics or providers make false claims about their success or perform procedures that harm their patients. However, reliance on practice of medicine and licensing may be ineffective; state medical boards are reticent to turn against one of their own even in the face of repeated patterns of bad behavior.[22]

Much of the innovation in the space of reproductive medicine is happening in the laboratory, not the clinic, and procedures are performed by embryologists (scientists usually with masters or doctorate level training who create and manipulate embryos), not physicians. States do not license embryologists; like laboratories, embryologist certification is available but optional.[23] IVF clinics rarely require a license of the physical space separate from the professional license held by the providers who practice within it. Without enacting licensing and regulatory authority over labs, clinics, and embryologists, states currently have little ability to intervene. However, there has been some recent legislative action to require licensing of labs that handle embryos.[24]

State law also governs tort claims for medical malpractice or other harms caused by mistakes in the fertility industry. However, the tort system leaves plaintiffs, in cases against fertility clinics and laboratories, empty handed due to its unwillingness or inability to recognize and monetize the types of harms caused by mistakes in reproduction.[25] Finally, similar to the FTC at the federal level, state attorneys general have enforcement power over fraud and unfair trade practices within their state, but none have taken actions similar to the FTC's.

15.2.3 *Professional Self-Regulation*

Professional self-regulation plays an important role in the US fertility market. ASRM is the most influential governing body; its Practice and Ethics Committees issue guidelines and reports on clinical practice and guiding principles, respectively.[26] Compliance with ASRM recommendations is not legally required, nor does ASRM have enforcement power. In addition, ASRM has been criticized for its inherent conflict of interest, since its members are those that have a financial stake in the industry's success.[27]

[22] Dov Fox, Birth Rights and Wrongs: How Medicine and Technology are Remaking Reproduction and the Law 27 (2019).
[23] American Society for Reproductive Medicine, supra note 15.
[24] Assemb. 4605, 218th Leg. (N.J. 2018).
[25] Fox, supra note 22.
[26] Daar, supra note 13.
[27] Andrea Preisler, Assisted Reproductive Technology: The Dangers of an Unregulated Market and the Need for Reform, 15 DePaul J. Health Care L. 213 (2013).

The ASRM Ethics Committee issued an opinion on innovative new techniques in 2015. It stated:

> Consider the consequences of bringing interventions to practice before they have been adequately studied and sufficiently validated … a new practice becomes commonplace before there is evidence to support its effectiveness … enthusiasm to address a vexing clinical problem led to the premature adoption of a new treatment. Such enthusiasm can lead to dissemination of an innovative treatment through media reports, lectures, and conferences before adequate data are available and before peer review has been accomplished. Early adoption can be confusing for patients, who may not understand that a treatment they have read about lacks a basis in evidence and may, in fact, do them more harm than good.[28]

The tension between the benevolent desire to help patients and the ethical necessity for patience to first produce robust and reliable data, coupled with the lack of federal funding leaves clinics with three options: 1) subsidize research – bear the cost of innovation and do not charge patients for unproven procedures/new technologies; 2) focus on static clinical care and refuse to offer any innovative treatments to patients; or 3) adopt a problematic hybrid approach by charging patients for unproven innovative treatments. This third scenario – of conflating research (generating generalizable knowledge through a process in which patients understand they may not benefit from participation) and clinical care – is the problematic approach the ASRM guidance seeks to discourage; it is also the behavior that has given rise to the growing number of stories of patients who needlessly lost embryos due to the widespread use of PGS and calls for concern over add-ons.

15.3 FDA REGULATION OF REPRODUCTIVE TECHNOLOGY DEVICES (OR EMBRYOS?)

The FDA's regulation of ART is limited to its authority under the Food Drug and Cosmetic Act (FDCA)[29] and the Public Health Services Act (PHSA).[30] The jurisdictions of the FDA depends upon how a technology is used and how embryos are characterized. Coherently regulating many facets of ART under the FDCA and/or PHSA would require the FDA to decide: if an embryo is legally equivalent to a human warranting protection and the objects of regulation the devices used to manipulate it, or if the gestating human is to be protected and the embryo the object of regulation as a "biological product" or "drug" used to create a pregnancy. The legal, ethical, and political implications of such a determination may be one of many reasons the FDA has not actively exercised enforcement powers over add-ons and why categorization of embryos and ART innovations remains unclear. Since

[28] Ethics Committee of the American Society for Reproductive Medicine, Moving Innovation to Practice: a Committee Opinion, 104 Fert. Steril. 39, 40 (2015).
[29] 21 U.S.C. § 321 (2019).
[30] 42 U.S.C. § 262 (2019).

2015, Congress has signaled annually that it does not want to empower the FDA to make determinations with such vast societal implications.[31]

The FDA has classified one device used to manipulate embryos for implantation. This move implicates its jurisdiction over such devices; it also illustrates that it may be an ineffective regulator even if doing so is a proper exercise of its jurisdiction.

15.3.1 *Are Add-Ons Devices?*

Section 201(h) of the FDCA defines a medical device as "an instrument, apparatus . . . or other similar or related article . . .

2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
3) intended to affect the structure or any function of the body of man or other animals."[32]

To illustrate, consider lasers used for "assisted hatching." The laser is intended to weaken the outer layer of cells (the structure and function) of the embryo prior to implantation to increase the chances of implantation in the uterine wall. If lasers are medical devices, it would follow that the FDA concluded that the embryo is "body of man or other animals." As discussed below, if the "device" is intended to treat infertility, then the embryo would be the device itself, not the laser that manipulated it.

In 2004, the FDA received a premarket notification and a request for device classification for "Assisted Reproduction Laser Systems."[33] It granted the request and issued guidance to ensure its use is safe and effective.[34] Conversely, the Human Fertilisation and Embryology Authority (HFEA) in the United Kingdom deemed assisted hatching "experimental" and found no evidence of safety and effectiveness, and other researchers agree.[35] Guidance from the FDA identified many of the risks that have come into focus since 2004, including "damages to the embryo" and "ineffective treatment."[36] There have long been concerns about the FDA's ability to effectively compel postmarket surveillance that would be needed in light of the mounting evidence.[37] Taken collectively, FDA regulation of assisted hatching lasers

[31] Consolidated Appropriations Act of 2016, Pub. L. No. 113–114, § 749, 129 Stat. 2244; I. Glenn Cohen et al., Gene Editing Sperm and Eggs (not Embryos): Does it Make a Legal or Ethical Difference?, 48 J. L. Med. Ethics 619 (2020).

[32] 21 U.S.C. § 321(h).

[33] 21 C.F.R. § 884.6200(a).

[34] US Food and Drug Administration Reclassification Order 510k number K040045 (Nov. 4, 2004), www.accessdata.fda.gov/cdrh_docs/pdf4/K040045.pdf.

[35] Human Fertilisation & Embryology Authority, Treatment add-ons, www.hfea.gov.uk/treatments/treatment-add-ons/; Alteri et al., supra note 4.

[36] Id.

[37] Bridget M. Kuehn, IOM Urges FDA to Be More Aggressive in Monitoring Safety of Approved Drugs, 307 JAMA 2475 (2012).

may be a case study to illustrate that even if the FDA appropriately exercised its jurisdiction over medical devices (which is a big if), it is ill-suited to regulate effectively.

Now consider PGS. PGS is used to identify a condition – having an abnormal number of chromosomes. However, PGS tests an embryo, not "man or other animals." The FDA has asserted its enforcement power over genetic tests for human medical conditions;[38] however, FDA guidance regarding in vitro diagnostic testing expressly excludes "pre-implantation embryos," suggesting that a diagnostic device used on an embryo does not trigger the same regulatory attention as the homologous test on a human.[39]

15.3.2 *Are Add-On-Manipulated Embryos Biological Products or Drugs?*

The FDA regulates biological products through the PHSA,[40] and its applicability to the provision of sperm and eggs is often cited as the FDA's "only" role in regulating fertility services.[41] The purpose of the PHSA is to prevent the introduction, transmission, or spread of communicable disease (not ensure safety and efficacy of any clinical interventions).[42] Under the law, a biological product is:

> a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component . . . or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings.[43]

It is not clear that an embryo is an "analogous product." The listed products are components of a biological organism while an embryo is an organism in itself.[44] However, the FDA lists embryos as biological products in guidance regarding which types of biological specimens are considered biological products and which are devices.[45] Regulating embryos as biological products does not address the concerns raised by IVF add-ons. The purpose of regulating biological products is to prevent communicable disease transmission, so they do not undergo premarket review.

[38] Elizabeth R. Pike & Kayte Spector-Bagdady, Device-ive Maneuvers, FDA's Risk Assessment of Bifurcated Direct-to-Consumer Genetic Testing, in FDA in the 21st Century: The Challenges of Regulating Drugs and New Technologies 470 (Holly Fernandez Lynch & I. Glenn Cohen eds., 2015).

[39] Reference to FDA Guidance for Next Generation Sequencing and IVDs, www.fda.gov/media/99208/download.

[40] 42 U.S.C. § 262.

[41] I. Glenn Cohen et al., Losing Embryos, Finding Justice: Life, Liberty, and the Pursuit of Justice, 169 Ann. Internal Med. 800 (2018).

[42] 42 U.S.C. § 262(i)(1).

[43] Id.

[44] Elizabeth C. Price, Does the FDA Have Authority to Regulate Human Cloning?, 11 Harv. J. L. & Tech 619 (1998).

[45] FDA Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P's) Product List, www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/fda-regulation-human-cells-tissues-and-cellular-and-tissue-based-products-hctps-product-list.

However, different regulations apply if the product is more than "minimally manipulated."[46] The FDA has concluded that technologies such as human cloning and mitochondrial transfer constitute more than minimal manipulation and make them biologic drugs requiring premarket approval before use.[47] Some, but not all, add-ons would move embryos out of the "biological product" definition. Embryos screened for aneuploidy with PGS might remain biological products if the screening is considered minimal manipulated while others (such as embryos punctured to encourage hatching) would be considered drugs, adding further confusion to the regulatory patchwork.

Assuming an embryo is an analogous biological product or a drug depending upon how manipulated it is, the definition of a drug poses an additional question – is an embryo an article intended to affect the structure of function of the body? Its effect on the gestating person's body is the most compelling jurisdictional hook for FDA regulation of manipulated embryos as drugs. Courts have upheld the FDA's jurisdiction over regenerative medicine for similar biological specimens being (re) implanted into humans for treatment.[48] However, if add-on-manipulated embryos are drugs, every unique, manipulated embryo created could require preapproval. Such a regulatory scheme would likely bring using add-ons and the innovation creating them to a screeching halt.

Perhaps more importantly, such a conclusion, that a human embryo is the object of federal regulation, signals other normative values, which administrative agencies are not empowered to impose.

15.3.3 *Should Congress Expand FDA Jurisdiction to Include Embryos and the Devices Used to Manipulate Them?*

Currently, FDA regulation of manipulated embryos intended for transfer into a uterus to create a pregnancy is unclear at best. At worst, it is incoherent and intentionally obfuscated in order to side-step thorny ethical and political issues or to further particular ethical views. It is impossible for the FDA to regulate add-on-manipulated embryos without signaling their moral status as either worthy of protection like people or as articles to be regulated like devices, and administrative agencies are not the appropriate bodies to make such determinations.

Congress could address the issue by enacting legislation to expand the FDA's power to include regulation of human embryos; however, this is a politically untenable solution. Suppose conservative legislators proposed treating embryos like people, making nearly all add-ons drugs or devices. Such a move would raise questions about the permissibility of all IVF because the majority of cycles result

[46] 21 C.F.R. § 1271.3(f).

[47] Myrisha S. Lewis, Halted Innovation: The Expansion of Federal Control Over Medicine and the Human Body, 5 Utah L. Rev. 1073 (2018).

[48] United States v. Regenerative Sciences, LLC, 741 F.3d 1314 (D.C. Cir. 2014).

in discarding one or more embryos, and even conservative constituencies want access to IVF. Second, more liberal lawmakers are unlikely to favor federal oversight of ART. Many might fear that any federal regulation of reproduction, particularly one that implicates the legal status of embryos, could jeopardize reproductive justice by inviting restrictive regulations such as restricting access to abortion.

In sum, trying to twist the FDA's mandate into a mechanism to regulate add-ons or attempting to pass new legislation to expand its mandate are not feasible options. Even if either was successful, expanding the FDA's jurisdiction would only create an incomplete method to address the mounting concerns raised by information provided to patients about the value of add-ons in improving the likelihood of achieving a healthy, successful pregnancy.

15.4 MOVING CONSUMER PROTECTION (AND INNOVATION) FORWARD

In many ways, the HFEA in the United Kingdom provides the ideal example for the United States to adopt.[49] It would consolidate oversight into a central, federal agency and provide consumer-centric information to inform decision making. However, federal action to create a new agency charged with overseeing embryos and the fertility industry is not a pragmatic resolution for many of the same reasons a change to the FDA's charge is unlikely.[50]

Similarly, state action to regulate in this space may be difficult. Even if state action is plausible, forum-shopping lessons learned from areas related to ART governed by state law (such as surrogacy) teach us that national-level control is desirable. In light of these limitations, I propose a two-pronged solution: 1) amendments to FCSRCA to require fertility clinics and labs to report a list of all services it offers patients, and 2) enforcement by the FTC. In sum, the approach taken almost thirty years ago to rein in fertility clinics overstating their success rates should be similarly utilized to protect consumers from unproven add-ons that claim to improve success.

First, Congress should amend the FCSRCA to require clinics and labs to report a list of services it offers to its patients, particularly those it lists on its website and in promotional materials. In addition, it should expand reporting to link utilization of those technologies with the success rate reporting already required such as confirmed pregnancy and live births. While such a system would not offer the gold standard of randomized controlled trials for new technologies, it would generate retrospective studies to provide indicators of effectiveness. The additional reporting could provide an imperfect postmarket surveillance mechanism. As noted above, the FDA has underperformed in postmarket activity even in areas in which its regulatory power is clear. If a clinic is consistently selling its patients laser-assisted hatching but

[49] Gladys B. White, Crisis in Assisted Conception: The British Approach to an American Dilemma, 7 J. Women's Health 321, 327 (1998).

[50] Alicia Oullette et al., Lessons Across the Pond: Assisted Reproductive Technology in the United Kingdom and the United States, 31 Am. J. L. & Med. 419 (2005).

there is no evidence that it improved rates of success, clinics could be held accountable for representations made to patients about the value of assisted hatching.

Revisions to the FCSRCA could also include a mechanism by which the CDC, much like the United Kingdom's HFEA, could grade innovations based upon the data collected, and disseminate the evaluation publicly. This proxy for necessity/value addresses one of the unique problems posed by the direct-to-consumer nature of fertility services and could fill the void left by the lack of insurance providers' coverage decisions. Fertility market consumers' propensity to turn to the internet for guidance regarding fertility treatments suggests this could be an effective way to protect them from paying for unproven services. In addition, the data could be used by the FTC to trigger disclamatory language requirements or limit the types of representations that players in the ART market can make to consumers.

Amendments to the FCSRCA are politically feasible. Expanded reporting requirements do not involve governmental judgments regarding when life morally and legally begins. Moreover, the current political moment resembles the conditions that gave rise to the FCSRCA in 1992 – there is growing concern with new technologies thanks to popular press coverage.

To address pushback from the industry due to the cost of additional reporting requirements, Congress could make the legislation more attractive by limiting the FDA's role as it did regarding in the original FCSRCA, and explicitly place embryos and the devices used to manipulate them outside of the FDA's wheelhouse. Reporting requirements may seem like an inexpensive price to pay for protection from a more cumbersome regulatory scheme like premarket FDA approval.

Second, the FTC should exercise its enforcement power against clinics and labs that make unsubstantiated claims about the efficacy of add-ons. Given previous FTC activity on the heels of FCSRCA's passage, amendments to the FCSRCA and the public attention that could follow may be a good catalyst to motivate FTC enforcement. Expending federal funds is justified in light of the size of the fertility market. This work undertaken in conjunction with an updated FCSRCA would allow the FTC to gauge the veracity of claims clinics make about the ways the services they provide improve the likelihood of success. This is strikingly similar to the claims the FTC brought in the 1990s when clinics inflated or used deceptive methods of calculation to inflate about their IVF success rates.

As for those claims that may not go so far as to be deceptive but raise concerns given the consumer reliance on the clinic's expertise, FTC regulation of over-the-counter drugs and cosmetics advertising may be a helpful analogy to consider; it requires advertising to be truthful and substantiated by evidence.

In addition, FTC enforcement could apply across other parts of the fertility industry, including sperm, egg, and surrogacy brokers, and could be a centralized "sheriff." For example, sperm and egg banks make problematic representations regarding the traits and anonymity of sperm and egg providers. The FTC could provide an effective mechanism to address these concerns.

15.5 CONCLUSION

Consumers are willing to pay an unusually high emotional, physical, and financial price to have a chance at becoming a genetic parent. The evolution of the consumer-centric US fertility market and inefficient patchwork of overlapping regulatory bodies and legal systems has left them without sufficient safeguards against purchasing unproven interventions to increase their likelihood of success. The FDA is the familiar actor to protect patient consumers from unproven treatments; however, it is not clear if it is legally empowered to exercise jurisdiction, and it is undesirable and infeasible for Congress to expand its purview.

Greater FTC enforcement and legislation to expand reporting requirements represent politically feasible, appropriately consumer-protective, and innovation-preserving options to address the challenges posed by innovation in this unique industry. Hopefully, these changes will avoid a repeat of the devastating reality faced by many patients whose embryos were perhaps prematurely discarded and protect intended parents from harmful or opportunistic behavior in an already physically, emotionally, and financially draining process.