

# Northwestern Journal of International Law & Business

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Volume 39

Issue 2 *Winter*

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Winter 2019

## The 'Wild West' of Medicine: An Argument for Adopting the United Kingdom's 'HFEA' Framework, to Improve the Market for Assisted Reproduction in the United States

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### Recommended Citation

Ellen S. Fischer, *The 'Wild West' of Medicine: An Argument for Adopting the United Kingdom's 'HFEA' Framework, to Improve the Market for Assisted Reproduction in the United States*, 39 NW. J. INT'L L. & BUS. 225 (2019).  
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# The ‘Wild West’ of Medicine: An Argument for Adopting the United Kingdom’s ‘HFEA’ Framework, to Improve the Market for Assisted Reproduction in the United States

*Ellen S. Fischer*\*

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## I. INTRODUCTION

There is only one piece of federal legislation in the United States that explicitly regulates in vitro fertilization (“IVF”), called the United States Fertility Clinic Success Rate and Certification Act, which lays out success rate reporting requirements. Other pieces of federal legislation relate only tangentially to assisted reproduction or fertility clinics, which leads to redundancy and gaps in regulation, and, therefore, greater costs to consumers seeking service in the assisted reproduction market.

This paper will review how the current state of legislative redundancy and gaps creates negative incentives for assisted reproduction providers and poses risks for their customers of their services. I argue that the United States should adopt a regulatory scheme over the assisted reproduction market that is of similar rigor to the Human Fertilisation and Embrology Act scheme in the United Kingdom. By reviewing the process of assisted reproduction (specifically, in vitro fertilization), the risks to which patient-consumers are exposed, the lack of remedy in the current legal landscape, and the successes of the Human Fertilisation and Embrology Authority of the United Kingdom, I will show that legislation on assisted reproduction will help improve the protections for customers in the assisted reproduction market of the United States.

The executive director of the Center for Genetics and Society, Marcy Darnovsky, called the United States “the wild west of the fertility industry,” a sentiment echoed by many others in the field.<sup>1</sup> Because fertility touches on conception and embryos, which can be hot-button political issues, lawmakers have been resistant to touch it.<sup>2</sup> Assisted Reproductive

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<sup>1</sup> Michael Ollove, *Lightly Regulated In Vitro Fertilization Yields Thousands of Babies Annually*, THE WASHINGTON 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?utm\\_term=.7cafd4cd9bcf](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?utm_term=.7cafd4cd9bcf). For an article that describes effects that an absence of regulation has on the assisted reproduction market in terms of embryo storage, see Ariana Eunjung Cha, *The Struggle to Conceive with Frozen Eggs*, THE WASHINGTON POST (Jan. 27, 2018), [https://www.washingtonpost.com/news/national/wp/2018/01/27/feature/she-championed-the-idea-that-freezing-your-eggs-would-free-your-career-but-things-didnt-quite-work-out/?utm\\_term=.4de8addcd606](https://www.washingtonpost.com/news/national/wp/2018/01/27/feature/she-championed-the-idea-that-freezing-your-eggs-would-free-your-career-but-things-didnt-quite-work-out/?utm_term=.4de8addcd606).

<sup>2</sup> Michael Ollove, *States Not Eager to Regulate Fertility Industry*, THE PEW CHARITABLE TRUSTS (Mar. 18, 2015), <http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2015/3/18/states-not-eager-to-regulate-fertility-industry>. See also

Technology (“ART”), is a booming field: “[t]he number of IVF cycles done in the United States increased by 28% from 2003 to 2012, and that rising trend has spiked in recent years.”<sup>3</sup> About twelve percent of women have used ART, and about 1.5 percent of American children are conceived through ART.<sup>4</sup>

The World Health Organization defines infertility as “a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after [twelve] months or more of regular unprotected sexual intercourse[,],” for which “access to . . . care falls under the Convention on the Rights of Persons with Disability.”<sup>5</sup> Yet, ART coverage is not mandated under the *Patient Protection and Affordable Care Act*, despite requiring coverage for both infant care and maternity care.<sup>6</sup> Without the standards and oversight of either the insurance industry or the federal government, ART consumers are at the mercy of opportunistic providers.

Customers of ART are uniquely vulnerable, and deserve a market with thorough and unbiased oversight. The drive to reproduce is a powerful force for all people, and “the mere fact that so many infertile couples desperately seek reproductive technology . . . speaks to the centrality of procreation as a source of spiritual fulfillment for many people.”<sup>7</sup> But, unfortunately, many couples are unable to have children for a variety of reasons.

Adoption is not always an adequate alternative for infertile couples. For almost all people there is a strong emotional longing for genetically related children.<sup>8</sup> ARTs are a powerful advance in medicine that provide hope for childless couples. Unfortunately, in the United States, there is no uniform federal legislation that mandates how these treatments are administered, to whom they are available, how much they will cost, or even what clinics may perform them.<sup>9</sup> There is no body that ensures uniform care

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Dov Fox, *Reproductive Negligence*, 117 COLUM. L. REV. 149, 164 (2017) (noting that the historical stigma of infertility has contributed to a lack of federal regulation).

<sup>3</sup> Ellie Kincaid, *A Booming Medical Industry in the U.S. is Almost Totally Unregulated*, BUSINESS INSIDER (July 7, 2015, 3:50pm), <https://www.businessinsider.com/assisted-reproduction-ivf-industry-regulation-2015-6>.

<sup>4</sup> Ollove, *supra* note 1.

<sup>5</sup> WORLD HEALTH ORGANIZATION, *Sexual and Reproductive Health: Infertility Definitions and Terminology*, <http://www.who.int/reproductivehealth/topics/infertility/definitions/en/> (last visited Oct. 21, 2017).

<sup>6</sup> See The Patient Protection and Affordable Care Act, 42 U.S.C. § 18022(b)(1), which lists the “Essential Health Benefits” that every insurer must provide under the Patient Protection and Affordable Care Act.

<sup>7</sup> Note, *Assessing the Viability of a Substantive Due Process Right to In Vitro Fertilization*, 118 HARV. L. REV. 2792, 2805 (2005). (hereinafter *Assessing the Viability*).

<sup>8</sup> John D. Ingram, *Should In Vitro Fertilization Be Covered by Medical Expense Reimbursement Plans?* 7 AM. J. FAMILY L. 103 (1993).

<sup>9</sup> See M. Elliott Neal, *Protecting Women: Preserving Autonomy in the Commodification of Motherhood*, 17 WM. & MARY J. OF WOMEN & L. 611, 625 (2011) (noting that states have attempted to compensate for the lack of federal legislation).

from clinic to clinic, oversees the billing processes of those clinics, or issues licenses to administer ART to patients.<sup>10</sup>

In the United Kingdom, the *Human Fertilisation and Embryology Act* (“HFE Act”) authorized the Human Fertilisation and Embryology Authority (“HFEA”) to oversee accounts, record activities of fertility clinics in the United Kingdom, and issue licenses for providing ART treatment.<sup>11</sup> In other developed countries, more infertile couples are able to take advantage of IVF advances because of reimbursement and coverage schemes.<sup>12</sup> Infertile Americans—as consumers of ART services—deserve better protections, and American insurers—as potential cost-bearers for IVF care—deserve better predictability.

Because there is inadequate federal oversight<sup>13</sup> and because IVF injury often falls through the cracks of traditional medical malpractice regimes,<sup>14</sup> consumers lack sufficient protection, and insurance providers have difficulty structuring coverage for IVF, if they offer coverage at all. Private regulators, pricing schemes, and the existing legislation create adverse incentives for providers,<sup>15</sup> and the childless couples for whom these services provided hope are the ones who suffer. In vitro fertilization is the most common (and one of the most invasive) forms of ART,<sup>16</sup> and will be the vehicle through which this note explores a regulatory framework. An appropriate framework will create oversight over clinic certification, offered procedures, and clinic standards, and will create a process for reprimanding providers that violate the standards.

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<sup>10</sup> See Alicia Ouellette et al., *Lessons Across the Pond: Assisted Reproductive Technology in the United Kingdom and the United States*, 31 AM. J. L. & MED. 419, 420 (2005) (“U.S. law does not require licensing or accreditation of infertility programs and few regulations govern embryo research.”).

<sup>11</sup> See Human Embryology and Fertilisation Act of 1990 (“HFE Act”), §§ 6(1), 8(a) & 12. See Ouellette, *supra* note 10, at 422 (“In addition [to licensing], the HFEA produced a Code of Practice with guidelines on licensed activities, and keeps a register of information on donors, treatments, and children born through ART. It also publicizes its role, gives advice and information, and reviews new developments in the field.”).

<sup>12</sup> Katherine E. Abel, *The Pregnancy Discrimination Act and Insurance Coverage for Infertility Treatment: an Inconceivable Union*, 37 CONN. L. REV. 819, 822 (2005).

<sup>13</sup> See David Adamson, *Regulation of Assisted Reproductive Technologies in the United States*, 39 FAM. L. Q. 727, 731 (2005) (“[T]he Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA). . . required the following: annual reporting of clinic-specific success rates, listing of clinics that do not report, development of a model program for certification of embryo laboratories, and promulgation of criteria and procedures for approval of accreditation programs to inspect and certify embryology laboratories.”).

<sup>14</sup> See Fox, *supra* note 2, at 165-66 (“[T]he malpractice tort usually affords recovery only in cases like this one, in which a plaintiff suffers physical injury. Medical malpractice actions in particular tend to require proof of bodily harm that is missing in many devastating cases of reproductive negligence.”).

<sup>15</sup> See generally Thomas H. Murray, *Money-Back Guarantees for IVF: An Ethical Critique*, 25 J. OF L., MED. & ETHICS 292, 293 (1997).

<sup>16</sup> Abel, *supra* note 12, at 821.

## II. THE PROCESS OF IVF

Alternative Reproductive Technology to treat infertility is not a journey one would embark upon lightly. IVF is the most commonly used medical procedure to treat infertility.<sup>17</sup> During in vitro fertilization:

[t]he ovaries are artificially stimulated by hormones in order to produce more than one mature egg during the menstrual cycle, and then the eggs are removed from the ovaries using a needle-like instrument. One or more eggs are then fertilized in an artificial medium, such as a petri dish, using the husband's or a donor's sperm, and the eggs remain in this medium until they become fertilized and multiply into eight cells to become an embryo. These embryos are then reimplanted into the woman's uterus. Frequently a number of the embryos will be cryopreserved, or frozen, for future IVF attempts if the first treatment fails.<sup>18</sup>

The process is invasive, arduous, and intimidating for the vulnerable couples who seek it. In addition to the large medical risk to which IVF patients are exposed, there also is a “risk that emotionally vulnerable infertile couples may be exploited by opportunistic IVF providers.”<sup>19</sup> ART customers need a guarantee of a standard of treatment available at any clinic from which they might seek service. Consumers also need assurance that ART providers will be more concerned with their health (and the health of their fetus) than the clinic's success rate.

Finding an ART provider is as simple as a Google search. The phrase “how to find an IVF clinic” returns dozens of different clinics, boasting great success rates, money-back guarantees, and zero-down payments. But it is difficult to know which is the best option. By scrolling a bit further, a hopeful ART customer might find the Center for Disease Control and Prevention's ART Success Rates page.<sup>20</sup> Visitors can enter a zip code or state, and find the success rates, contact information, and clinic services available from those clinics.<sup>21</sup> Patient demographic information is limited to age and diagnosis.<sup>22</sup> The website does not provide information on malpractice suits, adverse health outcomes, or on financing.

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<sup>17</sup> See Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 608 (2003). Other forms of ART include Artificial Insemination, which “requires the least technological sophistication,” and Gamete Intrafallopian Transfer, “which delivers the sperm and harvested eggs . . . directly into the woman's fallopian tube . . . requiring the use of a laparoscope.”

<sup>18</sup> Abel, *supra* note 12, at 821.

<sup>19</sup> *Assessing the Viability*, *supra* note 7, at 2792.

<sup>20</sup> See Centers for Disease Control and Prevention, ART SUCCESS RATES, <https://www.cdc.gov/art/artdata/index.html> (last visited Oct. 28, 2017). The most recent clinic data available is from 2015.

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

Further, as technology advances, consumers of ART services need assurance that procedures physicians are providing have been thoroughly reviewed and tested for safety and effectiveness. As it stands, “The government plays essentially no role in reviewing new medical procedures . . . leaving the task of scrutinizing the safety and effectiveness of innovative techniques for biomedical researchers and professional self-regulation[.]”<sup>23</sup> Researchers and professional self-regulators have different incentives than government regulators. Because they lack enforcement power over ART providers, they are unable to ensure public safety or health. This is not to say that they are malicious, but that they lack the capacity to appropriately protect ART consumers, who are vulnerable because of the emotional difficulty of infertility and lack of legal recourses, from opportunistic providers.

### III. THE EFFECT

The range of harms that an ART consumer can experience when undergoing IVF treatment is staggering, and the lack of consumer protections exacerbates the potential harms. There are common errors, explored below, caused by many careless ART providers, but there are also cases of exceptional harm, which, as a matter of public health, we have an interest in preventing.

#### A. Multi-Fetal Pregnancy

When only one embryo is implanted, the chances for a successful pregnancy are only forty to fifty percent.<sup>24</sup> Because the United States places no limits on the number of embryos implanted in an IVF patient, and many ART providers implant several, the chances of multi-fetal pregnancies are greater.<sup>25</sup> The United States has a higher rate of multi-fetal pregnancy and preterm births than countries that provide insurance for IVF and place limits on embryonic transfer.<sup>26</sup> An Institute of Medicine report from 2006 noted that preterm births cost the United States \$26 billion, mostly in medical care, and hospitals are generally not able to recover their expenses.<sup>27</sup> Fertility clinics want to appear successful, and bear none of the

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<sup>23</sup> Noah, *supra* note 17, at 618.

<sup>24</sup> Camille M. Davidson, *Octomom and Multi-Fetal Pregnancies: Why Federal Legislation Should Require Insurers to Cover in Vitro Fertilization*, 17 WM. & MARY J. OF WOMEN & L. 135, 151(2010).

<sup>25</sup> Most Fertility Clinics Break the Rules, MSNBC.COM (Feb. 20, 2009), <http://www.msnbc.com/id/29305552/> (“[For] women under 35, government records show that just 83 of 426 clinics followed the [SART] guidance calling for one and no more than two embryos. The average for fresh embryos (as opposed to frozen) implanted in women in that age group ranged from a 1.4 to 4.8. The vast majority of the clinics averaged between two and three embryos.”).

<sup>26</sup> Davidson, *supra* note 24 at 149-50. *See also* Abel, *supra* note 12 at 822.

<sup>27</sup> *Id.* at 148 and 139.

costs associated with multi-fetal pregnancies, so there is no incentive for them to stop multi-embryonic transfer.<sup>28</sup> Rather, they congratulate their customers' pregnancy, and report another successful pregnancy.

Patients who undergo multi-fetal pregnancies experience a higher risk of ectopic pregnancy, gestational diabetes, and preeclampsia.<sup>29</sup> Older patients, in particular, are more likely to suffer damage to their cardiovascular and renal systems.<sup>30</sup> Parents of multiple children suffer psychological harm and fatigue, and are more likely to suffer "depression, alcohol and drug abuse, and divorce."<sup>31</sup>

The risks posed by multi-fetal pregnancies are not limited to the consumer. They put the ultimate product of the service, the fetus, in danger. Twins are born prematurely fifty-one percent of the time, and triplets are born prematurely ninety-one percent of the time.<sup>32</sup> (For context, single-fetus pregnancies only end in premature labor 9.4 percent of the time).<sup>33</sup> Preterm babies are usually low-weight, which increases medical care costs during their first year of life, and increases risk of death or serious disability later in life.<sup>34</sup> Moreover, the risk of major birth defects is higher among children born from multi-fetal pregnancies.<sup>35</sup> Those defects can include "blindness, brain damage, and respiratory problems."<sup>36</sup> Additionally, children born through IVF may suffer "higher blood pressure, adiposity, glucose levels, and . . . vascular abnormalities[.]"<sup>37</sup>

### B. Laboratory Mix-Ups

Currently, ART labs have no special licensing requirements.<sup>38</sup> The most common harms caused by IVF are mix-ups, including "mishandl[ing] sperm, eggs, or embryos . . . fertiliz[ing] eggs with strangers' sperm or implant[ing] embryos into the wrong person."<sup>39</sup> Though the phrase "mix-up" sounds lighthearted, the trauma of having an ART provider implant the wrong reproductive material into an ART consumer should not be understated. A study of ART labs in the United States showed "more than

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<sup>28</sup> Noah, *supra* note 17 at 626.

<sup>29</sup> *See generally id.* at 620-22.

<sup>30</sup> *Assessing the Viability*, *supra* note 7, at 2810 (Internal quotation marks omitted).

<sup>31</sup> Davidson, *supra* note 24, at 149. *Internal quotation marks omitted.*

<sup>32</sup> Davidson, *supra* note 24, at 147.

<sup>33</sup> *Id.*

<sup>34</sup> *See generally id.* at 147-49. Davidson also notes that children born through IVF (but not necessarily a multi-fetal pregnancy) are more likely to suffer cardiovascular, urogenital, and musculoskeletal defects than children conceived naturally.

<sup>35</sup> Noah, *supra* note 17, at 620-22.

<sup>36</sup> Note, *Assessing the Viability*, *supra* note 7, at 2809-10.

<sup>37</sup> Honor Whiteman, *IVF: Risks May Outweigh Benefits, Say Experts*, MEDICAL NEWS TODAY (Jan. 29, 2014), <https://www.medicalnewstoday.com/articles/271785.php>.

<sup>38</sup> Ouellette, *supra* note 10 at 429.

<sup>39</sup> Fox, *supra* note 2 at 193-94.

one in five report errors in diagnosing, labeling, and handling donor samples[,] and embryos for implantation.”<sup>40</sup> The rate of these mix-ups is unacceptably high considering the financial and emotional stakes of IVF.

Though ART laboratories have to be certified by the American College of Pathologists,<sup>41</sup> the standards they have to meet are general, and do not capture the needs an ART laboratory may have. The Centers for Disease Control’s (“CDC”) model laboratory program envisioned by the Fertility Clinic Success Rate and Certification Act<sup>42</sup> was never adopted across the United States, and neither performance criteria nor approval standards were issued.<sup>43</sup> A lab in California had mold in the area where embryos were stored and was “cited for not properly training staff and storing drugs.”<sup>44</sup>

#### IV. PHYSICAL INJURIES

Unfortunately, when undergoing IVF procedures (or other procedures meant to facilitate pregnancy) ART customers often suffer physical harm. In an article on physician probation, *Consumer Reports* highlights Dr. Leonard Kurian of southern California, who “removed the wrong ovary from a 37-year-old woman . . . .”<sup>45</sup> The California State Medical Board found that he “[f]ailed to provide her informed consent,” and failed to use “a detailed history and physical exam to formulate a . . . plan of treatment.”<sup>46</sup> Kurian treated another woman without having a history of previous pregnancies, a list of her medications, or a family history.<sup>47</sup> On a different woman, Kurian performed a labiaplasty without sufficient knowledge or training.<sup>48</sup>

Malissa Pineda went to Dr. Rifaat Salem because of his success rate, but her experience was hardly happy and successful.<sup>49</sup> After implanting

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<sup>40</sup> *Id.* at 152.

<sup>41</sup> Ollove, *supra* note 1.

<sup>42</sup> See U.S. Fertility Clinic Success Rate and Certification Act, 42 U.S.C. § 263 (hereinafter “FSCRCRA”).

<sup>43</sup> Adamson, *supra* note 13, at 732.

<sup>44</sup> Bernice Yeung & Jonathan Jones, *When Pregnancy Dreams Become IVF Nightmares*, REVEAL NEWS, (Jun. 01, 2017), <https://www.revealnews.org/article/when-pregnancy-dreams-become-ivf-nightmares/>.

<sup>45</sup> Rachel Peachman, *What You Don’t Know About Your Doctor Could Hurt You*, CONSUMER REPORTS, (Apr. 20, 2016), <https://www.consumerreports.org/cro/health/doctors-and-hospitals/what-you-dont-know-about-your-doctor-could-hurt-you/index.htm> [<https://perma.cc/SW8P-ZPPF>].

<sup>46</sup> Leonard Sunil Kurian, Case No. 05-2011-214708. ¶ 42 (1-2) (Med. Bd. of Cal. Dep’t of Consumer Affairs Apr. 8, 2014) (first amended accusation).

<sup>47</sup> *Id.* at ¶ 28 (1).

<sup>48</sup> *Id.* at ¶ 77 (1).

<sup>49</sup> Yeung, *supra* note 44. Salem’s aberrant behavior is well-documented in a constellation of suits. See First Amended Complaint for Rodriguez v. Salem, BC626618 (Super. Ct. Cal. 2017); Said v. Salem, PC040905 (Sup. Ct. Cal. 2008); *Young v. Salem*, YC

three embryos in Pineda and instructing her to stay on bed rest, Salem asked her to come back into the office.<sup>50</sup> His embryologist explained that there was an error with her embryos, and Salem asked if they wanted to have the embryos out that day or the next day.<sup>51</sup> He did not explain what procedure would get them out, and did not get Pineda's informed consent.<sup>52</sup>

Pineda described feeling a "painful scraping" when she was having the embryos removed, which was a dilation and curettage, an abortive procedure.<sup>53</sup> As a result of the procedure, Pineda "started having fits of rage and anger. She was crying all the time. She couldn't sleep. She did her best to push those feelings out of her mind because she believed staying positive would help her get pregnant more easily."<sup>54</sup> The trauma she experienced caused anxiety, poor memory, and panic attacks.<sup>55</sup>

While Malissa Pineda's story is an extreme example, it is not completely anomalous. At least one other woman alleged that Salem had performed a similar "follow-up surgery" on her.<sup>56</sup> If you find the current state of IVF in the United States shocking, it can be explained by the business-oriented development of ART in the United States, the lack of uniform and comprehensive federal oversight, and the inadequacy of the legal system to respond to ART harm.

## V. THE CURRENT (LACK OF) FEDERAL REGULATION

The ART field in the United States is "a field characterized by strong anti-regulatory sentiment because it evolved as a business, not a research enterprise. . . ."<sup>57</sup> This resistance, coupled with the fact that reproduction is a political lightning rod,<sup>58</sup> means there is only one piece of legislation that explicitly calls out IVF providers.<sup>59</sup> The United States Fertility Clinic Success Rate and Certification Act ("FCSRCA"), passed in 1992, requires only that fertility clinics report their rate of successful pregnancies to

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050743 (Sup. Ct. Cal. 2005); Complaint, *Domingo v. Rosenberg*, BC563660 (Super. Ct. Cal. 2008).

<sup>50</sup> Yeung & Jones, *supra* note 44.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

<sup>53</sup> *Id.*

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> *Id.* See also *Said v. Salem*, PC040905 (Sup. Ct. Cal. 2008).

<sup>57</sup> Ollove, *supra* note 1.

<sup>58</sup> Ollove, *supra* note 2 (*Pew Charitable Trusts*).

<sup>59</sup> There are other federal healthcare programs that can affect ART providers, but they are not uniform, and can lead to redundancy and confusion. See Davidson, *supra* note 24, at 728 (noting that the Federal Clinical Laboratory Improvement Act of 1988 governs labs that test hormones, the National Institutes of Health regulates funding, the Food and Drug Administration regulates genetic testing, the Federal Trade Commission regulates clinic advertising, and the Centers for Medicare and Medicaid Services sets payment levels).

CDC.<sup>60</sup> However, the FCSRCA “fails to give the CDC the authority to enforce the data-reporting requirement, and simply outlines a voluntary system of licensing that has not been implemented or enforced.”<sup>61</sup> Clinics that do not report to the CDC face no legal consequences.<sup>62</sup> Further, the FCSRCA “did not . . . create any mechanism for reporting adverse events encountered during fertility treatments.”<sup>63</sup>

The FCSRCA requires that fertility clinics report success rates, which are then made publicly available. As a result, providers are incentivized to make their clinics appear as successful as possible, so they can attract more ART customers. Because the odds of successful pregnancy resulting from IVF are so low,<sup>64</sup> profit incentives led to the practice of multi-embryonic transfers.<sup>65</sup> Success rate reporting, combined with the advent of money-back guarantees,<sup>66</sup> drives providers to do what it takes to ensure a greater chance of success from one cycle of IVF. This often means “a higher dose of fertility drugs, a more invasive egg retrieval, implanting more embryos (and possibly having to eliminate some to improve the survival chances of the others).”<sup>67</sup>

Not only do multi-gestational pregnancies pose many health risks for the consumers, multi-gestational pregnancies pose a financial risk to the insurer that disincentivizes coverage. Maternity benefits packages generally include “coverage for labor and delivery, regardless of the number of children.”<sup>68</sup> But, for multi-gestational pregnancies, those costs multiply. Other countries have recognized the ugly risks of implanting multiple

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<sup>60</sup> FRCSA, *supra* note 42, 42 U.S.C. § 263(a)(1), set out the reporting requirements. The reporting results can be accessed through the Centers for Disease Control Website, at <https://www.cdc.gov/art/nass/index.html> [<https://perma.cc/Q44Q-HDBW>]. The data collected includes: patient demographics, obstetric and medical history, infertility diagnoses, clinical parameters of the ART procedure used, and information about the resulting pregnancies and births.

<sup>61</sup> Ouellette, *supra* note 10, at 422.

<sup>62</sup> *Id.* at 420. Further, compliance with the reporting requirements was entirely voluntary, and no penalties would result from failing to report. See Lee Kuo, *Lessons Learned from Great Britain’s Human Fertilization and Embryology Act: Should the United States Regulate the Fate of Unused Frozen Embryos*, 19 LOY. L.A. INT’L & COMP. L.J. 1027, 1032 (1997).

<sup>63</sup> Noah, *supra* note 17, at 615.

<sup>64</sup> See Davidson, *supra* note 24, at 151 (“A successful pregnancy occurs only forty to fifty percent of the time when a single embryo is transferred for implantation[.]” so “each attempt at [in vitro fertilization] is a financial gamble[.]” but “[s]uccess rates increase as the number of embryos increase.”) (internal quotation marks omitted).

<sup>65</sup> Noah, *supra* note 17, at 626.

<sup>66</sup> Murray, *supra* note 15, at 292.

<sup>67</sup> *Id.* at 293. See also Note, *supra* note 7, at 2811 (“[D]octors may transfer excessively high numbers of embryos in order to inflate the clinic’s success rate figures without heeding the risks to patient health[.]”, or “may start fertility treatment . . . before a woman’s infertility can be confirmed.”).

<sup>68</sup> Davidson, *supra* note 24, at 142.

embryos, and have limited the number of embryos to two-to-four per cycle to reduce the chance of multi-gestational pregnancy.<sup>69</sup> Many of the same countries provide coverage for IVF, which shows that they have “lower rates of embryo implantation and lower rates of multi-fetal pregnancy than the United States.”<sup>70</sup> The United States has taken no steps to reduce the incentives that lead to multi-embryonic transfers. But, by creating a system that reduces multi-embryonic transfer, the United States could create greater confidence in the effectiveness of ART treatment, and ensure that ART patients are exposed to fewer of the health risks that multi-embryonic transfers pose.

The FCSRCA did call for the development of a model program for certifying labs and creating criteria and procedures for ART programs.<sup>71</sup> And the CDC developed the program; however, “since responsibility for implementing such programs is a state function, no national certification program was actually implemented . . . for financial . . . reasons.”<sup>72</sup> But even in the program that the CDC developed, there were no minimum safety requirements for ART procedures.<sup>73</sup> Because there is no federal program that explicitly oversees and provides guidance for ART providers, it can be difficult for consumers to compare clinics without relying on professional regulators that lack the capacity to enforce their standards.

The FCSRCA, though well-intentioned, is inadequate to protect ART customers. It does not establish clear, mandatory standards for clinic licensing. First, it does not establish minimal safety requirements for physicians and clinics. Second, it does not establish any oversight body. Third, it has no enforcement mechanism. And finally, it does not provide any consumer protections to ART customers from ART providers. Overall, it fails to address and resolve the key problems posed by the ART market. And though there are other federal healthcare programs that may reach IVF, “there are multiple overseeing authorities,” which “has resulted in inconsistencies, duplication, and . . . inappropriate regulations.”<sup>74</sup> As a result, insurers do not feel comfortable covering ART, and ART consumers suffer. Should Congress pass legislation that relates to ART generally, or IVF specifically, it must create a body that can oversee licensing, safety standards, accounting and records, and policies of IVF clinics in the United States.

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<sup>69</sup> Noah, *supra* note 17, at 620-21. See also Adamson, *supra* note 13, at 740.

<sup>70</sup> Davidson, *supra* note 24, at 149-50.

<sup>71</sup> See FCSRCA 42 U.S.C. § 263a (1997).

<sup>72</sup> Adamson, *supra* note 13, at 732. There has not been any promulgation of standards for fertility clinics.

<sup>73</sup> Neal, *supra* note 9, at 624.

<sup>74</sup> Adamson, *supra* note 13, at 737.

## VI. THE (INADEQUACY OF) STATE REGULATION

As it stands, the IVF market in the United States is governed by “a patchwork of private insurance and enterprise, state law, and federal regulation.”<sup>75</sup> As wielders of police powers, states generally have authority over family law and health.<sup>76</sup> And states have a large interest in regulating IVF as a matter of public health, because of the high risk of multiple pregnancies. Not only do multiple pregnancies mean increased cost, but they also generally result in adverse health events for both the newborn and the pregnant individual.<sup>77</sup> Still, states have largely abdicated that responsibility when it comes to ART, failing to implement safety standards or model programs for IVF clinics.<sup>78</sup> A Washington Post article from 2015 noted that states do not regulate “how many children may be conceived from one donor, what types of medical information or updates must be supplied by donors, which genetic tests may be performed on embryos, how many fertilized eggs may be placed in a woman or how old a donor can be.”<sup>79</sup>

Some states have indirectly regulated IVF by mandating insurance coverage for the procedure. However, in states that have statutory mandates for IVF coverage, requirements vary widely from “age restrictions for patients who seek the service, number of employees necessary for employers to be covered under the legislation, residence of the insured, number of in vitro cycles covered, number of embryos transferred per cycle or lifetime, whether donor eggs may be used, and lifetime monetary caps.”<sup>80</sup> Some states only allow for insurance providers to offer IVF coverage “where a woman’s eggs are fertilized with her husband’s sperm.”<sup>81</sup>

Though variance in state regulation is understandable, given the different preferences in each state, when it comes to healthcare and insuring, the differences can have harmful results. For example, “when an individual works in one state but the insurance plan is from another state, she is not necessarily covered by the state plan mandating insurance

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<sup>75</sup> Joan Mahoney, *Great Britain’s National Health Service and Assisted Reproduction*, 35 WM. MITCHELL L. REV. 403, 404 (2009).

<sup>76</sup> See Seema Mohapatra, *Stateless Babies & Adoption Scams: A Bioethical Analysis of International Commercial Surrogacy*, 30 BERKELEY J. INT’L L. 412 (2012) (noting that the wide variety of surrogacy regulation from state-to-state causes great expense and confusion).

<sup>77</sup> Note, *supra* note 7, at 2809-10.

<sup>78</sup> Ollove, *supra* note 1.

<sup>79</sup> *Id.* See Neal, *supra* note 9, at 625 (noting that licensure requirements are a method through which states regulate ART providers).

<sup>80</sup> Davidson, *supra* note 24, at 169. Despite the fact that there are limits on coverage, some argue that this is still better than nothing, given that mandatory coverage gives insurers a stake in improving the quality and consistency of IVF care. See Note, *In Vitro Fertilization: Insurance and Consumer Protection*, 109 HARV. L. REV. 2092, 2104 (1996).

<sup>81</sup> Davidson, *supra* note 24, at 169.

companies to cover the procedure.”<sup>82</sup> Meaning, a woman who lives and works in Chicago, whose employer uses Blue Cross Blue Shield of Missouri, will be subject to the limitations that Missouri places on ART and IVF. Later, I will explore how this may provide Congress justification to regulate the ART market, because it implicates the commerce clause.

## VII. PRIVATE REGULATORS, PUBLIC COST

The United States ART market is regulated primarily by private health provider associations, namely the Society for Assisted Reproductive Technology (“SART”) and the American Society for Reproductive Medicine (“ASRM”).<sup>83</sup> Moreover, until passage of the FCSRCA, data collection on ART rested on those two organizations.<sup>84</sup> Membership in these organizations is entirely voluntary,<sup>85</sup> but, as SART notes on its membership page, joining them links providers with potential ART customers seamlessly.<sup>86</sup>

It is important to note that, although they have been involved in passing limited legislation<sup>87</sup> and work in collaboration with public entities,<sup>88</sup> SART and ASRM are private entities. SART is incorporated as an entity separate from ASRM, but members are required to join ASRM too.<sup>89</sup> Members pay an annual fee of three hundred dollars, a data collection fee of five hundred dollars, and other additional fees.<sup>90</sup> That private regulators dominate the industry is not surprising. The National Institutes of Health has limited ability to fund human embryonic research, consequently, IVF was primarily developed privately, as a consumer health service, as opposed to a research endeavor.<sup>91</sup> Private development (combined with the political lightning rod of reproductive rights) meant that IVF could escape government oversight and regulation.<sup>92</sup> And without the watchful eye of a

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<sup>82</sup> *Id.* at 169-70.

<sup>83</sup> Society for Assisted Reproductive Technology, <http://www.sart.org>, (last visited October 21, 2017). American Society for Reproductive Medicine, [http://www.reproductivefacts.org/?vs=1&\\_ga=2.245256773.1376975830.1508602543-1806400130.1508602543](http://www.reproductivefacts.org/?vs=1&_ga=2.245256773.1376975830.1508602543-1806400130.1508602543) (for patients), <http://www.asrm.org/?vs=1> (for providers)(last visited October 21, 2017).

<sup>84</sup> Ouellette et al., *supra* note 10, at 424.

<sup>85</sup> *Id.* at 429.

<sup>86</sup> *Join SART: Benefits of SART Membership*, SOC’Y FOR ASSISTED REPROD. TECH., (last visited October 21, 2017) <http://www.sart.org/professionals-and-providers/join-sart/>.

<sup>87</sup> See Davidson, *supra* note 24, at 731 (noting SART’s involvement in the FCSRCA).

<sup>88</sup> See *National ART Surveillance*, CENT. FOR DISEASE CONTROL AND PREVENTION, (January 9, 2019), <https://www.cdc.gov/art/nass/index.html> (noting the CDC’s collaboration with SART for reporting).

<sup>89</sup> Ouellette, *supra* note 10, at 424.

<sup>90</sup> *Id.* at 424-25.

<sup>91</sup> See Kincaid, *supra* note 3.

<sup>92</sup> *Assessing the Viability*, *supra* note 7, at 2794. See also Ollove, *supra* note 1 (“Debra Mathews of the Johns Hopkins Berman Institute of Bioethics agrees that the industry is

regulatory overseer, ART clinics may put profits and reputation of success above all else, even if it means their patients suffer adverse consequences from higher doses of fertility drugs, multi-fetal pregnancies, or invasive procedures.<sup>93</sup>

SART is not an accrediting agency, and only controls the behavior of its members.<sup>94</sup> The most significant role that both SART and ASRM have is issuing practice guidelines to their membership. A *Business Insider* report notes that practice committees meet to write opinions on new ART procedures, treatments, and research, and to issue guidance.<sup>95</sup> However, “[n]ew procedures do not have to be approved before they can be performed in clinics,” and providers do not have to adhere to the practice committee guidance.<sup>96</sup> In fact, current data shows that most fertility clinics do not follow SART or ASRM guidance.<sup>97</sup> A representative of the California-based Center for Genetics and Society noted that “[t]here are enough clinics that quite openly flout professional guidelines that we really do need to start thinking about public policy in this area.”<sup>98</sup> SART may promulgate guidelines that would mitigate the public health and cost risks associated with IVF, but, as the data shows, most fertility clinics do not heed those guidelines.

But, despite the brazen violations of their guidelines by ART providers, there is little SART and ASRM can do in terms of enforcement. The most drastic measure that SART can take in response to transgressions by ART providers is to revoke membership.<sup>99</sup> But, “[t]his does nothing to improve the quality of a clinic for which membership status is not important.”<sup>100</sup> As much as SART and ASRM may cherish their role as the overseers of the ART industry in the United States, they are clearly having little effect on increasing the quality of assisted reproductive healthcare. If membership (and, by extension, adherence to membership requirements) is optional, and their members are not reprimanded for the harm they cause to vulnerable ART customers, something else must be done.

Customers navigating the ART industry deserve regulation that clears the landscape, so they can find, access, and benefit from quality care. Ouellette identifies four key issues resulting from the lack of ART regulation in the United States, all of which affect ART consumers:

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lightly regulated because ‘assisted reproduction has grown up as a medical services business not under the auspices of medical research.’”).

<sup>93</sup> Murray, *supra* note 15, at 293.

<sup>94</sup> *Id.* at 434.

<sup>95</sup> Kincaid, *supra* note 3.

<sup>96</sup> *Id.*

<sup>97</sup> Davidson, *supra* note 24, at 150.

<sup>98</sup> Most Fertility Clinics Break the Rules, MSNBC.COM, (Feb. 20, 2009), <http://www.msnbc.com/id/29305552/> (internal quotation marks omitted).

<sup>99</sup> Ouellette, *supra* note 10, at 434.

<sup>100</sup> *Id.*

[1] Poor quality clinics will remain open and will propagate morally questionable and/or sloppy clinical practices, whether on purpose or unintentionally. Some of these cases will make headlines while others will go unpublicized. [2] The availability, reliability, and clarity of ART success rate data will continue to be poor so that consumers will have difficulty determining the quality of individual clinics. [3] Clinics that cut corners on voluntary data reporting, advertising, and practice guidelines will achieve commercial success at the expense of better quality clinics with whom they compete. [4] Poor quality clinics will harm the reputation of the field of ART as a whole.<sup>101</sup>

An effective regulatory scheme will: promulgate standard operating procedures and expectations for care, adequately supervise clinics to ensure they are meeting those standards, keep detailed records, make the records available to consumers, create limits on advertising, and work to ensure that ART has a reputation for reliability in the United States.

## VIII. THE GAPS OF THE CURRENT LEGAL REGIME

Despite the horrifying consequences that can happen in the unregulated market, patients who suffer harm as a result of the lack of oversight of the ART market will find no hope in the current legal regime. Despite having theoretical options in medical malpractice law, contract law, and negligence tort law, courts are not interested in providing relief. In these traditional areas of the law, courts lack the experience or imagination necessary to handle the nuance of cases in which reproductive harm (that is largely emotional) is at the epicenter of the case.

### A. Medical Malpractice

Unfortunately, traditional medical malpractice regimes do not incentivize providers to align their behavior to provide a higher level of care to ART patients. Fox notes that “[m]alpractice actions . . . call for . . . more tangible setbacks to the injured party’s person or possessions[.]” and that courts generally do not offer relief when providers “negligently deprive, impose, or confound procreation[.]” because there is often not a physical harm or property loss.<sup>102</sup> Since medical malpractice generally requires physical harm, in cases where sperm or ova are damaged, destroyed, lost, misappropriated, or otherwise harmed, relief is not possible from medical malpractice. This means that, even if ART consumers could access relief through tort law, medical malpractice insurance would not pay out, and relief would be limited to the personal assets of the provider. The current legal options do not provide ART consumers with adequate protection, given the stakes of reproductive medicine.

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<sup>101</sup> *Id.*

<sup>102</sup> Fox, *supra* note 2, at 154.

As a result, ART consumers who suffer “switched sperm, lost embryos, and misdiagnosed fetuses”<sup>103</sup> have no legal recourse, and must simply tolerate it, because there is no physical harm (or at least barely detectable physical harm). Though they may be able to state a claim for negligent infliction of emotional distress, “[c]ourts hardly ever let plaintiffs recover for standalone emotional harm.”<sup>104</sup> There are currently “twenty states [that] refuse to consider the merits of [] professional-malpractice actions against forced procreation.” That is, when providers fail to provide testing (or miscommunicate testing), which results in a child being born with an anomaly, there is no recourse against the provider.<sup>105</sup> Though many genetic anomalies may be harmless, in cases of serious genetic illnesses, ART consumers may be seriously harmed by that negligence, and they lack the ability to seek compensation for that harm.

### *B. Contract, Tort, and Property Claims*

Contract cases are complicated by the fact that many ART providers decline to promise specific results,<sup>106</sup> so it’s difficult to definitively say that they violated the terms of their agreements. And because many of the harms are emotional, lacking an economic or physical component, tort law often declines a remedy as well.<sup>107</sup> Property law doesn’t recognize the “symbolic value of . . . eggs and embryos or the costly procedures required to extract or create them.”<sup>108</sup> Often, reproductive misconduct deprives patients of the ability to procreate in the future, and courts are not yet able to deal with that. Though it is outside the scope of this article, the lack of an adequate cause of action for reproductive harm is reflective of the private, market-driven, and unregulated ART industry in the United States. Providers can run amok, and ART consumers, lacking adequate protection from the government, are harmed. Legislation that set up a regulatory body could also introduce causes of action for ART consumers who experience harm resulting from negligent reproductive healthcare providers.

## IX. THE UK MODEL

In the United Kingdom, the Human Fertilisation and Embryology Act of 1990 (“HFE Act”) empowered the Human Fertilisation and Embryology Authority (“HFEA”) to license, oversee, and promulgate codes of practice for in vitro fertilization.<sup>109</sup> The HFE Act was developed after an extensive

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<sup>103</sup> *Id.* at 159. Fox further notes that because of the “sparse reporting requirements” in the United States, there is no way to know exactly how frequently these “mix-ups” happen.

<sup>104</sup> *Id.* at 169.

<sup>105</sup> *Id.*

<sup>106</sup> *Id.* at 154.

<sup>107</sup> *Id.*

<sup>108</sup> *Id.*

<sup>109</sup> *See HFE Act, supra* note 11, at §§ 1-4.

investigation into the public health implications of ART, conducted subsequent to the first successful “test tube” birth in the United Kingdom.<sup>110</sup> The United Kingdom opted for a streamlined and authoritative approach, where the United States opted to allow the industry to develop through the market. Having an expert authority regulating the industry has resulted in high-quality research and practice, putting the United Kingdom at the forefront of the ART field.<sup>111</sup> By adopting a similar framework, the United States could increase the predictability and safety of in vitro fertilization, reduce adverse incentives, make it more appealing for insurers to provide coverage for in vitro fertilization, and increase the quality and amount of research that advances ART and infertility care.

### A. Licensing

HFEA is the sole body authorized to oversee all fertility clinics and human embryo research in the United Kingdom.<sup>112</sup> It issues licenses to any clinics and laboratories operating in the ART field, which fall into one of three categories: “licenses for fertility treatment, licenses for embryo storage, and licenses for research on human embryos or gametes.”<sup>113</sup> Whereas in the United States, accreditation is an optional undertaking for an ART clinic, British law mandates that any embryology or fertilization enterprise get and maintain a license.<sup>114</sup>

The HFE Act sets out general conditions for all licensees, as well as specific conditions applying to the categories.<sup>115</sup> The general conditions for licensees alone are far more extensive than the CDC’s success rate reporting requirements. The HFE Act requires that licensees maintain adequate books and records, and supply copies or extracts to HFEA upon request.<sup>116</sup> The HFE Act also mandates:

that any member or employee of the Authority, on production, if so required, of a document identifying the person as such, shall at all reasonable times be permitted to enter those premises and inspect them (which includes inspecting any equipment or records and observing any activity).<sup>117</sup>

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<sup>110</sup> Erin L. Nelson, *Perspectives on the Regulation of Assisted Reproductive Technologies in the United Kingdom and Canada*, 43 ALTA. L. REV. 1023, 1028 (2006)(Called the “Warnock Committee,” after its chairperson, the Committee came to the conclusion “that regulatory oversight of ARTs and embryo research was required to protect the public, and that the regulatory function should be played by an expert body[.]”).

<sup>111</sup> *Id.* at 1047.

<sup>112</sup> Ouellette, *supra* note 10, at 420.

<sup>113</sup> *Id.* at 428.

<sup>114</sup> *Id.* at 431.

<sup>115</sup> HFE Act, *supra* note 11, at §§ 12-15.

<sup>116</sup> *Id.* at §12(d),(g).

<sup>117</sup> *Id.* at § 12(b).

Licensees submit themselves to rigorous oversights by a public body, and inspections at any time. In contrast, SART member clinics in the United States only have to be inspected every two years.<sup>118</sup>

An anti-regulation argument against the kind of oversight that the HFE Act employs might suggest that worrying about inspections prevent a clinic from being able to operate freely. ART industry actors in the United Kingdom suggest that this is not the case. In a press release, the British Fertility Society (“BFS”) expressed its belief that the HFE Act “has been of enormous reassurance to the public and to those scientists and clinicians working in what is often perceived as one of the most controversial areas of medical practice.”<sup>119</sup> The BFS also noted that the IVF clinics in the United Kingdom licensed by the HFEA, “have worked effectively for many years within this framework, providing the highest quality of care for patients.”<sup>120</sup>

### *B. Guidance and the Code of Practice*

The HFE Act mandates that HFEA promulgate a *Code of Practice* (“Code”).<sup>121</sup> The Code is drafted by the HFEA, approved (or disapproved) by the Secretary of State, and, after approval, sent to Parliament.<sup>122</sup> The HFE Act notes a number of potentially appropriate subjects for the Code, and the HFEA has done its best to issue detailed guidance.<sup>123</sup> Though violating of the Code may not be enough to start proceedings against the offender, a licensing committee may review whether any licensing conditions were violated and may consider the Code violation in its determination.<sup>124</sup>

The Code allows HFEA to “establish[] boundaries beyond which treatment and research may not venture, define[] technologies to be licensed, and determine[] the legal status of the resulting children.”<sup>125</sup> To issue up-to-date and comprehensive guidance, the HFEA employees a

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<sup>118</sup> Ouellette, *supra* note 10, at 425.

<sup>119</sup> *Regulation of Assisted Reproduction in the UK*, BRITISH FERTILITY SOCIETY, (Feb. 16, 2006), <https://britishfertilitysociety.org.uk/press-release/regulation-of-assisted-reproduction-in-the-uk/>.

<sup>120</sup> *Id.*

<sup>121</sup> HFE Act, *supra* note 11, at § 25(1).

<sup>122</sup> *Id.* at § 26.

<sup>123</sup> Nelson, *supra* note 110, at 1029 (“The [HFEA] *Code of Practice*, now in its sixth iteration, provides detailed guidance regarding the following: qualifications and responsibilities of staff employed by licensed centres; facilities and administrative procedures for licensed centres; assessments of the welfare of the child and of persons seeking treatment; assessment and screening of potential gamete donors; provision of information to donors and to service recipients; consent; counselling; use, storage and handling of gametes and embryos; research; records and confidentiality; complaints; preimplantation testing; witnessing clinical and laboratory procedures; and intra-cytoplasmic sperm injection.”)(Internal quotation marks omitted).

<sup>124</sup> HFE Act, *supra* note 11, at § 25(6)(a-b).

<sup>125</sup> Kuo, *supra* note 62, at 1036.

“horizon scanning panel”, which serves to identify “new developments that may impact on the field of ART or embryo research.”<sup>126</sup> It uses “issues identified in journal articles, conferences and/or suggestions and advice from international experts in the field of ART and embryo research via internet communication, questionnaires and a meeting once a year.”<sup>127</sup> There is not legislation in the United States nor guidance from the CDC on what new treatment or technology may be used on patients.

### C. Register

In the United States, information collection by the CDC is strictly limited to success rate data.<sup>128</sup> The HFE Act requires that the HFEA maintain a register of any information relating to “the provision of treatment services for any identifiable individual, the keeping or use of the gametes of any identifiable individual or of an embryo taken from any identifiable woman,” or if the information “shows that any identifiable individual was, or may have been, born in consequence of treatment services.”<sup>129</sup> Those who may be concerned about a lack of privacy can sleep easily knowing that no one in the HFEA may disclose any of the information in the register, except to the Registrar General or other employees of HFEA.<sup>130</sup> Not only does this register allow the HFEA to monitor for potential violations of the Code or of the HFE Act, it also facilitates new and enlightening statistics about the state of IVF in the United Kingdom. In the United States, the lack of information leaves most of us in the dark when it comes to the ART industry.

### D. Enforcement

In the United States, there are “no legal consequences for non-accredited [clinics]”, nor is there a “consumer-recognized seal of approval or standard symbol that conveys that any minimum standards of quality have been met.”<sup>131</sup> HFEA, on the other hand, is authorized to “refuse, revoke, or suspend a license,” and may submit clinics and laboratories that violate the HFE Act to the Director of Public Prosecutions.<sup>132</sup> If convicted, violators “may be charged with a prison term of up to ten years and a fine.”<sup>133</sup> For violations of HFEA’s Code of Practice, licensees may have

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<sup>126</sup> Sonia Allan, *Regulatory Design Strategies and Enforcement Approaches for Research Involving Suman Embryos and Cloning in Australia and the United Kingdom – Time for a Change*, 32 SYDNEY L. REV. 617, 623-24 (2010).

<sup>127</sup> *Id.*

<sup>128</sup> Kuo, *supra* note 62, at 1036.

<sup>129</sup> HFE Act, *supra* note 11, at § 31(1-2).

<sup>130</sup> *Id.* at § 33.

<sup>131</sup> Ouellette, *supra* note 10, at 430 (internal quotation marks omitted).

<sup>132</sup> *Id.* at 428.

<sup>133</sup> *Id.*

their licenses reviewed and revoked.<sup>134</sup> During premises inspections, an HFEA inspector is authorized to take possession of anything, which may be relevant to a license violation or that may be used in evidence in proceedings, and may take steps to preserve anything necessary.<sup>135</sup> The HFE Act also authorizes Justices of the Peace to issue warrants on the oath of a member or employee of HFEA, given reasonable grounds for suspecting a violation of the HFE Act.<sup>136</sup>

## X. SCHEMES FROM OTHER COUNTRIES

The per capita usage of IVF procedures is far higher in other developed countries such as Australia, France, Japan, and Germany.<sup>137</sup> By using social security reimbursement strategies or cost-sharing schemes, they are able to increase the number of people who are able to take advantage of new ART technology to grow their families.<sup>138</sup> Like the United Kingdom, Australia enforces standards with criminal sanctions.<sup>139</sup> These countries also place important limits on IVF that reduce the likelihood of multi-fetal pregnancies and increase the safety of IVF practice, even if they do not have quite as rigorous a framework as the United Kingdom.<sup>140</sup>

In Germany, for example, *The Embryo Protection Act of 1990* limits the number of embryos that may be collected for fertilization to three.<sup>141</sup> Germany uses a managed care system, where medical innovation must be evaluated for coverage through an application that “must describe the usefulness of the new procedure, its medical necessity, and its cost-effectiveness compared to already covered care.”<sup>142</sup> The Joint Federal Committee must, in particular, adopt guidelines for “medical services in cases of infertility.”<sup>143</sup>

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<sup>134</sup> HFE Act, *supra* note 11, at § 25(6)(a-b).

<sup>135</sup> *Id.* § 39(1).

<sup>136</sup> *Id.* § 40.

<sup>137</sup> Abel, *supra* note 12, at 822.

<sup>138</sup> *Id.*

<sup>139</sup> Allan, *supra* note 124, at 621.

<sup>140</sup> Australia’s limits on ART are arguably not conducive to increasing use of IVF services. See Adamson, *supra* note 13, at 739-740 (“Australia, and particularly the state of Victoria, has strongly regulated IVF since 1984 with The Medical Procedures (Infertility) Bill. The bill defined life as starting at the time of fertilization, mandated a two-year wait for commencement of IVF unless both fallopian tubes were blocked, made a second medical opinion necessary before IVF could be performed, did not allow the physician initially recommending IVF to perform the procedure, and made marriage compulsory before a couple could gain access to reproductive technology.”).

<sup>141</sup> Adamson, *supra* note 13, at 740.

<sup>142</sup> Ursula Weide, *Coverage and Medical Necessity Determinations: U.S. Managed Care Treatment Decisions versus German Administrative Rulemaking*, 8 ILSA J. INT’L & COMP. L. 507, 567 (2002).

<sup>143</sup> *Id.* at 563.

Though the German regulations do not reach quite as far into the ART industry as those in the United Kingdom, they establish far more control than the United States. Germany places limits on the number of ova that can be harvested, and creates an oversight process for evaluating innovative treatments and procedures. By doing this, Germany reduces the number of multi-fetal pregnancies<sup>144</sup> and ensures that all the procedures being practiced on German ART consumers are adequate, safe, and thoroughly tested.

## XI. A BETTER REGULATORY SCHEME

The comprehensive regulatory framework of the HFE Act and HFEA protects British ART consumers from opportunistic ART providers much more effectively than the regulations in the United States. The HFE Act also has consequences in place when ART providers engage in inappropriate conduct, which poses a risk to British ART consumers. Why can't ART consumers in the United States be protected in a similar way? As previously noted, reproductive healthcare tends to be a political lightning rod that members of Congress want to avoid, but there's another explanation.

The private regulators that were so involved in the drafting and passage of the FCSRCA and “the multibillion-dollar fertility industry in America mount[] powerful lobbying forces against occasional calls for regulation.”<sup>145</sup> The United States healthcare is market-driven: “[s]elf-regulation is the longstanding tradition for medical professionals.”<sup>146</sup> By contrast, the National Health Service (“NHS”) funds most healthcare in the United Kingdom. The NHS covers “health care and social costs for children born of ART, even if those costs are extraordinary as a result of the actualized risks of privately funded ART procedures.”<sup>147</sup> And though private health providers may set their own rates,<sup>148</sup> under certain conditions, IVF is covered under the NHS.<sup>149</sup>

Still, the physical and psychological health of uniquely vulnerable consumers should be more important to members of Congress, and they should act. Justification for legislation of this kind could potentially be found in the Commerce Clause of the Constitution,<sup>150</sup> given that unequal

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<sup>144</sup> See Davidson, *supra* note 24, at 149 (noting that other developed countries have a lower rate of multi-fetal pregnancies than the United States).

<sup>145</sup> Fox, *supra* note 2, at 149.

<sup>146</sup> Ouellette, *supra* note 10, at 444.

<sup>147</sup> *Id.* at 445.

<sup>148</sup> See *Costs and Funding*, HUM. FERTILISATION & EMBRYOLOGY AUTHORITY (last visited January 23, 2018), <https://www.hfea.gov.uk/treatments/explore-all-treatments/costs-and-funding/>.

<sup>149</sup> See National Health Service, *Availability*, (Jan. 23, 2018), <http://www.nhs.uk/Conditions/IVF/Pages/Availability.aspx>.

<sup>150</sup> United States Constitution, art. I, § 8, cl. 3.

treatment of IVF in one state could affect the IVF market in a neighboring state.<sup>151</sup>

Currently, data shows that most clinics in the United States do not follow SART and ASRM guidelines.<sup>152</sup> There are no teeth behind the private regulators' guidance; the most that SART and ASRM can do to a noncompliant clinic is to revoke their membership status.<sup>153</sup> Perhaps an aggrieved ART consumer could bring a malpractice suit, but it may never make it to the court, either because it doesn't adequately meet the requirements of medical malpractice,<sup>154</sup> or because it's settled. At the end of the day, the clinic faces no consequences, and can keep attracting patients via an ill-advised success rate system.

An ideal framework of ART regulation will be independent, will take into account patients, providers, and the public, and will be free from political, religious, or moral agendas.<sup>155</sup> If the United States were to adopt a framework modeled after the HFE Act and HFEA, it should be sure to adopt a licensing requirements, an inspection system, and an enforcement mechanism. By adopting those provisions, ART providers would have clear licensing conditions to follow, as opposed to optional accreditation. Clear standards of practice could be promulgated to all fertility and embryology entities in the United States, as opposed to the SART membership standards. And, those standards could be backed up by enforcement mechanisms, both civil and criminal.

## XII. JUSTIFICATION FOR REGULATION

Congress can regulate channels of commerce (like common carriers and motels), instrumentalities of commerce (things moved through interstate commerce), and activities having significant impact on interstate commerce (like pricing goods that may be moved through interstate commerce).<sup>156</sup> Because of the way the insurance market operates state-by-state, and because ART customers may travel to specific ART providers in other states, the current ART market implicates the commerce clause, which would provide Congress justification for regulating it.<sup>157</sup> Some states disincentivize use of ART by single mothers and gay couples. This doesn't mean that those people will remain childless, but, more likely, it means that they will travel to another state to get it. Further, some states limit the ways that insurance companies can cover ART. If a woman lives in Illinois, but

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<sup>151</sup> See generally, *Gonzales v. Raich*, 545 U.S. 1 (2005).

<sup>152</sup> Davidson, *supra* note 24, at 150.

<sup>153</sup> Ouellette, *supra* note 10, at 434.

<sup>154</sup> See generally Fox, *supra* note 2, at 154.

<sup>155</sup> Adamson, *supra* note 13, at 737-38.

<sup>156</sup> *United States v. Lopez*, 514 U.S. 549 (1995).

<sup>157</sup> The lack of uniform law concerning surrogacy poses similar problems. See generally Mohapatra, *supra* note 76, at 412.

her employer provides Blue Cross Blue Shield of Missouri, she is subject to the limitation that Missouri places on insurers. Because of the way laws in one state can affect residents of another state, Congress could suggest that ART is an instrumentality of commerce, and pass regulation that improves the quality of ART care for consumers and provides an enforcement mechanism for reprimanding substandard care.

Without comprehensive legislations, Congress could instead make infertility treatment an essential health benefit under the Patient Protection and Affordable Care Act (“ACA”). Currently, the ACA mandates coverage for infant and maternity care.<sup>158</sup> By making infertility treatment an essential health benefit, Congress would enable insurance companies to set limits on procedures and standards of treatment. Insurance companies “could use the industry information from ASRM and SART to set guidelines for reimbursements and then mandate that coverage be provided only for clinics that report according to federal law or adhere strictly to professional guidelines.”<sup>159</sup> Insurance companies could then link clinic reimbursement “to a requirement that physicians either follow industry guidelines or justify why they did not follow the guidelines.”<sup>160</sup> So, by mandating coverage for infertility care, Congress could improve the standards of care for IVF, artificial insemination, gamete Intrafallopian transfer, and other ART services that are inherently risky.

This may not happen, given the politicized nature of the ACA in particular and health care in general.<sup>161</sup> Congress may not be moved to increase Essential Health Benefits under the ACA any time soon. That said, if Congress fails to act in the best interests of ART consumers in the United States, insurance companies could pick up the slack. It is to insurance companies benefits to ensure that healthy children are born through IVF, so they will not have to pay for as expensive infant care resulting from multi-

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<sup>158</sup> See The Patient Protection and Affordable Care Act, 42 U.S.C. § 18022(b)(1), which lists the “Essential Health Benefits” that every insurer must provide under the Patient Protection and ACA.

<sup>159</sup> Davidson, *supra* note 24, at 159 (Internal quotation marks omitted).

<sup>160</sup> *Id.*

<sup>161</sup> See generally Juliet Eilperin, Amy Goldstein, and Carolyn Y. Johnson, *White House’s decision to stop ACA cost-sharing subsidies triggers strong opposition*, THE WASHINGTON POST, (Oct. 13, 2017) [https://www.washingtonpost.com/politics/white-house-tells-court-it-is-immediately-stopping-aca-cost-sharing-subsidies/2017/10/13/4c404234-b01d-11e7-be94-fabb0f1e9ffb\\_story.html?utm\\_term=.52ee5e82a4af](https://www.washingtonpost.com/politics/white-house-tells-court-it-is-immediately-stopping-aca-cost-sharing-subsidies/2017/10/13/4c404234-b01d-11e7-be94-fabb0f1e9ffb_story.html?utm_term=.52ee5e82a4af); Amy Goldstein & Juliet Eilperin, *Federal judge refuses to order the Trump administration to resume ACA Payments*, THE WASHINGTON POST, (Oct. 25, 2017) [https://www.washingtonpost.com/national/health-science/cbo-forecasts-that-alexander-murray-health-care-plan-would-slightly-lower-deficit/2017/10/25/8f8fd8c2-b998-11e7-be94-fabb0f1e9ffb\\_story.html?utm\\_term=.290c5a748b4e](https://www.washingtonpost.com/national/health-science/cbo-forecasts-that-alexander-murray-health-care-plan-would-slightly-lower-deficit/2017/10/25/8f8fd8c2-b998-11e7-be94-fabb0f1e9ffb_story.html?utm_term=.290c5a748b4e); Amy Goldstein, *ACA enrollment schedule may lock millions into unwanted health plans*, THE WASHINGTON POST, (Oct. 20, 2017) [https://www.washingtonpost.com/national/health-science/aca-enrollment-schedule-may-lock-millions-into-unwanted-health-plans/2017/10/20/c2171008-b5ce-11e7-a908-a3470754bbb9\\_story.html?utm\\_term=.3dde6f4527c](https://www.washingtonpost.com/national/health-science/aca-enrollment-schedule-may-lock-millions-into-unwanted-health-plans/2017/10/20/c2171008-b5ce-11e7-a908-a3470754bbb9_story.html?utm_term=.3dde6f4527c).

fetal births.

### XIII. CONCLUSION

Oversight of ART generally, and IVF in particular, would be beneficial to the ART market in the United States. It could create a reliable, predictable market for consumers and insurers. It would create protections for consumers who currently lack legal recourse for harms suffered through ART. Insurance companies could use the guidance provided by a federal regulatory body to determine which procedures are best suited for coverage, which could protect consumers from undergoing ineffective or unreliable procedures.

Most importantly, regulation would increase trust of ART and use of ART, by normalizing the process and making it more familiar to the public. By regulating the market, Congress could create a partnership between ART consumers, ART providers, and the public, thereby creating a forum for public debate about infertility treatment and the ART market.<sup>162</sup> IVF provides hope to infertile couples all over the world, but if providers' interest is placed above consumers' interest and public health, generally, it's less likely that anyone will want to take advantage of the technological advance.

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<sup>162</sup> Adamson, *supra* note 13, at 737.