

**THE FERTILITY CENTER
REGULATION CRISIS
IN THE UNITED STATES**

*An Issue Brief From
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August 7, 2019

EXECUTIVE SUMMARY

The \$2.1 billion fertility center industry in the United States is big business. More than one out of 10 women end up seeking out fertility-related services from 480 U.S. clinics, resulting in 69,000 live births a year – nearly 2 percent of all children born annually.

Despite the high cost of fertility procedures and the enormous stakes for individuals and couples seeking to create families, fertility centers are almost entirely unregulated today, unlike the tighter oversight in such nations as Estonia, Abu Dhabi, Germany and the United Kingdom. U.S. clinics are subject to far tighter state and federal controls.

For U.S. fertility centers, the result is a “near Wild West” situation where meaningful oversight is absent, error reporting is essentially voluntary, and tragic cases of lost, destroyed or otherwise improperly handled embryos appear to be on the rise. As one expert notes, America’s hands-off approach to oversight of reproductive practices has “left a gaping hole for a booming, unregulated market fraught with fraud and abuse.” In 2016, a national ratings website found that 18-24 percent of fertility patients reported damaged or destroyed samples, among a host of other errors.

In the absence of meaningful state and regulatory oversight of the fertility center world, it would be comforting to think that a system of industry self-regulation would work as a substitute. But what self-regulation exists today is weak and full of holes.

Where could the United States turn to for a model to regulate fertility clinics?

In the United Kingdom, a national agency requires that all facilities comply with a standard of professional conduct that covers “all details of the clinical and embryological practice associated with assisted reproductive technology.” That agency is the Human Fertilization and Embryology Authority (HFEA), which has been in operation since 1990.

The HFEA oversees nearly every aspect of 69,000 fertility procedures a year at 131 licensed clinics in the United Kingdom. The key elements of the work of the Authority are as follows: (1) clinics must apply for a license from the Authority to operate; (2) licenses are granted for up to four years at a time; (3) inspections are carried out every two years and can be done on a surprise basis; (4) inspections can result in recommended changes to clinic practices and even outright license revocation; (5) the Authority sets standards for clinics to ensure high quality care; (6) it also provides guidance to clinics and research centers on how to meet all legal requirements. The HFEA’s actions are highly transparent, including the online publication of the outcomes of all clinic inspections. It also provides the public with information about IVF and other procedures.

HFEA focuses on uniform application of a tough licensing process in a highly visible way that would work like an antiseptic to cleanse the U.S. fertility center system of much of what now ails it ... and boost confidence among the consumers who rely on it. In the face of what appear to be serious and otherwise intractable problems in the U.S. ART industry, the time has come to consider a uniform national solution patterned on the British model.

MASSIVE PROFITS WITHOUT REGULATION

Fertility centers are a highly lucrative and fast-growing industry in the United States:

1. [7.3 million women \(12 percent\) seek out fertility-related services in their lifetime.](#)
2. An estimated [9 percent of men and 11 percent of women](#) of reproductive age in the United States have experienced fertility problems.
3. In vitro fertilization (IVF) and similar technologies result in [69,000 live births](#) a year — 1.7 percent annually of all those born in the U.S.
4. At a cost of \$15,000-\$20,000 per cycle, an estimated [284,000 assisted reproduction technology \(ART\) “cycles”](#) were performed in the U.S. in 2016.
5. There are roughly [480 fertility centers](#) in the nation.
6. The U.S. fertility center market has had rapid and growing prosperity. It had [an estimated \\$2.1 billion in revenue in 2018.](#)

Despite the importance of what happens in fertility centers, **the United States imposes virtually no state or federal oversight of assisted reproductive technology (ART) practitioners.** [According to the International Federation of Fertility Societies](#), “the U.S. stand(s) out among developed countries for its failure [to] rein in wrongdoing” at fertility centers. In fact, [the United States imposes more local, state, and federal oversight of nail salons](#) than it does fertility clinics.

The result is [a near “Wild West” situation](#) where almost anything goes ... and almost no one knows what has gone on:

Few . . . specialties in the United States are as opaque as assisted reproductive technology. ART operates free of regulation about serious and preventable kinds of errors that might be called ART ‘never events’: the destruction, contamination, misdiagnosis, and switching of materials that cannot be chalked up to inevitable slips of hand or reasonable lapses in judgment. Elsewhere . . . these kinds of mistakes — surgery on the wrong body part or patient, for example — are publicly reported by mandate But no system exists to track similar such transgressions when they take place at fertility clinics, sperm banks, egg vendors, or surrogacy agencies.

Just how unregulated a situation exists today for fertility centers? Not only is there no cop on the beat, there hasn’t even been a first brick laid for the police station. [As one observer has noted:](#)

U.S. legislatures and agencies decline to regulate reproductive negligence. The only federal laws that deal with reproductive technology ask practitioners to do no more than screen donors for communicable diseases and disclose estimated rates at which

patients get pregnant. And even then, it imposes no penalty on clinics that refuse to report or deliberately embellish these outcomes. The 12 percent that don't comply are free to continue operating.

This hands-off approach to reproductive practice has, [in the words of one legal scholar-turned-policy analyst at the American Medical Association](#), “left a gaping hole for a booming, unregulated market fraught with fraud and abuse.”

The limited fragmentary data that we do have about ART-related results are disturbing:

1. A 2008 survey of nearly half of all U.S. fertility clinics found that more than one in five [misdiagnosed, mislabeled, or mishandled](#) reproductive materials.
2. A 2014 study revealed that popular methods of prenatal screening for fetal abnormality sound “[a false alarm half of the time.](#)”
3. And in 2016, a national ratings website found that 18-24 percent of fertility patients reported [damaged or destroyed samples](#) among a host of other errors.

In the absence of meaningful state and regulatory oversight of the fertility center world, it would be comforting to think that a system of industry self-regulation would work as a substitute. But what self-regulation exists today is weak and full of holes.

Front and center in the fertility center self-regulatory scheme is the [American Society for Reproductive Medicine](#) (ASRM) and its reporting arm, the [Society for Assisted Reproductive Technology](#) (SART). In theory, ASRM issues minimum standards for reproductive practices to its members at fertility clinics and sperm banks. Those recommendations, however, are entirely voluntary and appear to be widely ignored.

[Critics argue that ASRM's main function is to advance the business interests of its members, unfettered by government regulation.](#) A medical ethics expert noted:

It's a field characterized by strong anti-regulatory sentiment because it evolved as a business, not a research enterprise.

A leading expert on the intersection of bioethics and the law stated that [ASRM has an inherent bias](#):

The industry has done a good job of trumpeting its self-regulation as a reason for regulators not to get involved. Critics of ASRM think that it's too close to the regulated community—basically, it's made up of the regulators—and some of the decisions being made are driven by the interests of people providing the medicine, not always the patients.

To their credit, SART and ASRM have attempted to step into the void left by a lack of regulation. SART offers clinics membership, provided that they accredit their laboratory

every two years. But it does not have sufficient staffing to ensure that the accreditation process is anything other than a glorified honor system.

MAJOR CATEGORIES OF FERTILITY CENTER ABUSES

In the absence of regulatory oversight, the only available information on accountability for wronged fertility center patients is found in insurance claims and court rooms. These claims and cases provide some of the limited information about the type and extent of ART abuses happening in the U.S. today. [A legal scholar and author on the topic noted:](#)

I suspect this happens a lot more often than we know, but because of the lack of regulation and transparency, we don't really know. We need mandatory reporting whenever there are mishaps like this. It's important that when this happens, we find out more about it, because that's the only way we'll be able to better safeguard people and their precious reproductive material.

A [2017 analysis of the outcomes of claims in assisted reproductive technology over a 10-year period from a single carrier](#) looked at the frequency of claims, the basis for the claims, and the outcomes of settled claims. The claims were monitored within only one insurance carrier between 2006 and 2015, covering only 10 of the roughly 480 ART practices in the U.S.

Key findings were as follows:

1. There were 176 incidents.
2. Average award was \$717,238.
3. Misdiagnosis and lack of informed consent accounted for 76 percent of award dollars.
4. The two highest awards were for cancer and genetic misdiagnosis.
5. Errors in handling of embryos were highest in frequency, accounting for 38 percent of claims paid.

A different and somewhat fuller picture of what is happening with IVF cases may be seen in the hundreds of ART-related cases now being handled by U.S. law firms. With [media accounts of fertility center incidents dating back to 1976](#), victims' lawsuits have been the driver in building societal awareness. Having represented more than 200 clients who have been the victims of fertility-center misconduct, [Peiffer Wolf Carr and Kane](#) (Peiffer Wolf) is handling [major fertility center abuses are seen in the following areas:](#)

1. ***Large-scale cases of lost or destroyed embryos.*** In March 2018, two large-scale embryo destruction events occurred at the Pacific Fertility Center in San Francisco and the University Hospitals Fertility Center (UHFC) in Cleveland, OH. In both cases,

cryogenic storage units failed, resulting in the loss of thousands of eggs and embryos for approximately 600 families at Pacific and nearly 1,000 families at UHFC. At both fertility centers, remote alarms were supposed to be deployed to prevent such events.

2. ***Individual cases of lost or destroyed embryos.*** Peiffer Wolf is frequently contacted by individuals and couples whose eggs or embryos were discarded without their authorization. Some of these people cannot create more eggs or embryos. The discarded eggs and embryos were their last hope for having children. Even if they can replicate the process for obtaining more eggs or embryos, the misconduct of the fertility center effectively requires people to undergo another surgery that is both physically painful and emotionally taxing.
3. ***Mishandled embryos that result in live births.*** In one of the worst and most widely publicized fertility center tragedies in U.S. history, a Los Angeles area couple sued the CHA Fertility Center in Los Angeles, after the couple's embryo (along with that of *yet another* couple) was incorrectly implanted in the womb of a New York woman. When the LA couple's child was born, they had to go to court in New York to recover their child and bring it home. In the process, CHA also either destroyed or misplaced another egg from the couple. To this day, CHA has no idea whose embryos it placed into the Los Angeles woman.
4. ***Improperly fertilized embryos.*** The Cartellone family of Delaware, OH, is bringing a lawsuit against the Christ Hospital/Greater Cincinnati Institute for Reproductive Health. After recently purchasing Ancestry.com DNA kits for her family, 25-year-old Rebecca Cartellone learned that her father, Joseph, is not her biological father. Through independent research, the Cartellones believe that Rebecca's biological father is likely one of a small handful of men— including a doctor at The Christ Hospital. In October 1993, the Cartellones sought IVF services at The Christ Hospital and the Greater Cincinnati Institute for Reproductive Health to use mother Jennifer's egg and Joseph's sperm to create embryos for transfer to Jennifer. In February 1994, Jennifer became pregnant with Rebecca. Additional paternity testing has confirmed that the sperm of a stranger, not Joseph's sperm, was used to create the embryo that was transferred to Rebecca.

A REGULATORY PATH FORWARD FOR U.S. FERTILITY CENTERS

Of the estimated 103 countries around the globe with fertility centers, 42 operate with legislative oversight, 26 with voluntary guidelines, and 35 operate with neither. For the most part, the United States falls into the "voluntary guidelines"/"neither" categories, providing for [far less oversight than other nations, including Abu Dhabi, Estonia, Germany, and the United Kingdom.](#)

In the United Kingdom, a national agency requires that all facilities comply with a standard of professional conduct that covers "[all details of the clinical and embryological practice](#)

associated with assisted reproductive technology.” That agency is the Human Fertilization and Embryology Authority (HFEA).

The UK’s HFEA was first framed in [legislation in 1990](#). It oversees nearly every aspect of [69,000 fertility procedures a year at 131 licensed clinics in the United Kingdom](#). The key elements of the work of the Authority are as follows:

1. Clinics must apply for a license from the Authority to operate.
2. Licenses are granted for up to four years at a time.
3. Inspections are carried out every two years and can be done on a surprise basis. As the Authority notes: “Sometimes we inspect clinics and centers more frequently if we need to, for example if something has happened to cause us concern, such as an incident or complaint.”
4. Inspections can result in recommended changes to clinic practices and even outright license revocation.
5. The Authority sets [standards for clinics to ensure high quality care](#).
6. It also provides guidance to clinics and research centers on how to meet all legal requirements.

The Authority’s actions are highly transparent, including the online publication of the outcomes of all clinic inspections. It also provides the public with information about IVF and other procedures.

Beyond defining the regulatory duties of the HFEA, the UK places [specific requirements on fertility center operators](#), which are obligated to:

1. Treat prospective and current patients and donors fairly and ensure that all licensed activities are conducted in a non-discriminatory way.
2. Respect the privacy, confidentiality, dignity, comfort, and well-being of prospective and current patients and donors.
3. Demonstrate respect for the special status of the embryo when conducting licensed activities.
4. Take account of the welfare of any child who may be born as a result of the licensed treatment provided by the center and of any other child who may be affected by that birth.
5. Give prospective and current patients and donors sufficient, accessible, and up-to-date information to enable them to make informed decisions.

6. Ensure that patients and donors have provided all relevant consents before carrying out any licensed activity.
7. Conduct all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors, and offspring.
8. Ensure that all premises, equipment, processes, and procedures used in the conduct of licensed activities are safe, secure, and suitable for the purpose.
9. Ensure that all staff engaged in licensed activity are competent and recruited in sufficient numbers to guarantee safe clinical and laboratory practice.
10. Maintain accurate records and information about all licensed activities.
11. Report all adverse incidents (including serious adverse events and reactions), investigate all complaints properly, and share lessons learned.
12. Ensure that all licensed research involving embryos meets ethical standards and is done only where there is both a clear scientific justification and no viable alternative to the use of embryos.
13. Conduct all licensed activities with regard for the regulatory framework governing treatment and research involving eggs or embryos within the UK, including:
 - Maintaining up-to-date awareness and understanding of legal obligations;
 - Responding promptly to requests for information and documents from HFEA; and
 - Cooperating fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation.

How well does the HFEA function?

In 2006, [the British Fertility Society noted](#): “Regulation serves many functions, not least the protection of patients embarking on ethically complex treatment. It provides reassurance to society that developments in a fast moving and controversial area . . . are monitored closely and that research involving human embryos is conducted within the rules laid down by Parliament. This regulatory framework, as administered successfully by the HFEA for the last 17 years, 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.”

More recently, [an independent report to the Parliamentary Under Secretary of State for Public Health and the Minister for the Cabinet Office](#) found in 2013 that: “Public confidence in the sensitive areas regulated by the Human Fertilization and Embryology Authority and the Human Tissue Authority (HTA) is high, and the regulatory arrangements play an important role in keeping it so. This is the most consistent message to come from my many discussions with stakeholders. While few believe that the current situation cannot be improved upon, the importance of avoiding making changes that would pose a significant risk to this confidence was stressed by many people. Time and again I heard that specialist expertise and focus in the bodies with regulatory oversight are important factors in maintaining this confidence. Furthermore, these strengths also help the UK’s international competitiveness.”

No system is perfect. Even with the far greater oversight in the UK, some mistakes still occur at its fertility centers. But far less than in the United States, where fertility clinics, sperm banks, and surrogacy agencies aren’t monitored or supervised in any meaningful way at the local, state, and federal levels.

The UK model of fertility center regulation bears consideration in the United States for the following reasons:

1. It is operated on a large scale (100+ clinics).
2. It oversees clinics run much like U.S. ART facilities.
3. It has a nearly 30-year track record.
4. It receives high marks for oversight and the public confidence it has instilled.

In short, HFEA focuses on uniform application of a tough licensing process in a highly visible way that would work like an antiseptic to cleanse the U.S. fertility center system of much of what now ails it ... and boost confidence among the consumers who rely on it, gambling both their hopes for a family and their life savings. In the face of what appear to be serious and otherwise intractable problems in the U.S. ART industry, the time has come to consider a uniform national solution patterned on the British model.

APPENDIX

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