

Why the IVF Industry Must Be Regulated

THE ISSUE

The Alabama supreme court ruling declaring embryos created through in vitro fertilization (IVF) are children for the purpose of a Wrongful Death of a Minor Child lawsuit. This drew the public's attention to how the IVF industry operates. Many likely do not know that IVF treatments in the United States rely on the routine destruction of embryonic life, either intentionally or through neglect. Clinics often create a surplus of embryos to test them for the "best" genetic profile or to select embryos based on sex or physical features. Clinics routinely destroy unwanted embryos and may freeze some for later use. The case in Alabama involved the death by neglect of frozen human embryos.

- Alabama's hasty legislative decision in March 2024 to give the fertility industry complete immunity from all civil and criminal liability in the practice of IVF fails to protect the interests of both parents and embryonic life. Why should the fertility industry be less regulated than fast food?
- Destroying or neglecting human embryos is not essential for IVF. In Louisiana, for example, an embryo protection act has been on the books since the 1980s, and IVF continues to flourish in the state. Similarly, many Western countries permit IVF but limit or prohibit the wanton transfer, production, and destruction of human embryos. Examples include Australia, France, Germany, Italy, and New Zealand.
- The well-being of children, not profit margins, should be the top priority when it

- comes to IVF and embryonic cryopreservation. The Alabama court decision reassures parents who rely on IVF that their children will receive the same legal protections as everyone else's.
- The hysteria about restricted access to IVF services in Alabama following the state Supreme Court's ruling in LePage v. Center for Reproductive Medicine is unwarranted. The petitioners' wrongful-death claim arose under the Alabama Wrongful Death of a Child Act after a patient at a nearby hospital entered an unsecured area and dropped a tank of frozen embryos. The state supreme court noted that its own precedents on statutory civil actions for the wrongful deaths of minor children have for decades included the unborn, and in recent years including those before "viability." The court wrote that there was no exception in the statute based on the location of the unborn child and therefore the statute ought to treat those in utero and those outside the uterus the same.
- IVF clinics in Alabama are not required to close. Rather, they need only require their employees to better secure their facilities, and exercise ordinary care—not negligence—in the handling of embryos. IVF patients in Alabama may rest assured that they can now pursue damages under the state's Wrongful Death of a Child Act when clinics act negligently. A legal remedy of that kind should be good news for all.
- The primary federal law tracking the practice of IVF is the 1992 Fertility Clinic

Success Rate and Certification Act. This law tasks the Centers for Disease Control and Prevention (CDC) with publishing pregnancy success rates for assisted reproductive technology (ART) fertility clinics in the United States. It also tracks certain outcomes, such as the type of live birth achieved: singletons or multiples, pre-term births, birth weight, and other physical outcomes.

- On the federal level, the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) are responsible for overseeing the medical and clinical standards, respectively.
- Most state laws regulate coverage and access for IVF treatments. Few state laws are designed to limit abuses of IVF or to account for moral and ethical concerns.

HOW MANY EMBRYOS ARE CREATED EACH YEAR? WHAT IS THE SUCCESS RATE?

Preliminary data from the CDC's

2021 "Assisted Reproductive Technology
Fertility Clinic and National Summary
Report" shows that

approximately 238,126 patients had 413,776 ART cycles performed at 453 reporting clinics in the United States, resulting in 112,088 clinical pregnancies, 91,906 live births (deliveries of one or more living infants), and 97,128 live born infants.... Approximately 2.3% of all infants born in the United States every year are conceived using ART.

Of assisted reproductive technologies—which include any infertility treatment handling egg or sperm—IVF consistently accounts for the majority of treatments. To date, over one million babies have been born using IVF. Another one million embryos are frozen in liquid nitrogen freezers. Considering the total number of live-born infants divided by the total number of ART cycles, this means that IVF has a success

rate of merely 23 percent. For women 40 years and older, the odds plummet to less than a $\underline{10}$ percent chance of success.

What these numbers do not include, however, are the *total* number of created embryos per live birth. The success rate above only counts embryos implanted in the womb. IVF treatments, however, routinely create a surplus of embryos out of convenience or cost concerns or for genetic filtering reasons.

No widely available recommendations or laws dictate the number of embryos created in an average IVF cycle. Typically, that number depends on a few factors, including the age of the eggs, their quality, and any underlying health problems. One report from the United Kingdom suggested that an average of 15 embryos are created in each cycle, such that only 7 percent of all created embryos result in a live birth. The remaining 93 percent are either destroyed or indefinitely frozen with tiny odds of ever being implanted.

Presuming a conservative estimate that only 10 embryos are created in an average round of IVF, this means that the 413,776 rounds of IVF reported in 2021 resulted in the creation of approximately 4.1 million embryos. When dividing the total number of live-born infants by 4.1 million, this would mean that only 2.3 percent of all embryos created in the United States result in the live birth of a baby.

The knowledge that IVF *can* work has lulled many women into a false sense of security that it *will* work in their case, while the fertility industry downplays the harsh realities of the process. Many large businesses offer to pay for women to freeze their eggs, reinforcing the idea that women can forgo their prime reproductive years because technology provides a simple surefire solution. This is simply not so.

CLINICS, OUTCOMES, AND COST

A single round of IVF costs anywhere from \$12,000 to \$30,000. A "round" refers to the process doctors follow to create the embryos. In

MARCH 19, 2024 | 3

2022, the global IVF industry was <u>valued at \$35</u> <u>billion</u>. On average, it is estimated that it costs <u>more than \$61,000</u> to achieve either a live birth or to determine that continued efforts are not likely to succeed.

There are profound moral issues with the way IVF is practiced in the U.S.—in many cases, amounting to eugenics. More than <u>75 percent</u> of fertility clinics offer preimplantation genetic testing for genetic issues; <u>73 percent offer</u> testing for sex selection or hair, eye, and skin color.

And the outcomes of the process are not neutral. Children born through IVF have a higher likelihood of <u>cancer</u>, <u>autism</u>, <u>minor cleft pallet</u>, or a congenital heart defect.

EIGHT PRELIMINARY POLICY RECOMMENDATIONS FOR CONGRESS

In order to regulate IVF with the well-being of parents and children in mind, Congress should:

- 1. Impose a standard of care in IVF clinics sufficient to prevent the wanton or careless destruction of embryonic human beings. The willful or reckless loss of an embryonic child should not be treated as a loss of merchandise where the parents simply get their money back. The law should recognize the gravity of the harm and allow parents proper compensation under the wrongful death provision. As the Alabama decision makes clear, parents should have legal recourse if a fertility clinic destroys their embryonic children due to willfulness, neglect, or carelessness.
- 2. Codify the recommended guidelines of the American Society of Reproductive Medicine to ensure that only one embryo is transferred into the intended mother at a given time. This avoids health complications for the mother, poor outcomes for the child, and decreases the risk for multiples.
- 3. Limit the number of embryos created per round of IVF to the number that the clinic intends to transfer at a given

time. There should be a maximum of three embryos created at one time if transfers with multiple embryos are allowed. This follows the practice in other countries, such as <u>Germany</u>, which limits the fertility industry to two-to-three embryos created at a time and requires clinics to only create the number of embryos they intend to transfer. A similar law in the United States would prevent the creation of a surplus of embryos to destroy or freeze indefinitely when the practice is not necessary for parents to have a successful outcome.

- 4. Mandate that fertility clinics secure true informed consent of both parents. Parents deserve to know precisely what the risks are for themselves and the embryos; the odds of success; the expected costs; the exact number of embryos to be created, when, and their disposition; and their legal rights if the clinic intentionally or negligently destroys their embryos.
- 5. Require clinics to secure true informed consent from women so they are fully informed of the odds of success or complications if they forgo natural reproduction by relying on egg or embryo cryopreservation. Although the moral calculus of freezing eggs is substantially different than creating or freezing embryos in IVF, egg harvesting and preservation is still done for the purpose of IVF.
- 6. **Prohibit anonymous egg and sperm donation in IVF treatments;** children
 have a right to know their biological parents.

 <u>Colorado</u> already has this law on the books,
 as do nations like Germany (where the law
 only applies to donor eggs).
- 7. Promote access to non-assisted reproductive technology fertility treatments, including medical, surgical, and natural alternatives. Congress should promote extensive diagnostic testing to determine the underlying cause of infertility, and an

opportunity to heal the underlying causes of infertility in both men and women. The law should ensure that couples have access to and explore treatments that can heal their infertility before they turn to IVF as a last resort.

8. **Prohibit the use of preimplantation genetic diagnosis (PGD).** The availability of embryonic genetic testing will all but

guarantee the creation and destruction of embryos in the pursuit of the "perfect" child based on sex, potential physical or mental traits, or the potential of inheriting a disease, even if remote. Australia, Canada, Germany, India, Italy, the United Kingdom—even China—each prohibit the use of PDG in certain cases.