# The Status of IVF in Alabama After State Supreme Court Decision That Embryos Are 'Children'

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The day before the *Dobbs* decision was issued in June 2022, Reed Smith published a <u>thought</u> <u>piece predicting the possible fallout of *Dobbs*</u> with respect to fertility and reproductive medicine. Less than two years later, we have seen the first major decision to test these theories.

On Feb. 16, the Alabama Supreme Court issued a bombshell ruling, holding that a frozen embryo in storage is the legal equivalent of a child under the law. See *LePage v. Center for Reproductive Medicine*, Nos. SC-2022-0515, SC-2022-0579, 2024 Ala. LEXIS 62 (Feb. 16, 2024). The case arose in the context of several couples who had undergone treatment through in vitro fertilization (IVF), which involves the fertilization of an egg outside the uterus. Several embryos created during this process were frozen and stored in the fertility clinic's laboratory located inside a hospital, which the majority opinion refers to as a "cryogenic nursery."

In 2020, an unauthorized person entered the fertility clinic, removed several frozen embryos, and dropped them, destroying the embryos. The plaintiffs brought suit against the fertility clinic and the association that owned and operated the hospital in which the clinic was located, alleging violation of Alabama's Wrongful Death of a Minor Act (the act), along with several other causes of action. This article focuses on the plaintiffs' wrongful death claims.

The trial court granted defendants' motion to dismiss, finding that the cryopreserved embryos do not fit within the definition of a "person" or "child" and thus could not give rise to a wrongful death claim. The plaintiffs appealed.

## The Court's Holding

Justice Jay Mitchell, elected to the Alabama Supreme Court in 2018, wrote for the majority, holding that "unborn children are 'children' under the act, without exception based on developmental stage, physical location, or any other ancillary characteristics."

By way of background, the act was first enacted in 1872 and provides a mechanism for a civil action for punitive damages in the event that "... the death of a minor child is caused by the

wrongful act, omission, or negligence of any person, persons, or corporation, or the servants or agents of either ... ." Code of Ala. Section 6-5-391(a). Actions under the act may be brought by the father or mother of the minor child, or the party having legal custody of the minor (including third parties with legal custody over the minor child). Additionally, in the event the father and mother are both deceased or if they decline/fail to commence the action within six months from the child's death, an action may be brought by a "personal representative" of the minor child. The act does not define "personal representative."

This is not the first time Alabama courts have confronted the question of whether an "unborn child" qualifies as a "minor child" under the act. In earlier cases addressing this question, Alabama courts have applied a narrower interpretation of the act and determined that no cause of action for wrongful death exists if the fetus was not viable. See, e.g., *Gentry v. Gilmore*, 613 So. 2d 1241, 1242 (Ala. 1993), and *Lollar v. Tankersley*, 613 So. 2d 1249, 1252 (Ala. 1993). In more recent cases, the court has expanded the protections of the act to "unborn children" at earlier stages of development. For example, in *Mack v. Carmack*, 79 So. 3d 597 (Ala. 2011), the court addressed the case of a woman who was 12 weeks pregnant and miscarried following a vehicle accident, and held that the act permitted an action for the death of the nonviable fetus.

In reaching its decision, the court reviewed the 2006 amendments to the Alabama Code defining homicide defenses, which revised the definition of "person" to include "an unborn child in utero at any stage of development, regardless of viability." Code of Ala. Section 13A-6-1(a)(3). The court concluded that the expanded definition of "person" under the criminal-homicide laws necessitated congruent expansion under the act to avoid a "perverse" outcome where an individual could be subject to criminal liability but immune from civil liability for the same conduct. *Mack*, 79 So. 3d at 611.

Similarly, in a 2012 case involving a wrongful death action for the stillbirth of a nonviable fetus, the court held, based on *Mack*, that "Alabama's wrongful-death statute allows an action to be brought for the wrongful death of any unborn child, even when the child dies before reaching viability." See *Hamilton v. Scott*, 97 So. 3d 728, 735 (Ala. 2012). The court relied on its precedent in *Mack* and *Hamilton* as well as the common dictionary definitions of "child" in reaching a similar holding here.

In addition to its prior decisions in *Mack* and *Hamilton*, the court relied on the Alabama Constitution, which, in a section titled "Sanctity of Unborn Life" ratified on Dec. 3, 2018, "acknowledges, declares, and affirms that it is the public policy of this state to ensure the protection of the rights of the unborn child in all manners and measures lawful and appropriate." See *LePage*, 2024 Ala. LEXIS 62, at \*12 (quoting Alabama Const. Art. I, Sec. 36.06(b)). Because "nothing about the act narrows that definition of 'minor child' to unborn children who are physically 'in utero,'" the court held that the phrase "minor child" in the act includes an "unborn" child "from fertilization until the age of majority."

The majority also rejected the defendants' arguments that, because "extrauterine children" are not protected by the state's criminal homicide laws, they therefore cannot be protected by the Act. In closing, the majority declared that "the text of the Wrongful Death of a Minor Act is sweeping and unqualified," holding that it "applies to all children, born and unborn, without limitation."

#### The Alabama Supreme Court Addresses the Impact on IVF

The majority briefly addressed the "public policy concerns" asserted by defendants and amicus from the Medical Association of the state of Alabama that "treating extrauterine children as 'children' for purposes of wrongful-death liability will 'substantially increase the cost of IVF in Alabama' and could make cryogenic preservation onerous." These concerns were swiftly dismissed as "belonging before the Legislature, not this court."

Chief Justice Tom Parker, who issued a separate concurring opinion, tackled the issue of IVF more directly. Following a lengthy discussion on the meaning of "sanctity" and drawing on sources as varied as Merriam-Webster's Collegiate Dictionary, books published by U.S. Supreme Court Justices Antonin Scalia and Neil Gorsuch, numerous theological writings, and the King James Bible, itself, Parker downplayed the potentially disastrous consequences that the court's decision may have on IVF in Alabama:

Although it is for the Legislature to decide how to address this issue, I note briefly that many other Westernized countries have adopted IVF practices or regulations that allow IVF to continue while drastically reducing the chances of embryos being killed, whether in the creation process, the implantation process, the freezing process, or by willful killing when they become inconvenient.

Going further, Parker discussed other countries' approaches to IVF, which, in his view, obviate the defendants' and amicus' concerns about the impact on IVF in Alabama:

For instance, in Australia and New Zealand, prevailing ethical standards dictate that physicians usually make only one embryo at a time. On the related issue of embryo transfers, which is the process of implanting the embryos into the uterus, in Australia and New Zealand over 90% of embryo transfers occur only one at a time. Likewise, European Union (EU) countries set a legal limit on the number of embryos transferred in a single cycle. In EU countries, 58% of embryo transfers involve just one embryo, and 38% involve two; thus, 96% of embryo transfers in EU countries involve two or fewer transfers at one time. Such limitations on embryo creation and transfer necessarily reduce or eliminate the need for storing embryos for extended lengths of time. Italy went one step further, banning cryopreservation of embryos except when a bona fide health risk or force majeure prevented the embryos from being transferred immediately after their creation. All of these measures protect the lives of the unborn and still allow couples to become parents. Therefore, although certain changes to the IVF industry's current creation and handling of embryos in Alabama will result from this decision, to the extent that Justice Greg

Cook is predicting that IVF will now end in Alabama, that prediction does not seem to be well-founded.

Notably, however, these proposed approaches focus mostly on limiting the number of embryos transferred, while, as discussed infra, the impact of the *LePage* decision is mostly on the number of embryos created and the treatment of those embryos, regardless of how many are ultimately transferred.

Cook, elected to the Alabama Supreme Court in 2022, took an originalist's approach and dissented on the basis that "the Wrongful Death Act does not address frozen embryos," and thus the court should not expand the meaning of the word "minor child" without intervention by the Legislature.

In his dissent, Cook recognized that "the main opinion's holding almost certainly ends the creation of frozen embryos through in vitro fertilization (IVF) in Alabama." He further predicted that "no rational medical provider would continue to provide services for creating and maintaining frozen embryos knowing that they must continue to maintain such frozen embryos forever or risk the penalty of a Wrongful Death Act claim for punitive damages."

Cook addresses the proposed solution offered by Parker and notes that "the Alabama Medical Association strongly disagrees with the suggestion that IVF in some other, reduced, form is practical, safe, or medically sound and has filed two amicus briefs exhaustively explaining these issues." Ultimately, he concludes: "It is not the place or time to decide whether the position of the chief justice or the position of the Alabama Medical Association is correct, moral, or ethical. It is not the place because these are questions for the Legislature and not this court."

Cook also highlighted that "not a single state has held that a wrongful-death action (or a criminal-homicide action) can be brought for the destruction of a frozen embryo," noting that many jurisdictions have expressly rejected such causes of action. Cook went on to point out that, while Alabama is not bound by the holdings of courts in other states, Alabama's position as the sole outlier following this decision serves as cause for Alabama to reexamine its conclusion.

## Setting the Table for Treatment of Embryos as 'Children' Under Other Alabama Laws

On its face, the court's holding is limited to the definition of "child" under the Alabama Wrongful Death of a Minor Act, which, as noted above, has a more limited application due to the restricted categories of persons with authority to bring an action (i.e., parents, personal representatives). However, the court's reliance on the Alabama Constitution's Sanctity of Life provisions has much broader implications and lays the groundwork for extrapolation of this holding to other Alabama laws.

Specifically, the majority opinion explains that the Alabama Constitution's "Sanctity of Unborn Life" section operates as a "constitutionally imposed canon of construction" that "requires courts to resolve ... ambiguity in favor of protecting unborn life" and "... directs courts to construe ambiguous statutes in a way that 'protects ... the rights of the unborn child' equally with the rights of born children, whenever such construction is 'lawful and appropriate.'" It remains to be seen how this position could be used in future cases to support expanded rights to embryos and expanded causes of action against health care providers and parents.

## A Note About the IVF Process

To understand the implications of Alabama's decision on IVF, it is necessary to understand at least some basic elements of the medical treatment involved.

According to the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology, IVF has been around for more than 40 years in the United States. The process involves surgically removing eggs from the ovaries and mixing or injecting them with sperm in a laboratory setting, and transferring them into the uterus, thus bypassing the Fallopian tubes. It is estimated that over 8 million babies, 2% of all births in the United States are the result of IVF.

Normally, the body ovulates one egg per month. Leading up to an egg retrieval surgery, the ovaries are stimulated through the administration of a variety of drugs over several weeks and under close monitoring by a health care professional. The goal is to grow as many eggs as possible for surgical retrieval before ovulation occurs. These eggs may be frozen for future potential use or combined with sperm in the hopes of creating one or more embryos. Depending on a variety of factors, it may take several cycles to obtain enough mature eggs to create even one embryo.

Once combined with sperm, the eggs are then observed for a period of several days to identify which have become fertilized and develop into a blastocyst. Not all eggs make it to this stage. Those that do are either transferred into the uterus or frozen for future potential use.

It is also possible to conduct preimplantation genetic testing at the stage prior to freezing the embryos. During this process, cells from an embryo are tested for potential genetic disorders. Preimplantation genetic testing is also used to identify embryos that are unlikely to successfully implant and develop into a healthy pregnancy. Notably, more than half of all miscarriages are attributed to randomly occurring chromosomal abnormalities in the fetus, many of which may be detected through this kind of testing. Patients commonly discard embryos that test positive for genetic disorders and only transfer and freeze those that are free from known genetic diseases.

Patients experience attrition at each stage of this process—egg retrieval, fertilization, development, genetic testing, freezing, thawing and transfer. In other words, not all retrieved eggs will be mature; not all mature eggs will fertilize; not all fertilized eggs will develop; not all embryos will be genetically normal; not all embryos will survive the freeze and thaw cycle; not all embryos transferred to a uterus will successfully implant; and not all implanted embryos will

result in a live birth. While some insurance coverage may exist for such treatments, many patients spend tens of thousands of dollars undergoing IVF to have children.

IVF is regulated by state and federal law, as well as professional self-regulation. Examples of state law regulation include medical licensing requirements, physician oversight through disciplinary action, and continuing medical education requirements. Federal regulation includes the Fertility Clinic Success Rate Certification Act (FCSRCA), mandatory reporting of data to the Centers for Disease Control (CDC), the Food and Drug Administration (FDA) regulation of drugs, devices, and donor tissue, and the Clinical Laboratory Improvement Act (CLIA).

The American Society for Reproductive Medicine (ASRM) and Society for Assisted Reproductive Technology (SART) also develop ethical and practice guidelines applicable to IVF, as well as membership requirements. The American Board of Obstetrics and Gynecology (ABOG) and American Board of Urology (ABU) develop and administer physician board certification. The College of American Pathologists (CAP) and Joint Commission establish programs for laboratory accreditation.

# Implications for IVF in Alabama and Beyond

Although Cook predicts in his dissent that "no rational medical provider would continue to provide services for creating and maintaining frozen embryos knowing that they must continue to maintain such frozen embryos forever or risk the penalty of a Wrongful Death Act claim for punitive damages," this remains to be seen. That said, the majority's holding will, without a doubt, have far-reaching implications on IVF in Alabama and beyond. Indeed, as of the publication of this article, at least one fertility clinic in Alabama—the University of Alabama at Birmingham Division of Reproductive Endocrinology and Infertility—has paused all egg fertilization and embryo development as a result of this decision.

To be clear, IVF is not immediately outlawed in Alabama. However, IVF providers may now face wrongful death actions and be exposed to civil liability in the event of embryo destruction, which commonly occurs in the IVF process, both intentionally and accidentally. One notable limitation on the risk of facing wrongful death actions is that such a lawsuit may only be brought by a limited universe of individuals, namely the parents, a legal custodian or a "personal representative."

However, the court's decision in this case could also be used as a basis for expanding the scope of other laws, including criminal statutes, to include embryos at all stages of development. The exact parameters of IVF's legality under this new legal regime in Alabama will be tested over years through lawsuits and criminal prosecutions. Accordingly, this decision could have a chilling effect on access to IVF in Alabama in the immediate term and raises significant concerns about the ability of providers to effectively offer IVF in Alabama.

# A Plethora of Uncertainty

Ultimately, the decision raises more questions than it answers, including the following, which are likely to receive attention in other states as well.

## Impact of Civil Liability Under the Wrongful Death of a Minor Act

- Are parents, IVF providers and storage facilities required to continue to store frozen embryos indefinitely?
- What if the parents are no longer able to financially afford to pay the storage fees? Are they required to transfer each embryo in an attempt to achieve a pregnancy? (Notably, each transfer cycle typically costs thousands of dollars.) May the storage facility discard the embryos at that point, which is typically the practice? Does the storage facility become the "legal custodian" of the embryo? What obligations does that impose upon the storage facility?
- Can the parents bring an action against the IVF provider or storage facility for failing to preserve the embryos in the event of nonpayment, even if they were unable or unwilling to pay for storage?
- Would abandoned embryos become wards of the state? What does "foster care" look like for an embryo-child? Would the state be permitted to transfer the embryo to someone else's uterus without the consent or against the wishes of the biological parents?
- Can IVF providers or storage facilities be held liable for wrongful death if a frozen embryo does not survive the thaw process or is damaged during a biopsy for genetic testing?
- Can transportation companies be held liable for the damage to embryos during transport? For example, it is common to store frozen embryos onsite at the fertility clinic for a period of time before transferring them to long-term storage.
- Where both parents have equal rights to bring an action under the act, can one parent bring a wrongful death action against the other? For example, if an embryo transfer is unsuccessful—meaning the embryo never implanted and there was never a positive pregnancy test—can a father bring a claim against the intended mother (e.g., if she misses a dose of medication, does not maintain a "healthy" diet, or has other co-morbidities that she is not effectively managing that he argues resulted in the unsuccessful transfer)?
- What constitutes "legal custody" of the embryos under the act and how can it be vested in one of the parents or another third party?

- The act also permits a "personal representative" to bring an action for wrongful death but does not define "personal representative." This has been construed as the administrator or executor of the deceased's "estate" in the context of general wrongful death actions.
- Who may be considered a "personal representative" of embryos?
- Will Alabama courts have the authority to appoint a personal representative (i.e., executor/administrator) for embryos in the event of the parents' death and/or waiver of their rights to bring a wrongful death action?
- Can the act be applied extraterritorially outside of Alabama? For example, if embryos may not be destroyed in Alabama, may they be transferred to another state where embryos are not considered "children" and destroyed there?
- Would anyone involved in transferring embryos that are later destroyed out of state be potentially implicated in a criminal conspiracy? For example, Alabama Attorney General Steve Marshall has indicated his desire to prosecute those who aid Alabamians in seeking access to abortion care in states where it is legal.
- Can IVF providers insulate themselves from liability under the Wrongful Death of a Minor Act by requiring parents to waive their rights to bring an action under the act? If so, could a "personal representative" still bring an action?

## **Freezing Embryos**

- What are the implications of suspending the development of an embryo if it is considered the equivalent of a child?
- Will it be possible to freeze future embryos in Alabama, or must all embryos be transferred to a uterus immediately? Transferring multiple embryos at once increases the risk of multiple gestations (e.g., twins, triplets), which are high-risk pregnancies by definition.

#### **Genetic Testing of Embryos**

- Will genetic testing of embryos still be possible under Alabama law? For example:
  - Can parents provide consent for their embryo to be biopsied for genetic testing?
  - Are parents permitted to discard embryos if genetic testing shows abnormalities, or a disease inconsistent with sustained life outside the uterus?
  - What happens if the parents or "legal custodians" of the embryos disagree on how to proceed following genetic testing?

 Will this result in a reduction or elimination of genetic testing of embryos? If so, what impact will this have on the outcome of pregnancies and life of the child (e.g., higher rates of failed embryo transfers, higher rates of miscarriages, higher rates of pregnancy complications, impact on the health of the child after birth)?

#### **Basis for Criminal Liability**

• Can the court's decision be used as a basis for extending criminal charges related to the destruction of an embryo, beyond civil liability for wrongful death?

## **Basis for Extension of Other Rights to Embryos**

- Could the court's holding here be used as a basis to support the extension of other rights to embryos and their parents (e.g., could parents claim unused, frozen embryos as "dependents" on their taxes)?
- What if a person engages in conduct during their pregnancy—including in the one-two weeks before the transferred embryo implants (and before a pregnancy test would be positive)—that the state believes endangers the "child," such as taking certain medication that may have a risk of birth defects? Can the pregnant person be detained or jailed until giving birth on the basis of "protecting" the embryo? Notably, federal civil rights lawsuits have been filed in Alabama based on alleged violations of constitutional rights of pregnant women detained in Alabama jails.

In the event of the parents' death:

- Will a guardian need to be appointed for the embryos?
- Will embryos have rights to inheritance in intestate succession as a relative of the decedent who was "conceived" before death, but not yet born?

#### **Increased Regulation**

This decision is likely to spur increased regulation in the areas we previewed in our prior thought piece, including:

- State licensing standards for embryo storage and transportation.
- Heightened requirements for handling and storing embryos.

## Increased Cost of IVF

Fertility clinics in Alabama that continue to provide IVF services are likely to have to increase their costs to address increased potential liability. For a service that is already cost-prohibitive to many patients, this has the potential to price even more patients out of this treatment. One in eight couples have trouble getting pregnant or sustaining a pregnancy and may require treatment of infertility, including IVF.

#### **Looking Ahead**

While the full impact of this ruling is still being vetted and ultimately will take shape over years of civil and criminal litigation, the potential implications for access to fertility treatments like IVF are abundantly clear.

As other states explore "personhood" laws and as similar litigation winds its way through their court systems, the potential impact to even more couples seeking to grow their families through IVF is apparent. Health care providers, clinics, laboratories, and essentially all participants in the IVF process should consult with legal counsel and carefully weigh the new risks presented by this decision.

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