IDEAS

The Real Lessons of the Alabama IVF Ruling

The regulation of the fertility industry is strangely underdeveloped, leaving parents, children, clinics, and practitioners lacking even basic information, protections, and boundaries.

By Yuval Levin and O. Carter Snead

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When the Alabama Supreme Court found on February 16 that frozen embryos are protected by the state's wrongful-death law in the same way that embryos inside a mother's womb are, it set off one of those depressing and familiar 21st-century political firestorms.

The court had heard a complicated civil case touching on questions about the rights of families undergoing in vitro fertilization and the responsibilities of the fertility industry—questions that have long been neglected, to the great detriment of the millions of American families who seek to have children by IVF each year.

But just about everyone with anything to say about the Alabama case has evaded these difficult questions and resorted instead to a more familiar framework: the debate over abortion. This is an understandable impulse—both involve human beings before birth. But it's not so simple. And for decades, the misguided conflation of abortion and reproductive technologies has left the regulation of the fertility industry strangely underdeveloped. Parents, children, clinics, and practitioners have been left, in turn, lacking even basic information, protections, and boundaries. The Alabama ruling, understood in its proper context, was not some theocratic power grab, but a straightforward statutory interpretation that should help our society grasp its responsibility to create better guardrails for this industry, and for the families involved.

In fact, the case had essentially nothing to do with abortion. Three families pursuing IVF sued their clinic after another patient apparently wandered into the facility's freezers without the staff realizing it and picked up a container of

embryos. The extreme cold burned that person's hand, causing them to drop the container onto the floor, which killed all of the embryos it held. The families contended that this amounted to negligence on the part of the clinic that had led to the wrongful death of their embryos, and brought a civil claim under Alabama's Wrongful Death of a Minor Act. The law has long been interpreted as applying to events that cause the death of a pregnant woman's unborn child, regardless of that child's gestational age. By the same logic, the families insisted, it should also apply to their embryonic children.

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The question before the court was whether the law could be read that way, or should be understood to have an (unwritten) exception for an unborn child outside a mother's body. In its decision, the court reasonably concluded that it was not appropriate to invent such an exception based simply on the location of the embryos. The law already applied to human beings before birth from the earliest stages of development, and there is no relevant biological distinction between embryos in freezers and embryos in the womb: Both are living, distinct, whole (albeit immature) organisms of the human species who will, given the necessary environment and support, move themselves along a seamless species-specific trajectory through the various stages of development. So the court concluded that the statute is meant to apply equally to IVF parents as to other parents whose embryonic children die because of the wrongdoing of others.

In other words, the state supreme court acted not to undermine the practice of IVF in Alabama but to protect the interests of IVF families. And it did so as the result of a law that has long been on the books, not because of any connection to abortion or to the federal Supreme Court's overturning of *Roe v. Wade*.

But because the case touched on questions relating to the unborn, it was immediately forced into the framework of abortion politics. Reporters across the nation asserted that the court had said that frozen embryos are legally identical to older children, that this was because of the federal Supreme Court's overturning of *Roe*, and that it meant the end of IVF in Alabama and perhaps elsewhere.

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Prominent Democrats quickly embraced this treatment of the case. President Joe Biden said the decision showed a "disregard for women's ability to make these decisions for themselves and their families," called it "outrageous and unacceptable," and stated: "Make no mistake, this is a direct result of the overturning of *Roe v. Wade*." Vice President Kamala Harris said the Alabama court was "robbing women of the freedom to decide when and how to build a family." These comments ignored the fact that the Alabama plaintiffs were IVF patients, not anti-abortion activists. And they failed to note that the Alabama law protecting unborn children from wrongful death outside the context of abortion predated and did not depend on the Supreme Court's recent abortion ruling.

Several fertility clinics in Alabama went along with the widespread misrepresentation of the case's implications, announcing that they would halt fertility treatment as a result of the court's ruling unless the state legislature acted to reverse the court's decision. This looks to have been less a response to a threat to the practice of assisted reproduction than a move to evade legal liability and oversight. The kind of scenario that unfolded in the clinic in question, with an unauthorized individual walking through the facility and handling frozen embryos, is obviously not how the IVF industry generally seeks to operate. It is precisely the kind of breakdown of standards that laws

against negligence exist to address, and which calls for greater industry regulation more generally. But instead, and in response to the widespread distortions of the case in the national media and to threats from clinics in the state to stop providing IVF treatments, the state legislature exempted the industry from (and thereby denied the families it serves) even the basic consumer protections available in every other domain, let alone the sorts of guardrails that should be available when vulnerable parents and children are involved.

The legislature quickly and overwhelmingly passed (and the governor immediately signed into law) a bill that created blanket civil and criminal immunity for any person or entity who causes "damage to or death" of an embryonic human being when "providing or receiving services related to in vitro fertilization." In its haste, the legislature created a bizarre anomaly. No other branch of medicine, and no other facet of the health-care industry, enjoys such freedom to act with impunity.

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The result was perverse but painfully familiar: Policy makers, practitioners, and political activists purporting (and in many cases genuinely intending) to act in the name of vulnerable parents and children instead only advanced the interests of an already-sheltered industry, and left a fraught and sensitive domain of our society even more exposed and unprotected.

This pattern has repeated itself for decades. And calls for doing better have gone unheeded for a generation. Two decades ago, in March 2004, the President's Council on Bioethics—a cross-ideological group of advisers brought together by George W. Bush—published a report that took up this subject in terms that continue to resonate. The two of us were members of the council's staff at the time and helped draft the document, a detailed inquiry

and set of recommendations titled "Reproduction and Responsibility."

At the outset, the council plainly articulated the connection between the abortion debate and arguments over assisted-reproductive technology (which it termed ART). That connection, then as now, stood in the way of a serious debate about appropriate regulations and protections for those who make use of ART. As the council put it, "Defenders of reproductive freedom want no infringement of the right to make personal reproductive decisions, and they fear that the regulation of ART might undermine the right to privacy." On the other hand, the report continued, "pro-life opponents of embryo destruction fear that the federal regulation of assisted reproduction or embryo research might give tacit or explicit public approval to practices that they find morally objectionable." The report added that there is "deep disagreement" among Americans about the moral status of human embryos outside the body, and that "this disagreement is one of the main reasons for the current relatively laissez-faire approach to regulation."

But the effect of this approach has been to leave families without crucial information and essential protections. As the council noted, there was (and is) "no comprehensive, uniform, and enforceable mechanism for data collection, monitoring, or oversight of how the new reproductive biotechnologies affect the well-being of the children conceived with their aid, the egg donors, or the gestational mothers."

Neither is ART subject to the kinds of rules and norms that govern clinical research or the development and sale of new drugs and medical devices. There is essentially no information about adverse effects involved in novel practices, and no requirements to produce or provide any.

A similar regulatory vacuum surrounds the kind of cryogenically stored embryos specifically at issue in the Alabama case. In the United States (unlike

in much of Europe), there are no standard rules or practices around the numbers of embryos created, how they are preserved and handled, and what becomes of those that are not implanted and brought to term. No information is required to be collected or made available to consumers about what effects extended cryogenic preservation might have on the children who are ultimately born. There is no legal or policy framework for dealing with the complicated circumstances that surround human beings in this earliest stage of development outside the womb. Indeed, no definitive information exists about the number of embryonic human beings currently in cryostorage in the United States, though it is often suggested that the number may exceed 1 million.

The only federal statute specifically dedicated to ART, the Fertility Clinic Success Rate and Certification Act of 1992, is a toothless consumer-protection law. It requires the CDC to propose a model program for the certification of embryo laboratories, with states free to voluntarily adopt the program. We see no evidence that this has had any perceptible effect on the industry's practices.

The law also has the CDC collect some very basic data on IVF success rates. But the CDC does not report information of crucial relevance to prospective patients: It provides no data on the types or rate of adverse health outcomes to mothers or children (beyond noting the percentage of term, normal-weight, and singleton births) or on the costs of procedures. It does not speak in any way to the fact that the boundaries between fertility treatment, biomedical research, and the commercial economy are permeable and unmonitored. And it has no mechanisms for reliable auditing or meaningful enforcement of reporting requirements. No state adequately addresses these concerns either.

There are no laws specifically designed to protect the health and flourishing of mothers undergoing IVF or their children. There are no limitations on practices (such as the creation and transfer of multiple embryos per cycle) that

might increase the risks of preterm births, low birthweight, and related adverse health consequences. Even though the CDC has noted a correlation between IVF and an increased incidence of birth defects and other maladies, there have been no federally funded longitudinal studies to explore such possibilities in depth. Clinics offer genetic screening and selection of embryos for nonmedical purposes, including sex selection (which, according to one recent academic study, is available in 73 percent of IVF clinics in the United States). Meanwhile, companies sell predictive tests for screening embryos and aggregating data to create "polygenic risk scores" for low intelligence (with the promise of testing for high intelligence in the near future). Other companies provide embryo screening for hair and eye color. People buy and sell sperm, eggs, and even "batches" of embryos at a discounted rate and organized according to preferred traits.

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The Alabama legislature could have responded to the state supreme court's decision by using the alleged egregious negligence of the clinic in question as an occasion to establish some rules for the practice of fertility treatment, including the creation, use, and storage of living human embryos. Instead, the state is removing itself further from the challenges involved. Alabama families will now have even less legal protection in their interactions with fertility clinics than the very little protection they had before.

The Alabama case, and the legislature's reaction to its aftermath, highlights the shallowness of our society's engagement with the benefits and challenges posed by artificial reproduction. Offering better protection to the families involved, rather than leaving them more exposed, would be the least a responsible state legislature could do in response to the circumstances revealed by the litigation.

But ultimately, consumer protection is only the most crude of the tools our society should employ to protect Americans in this sensitive domain. The would-be parents seeking fertility treatment and the children they bring into the world are not, first and foremost, consumers, let alone political combatants. They are families, held together by a bond of love and mutual obligation, and dependent upon one another and on the support of the larger society. Both the practice and the regulation of assisted reproduction should proceed from the understanding that the animating goal is to form a family, which requires consideration of both the parents and the children, at all stages of the children's development and at every step of the parents' treatment process.

In any decent society, parents and children have a claim on all of us for support. Such support calls for the quality that has been most sorely lacking in the political response to the Alabama controversy: responsibility. It demands that we see fertility treatment in all its human dimensions, that we sympathize with the people involved, and that we also grasp the ways in which the most vulnerable among them sometimes need protection.

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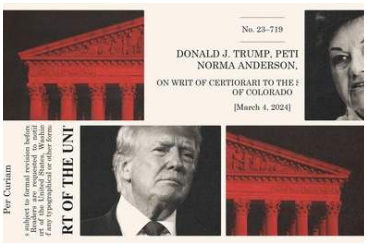

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