Responsible Self-Governance and Assisted Reproductive Technologies

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In February 2024, the Alabama Supreme Court ruled that the state's wrongful death statute offered an avenue of relief to a family alleging that an IVF clinic's negligence had led to the destruction of their embryonic offspring stored in that clinic's freezers. The Court concluded, correctly, that since the statute had already been authoritatively construed to protect human beings at the embryonic stage of development *in utero*, it likewise applied to living human embryos *ex utero* who were killed as a result of a defendant's negligence. The Court concluded that it was not its role to carve out judge-made exceptions to the scope of the statute, especially when the injured parents in cases such as this suffered the very same kind of injury as those who enjoyed the protection of the law, namely, the loss of their embryonic child due to the negligence of others. It was, the Court argued, for the state legislature to draw such lines, not for the judicial branch. It was a modest, commonsense decision by the Alabama Supreme Court.

Unfortunately, powerful political interests on the left immediately mobilized to create a false narrative that the Court had banned IVF in the name of a theological judgment concerning the value of human life at its earliest stages, and that this was simply a predictable consequence of the overturning of *Roe v. Wade* by the Supreme Court of the United States and the extremism of the pro-life movement. Enabled by some high-profile Alabama medical care providers, a sympathetic media, and prominent politicians, including then-President Biden and Vice President Harris, this false narrative took hold and spread across the nation for several weeks.

These events led, in turn, to Republicans both in Alabama and in Washington, DC to declare their passionate support for IVF and to resolve to find a legislative mechanism to increase access to it. (The Alabama state legislature went so far as to offer blanket immunity to clinics for any claims relating to "damage or death" of embryonic human beings during the provision of IVF treatment.) Enthusiasm for such a law appears to persist both as a policy matter and as a political strategy hoping to counter the relentless attacks on Republicans on the issue of abortion.

Given this appetite for federal legislation promoting IVF, it is useful to pause a moment to consider the complexity of the issue before moving forward. Yes, IVF has made it possible for many families to have the beautiful blessing of children. But the practice of IVF in America is also fraught with serious peril, especially in light of:

(i) the current state of non-regulation of the IVF industry as such (often described as a legal "Wild West" by commentators across the political spectrum);
(ii) the absence of longitudinal studies on the health and safety of children and mothers in this domain;
(iii) the speed with which experimental procedures in this field become routine practice;
(iv) the widespread use of ethically questionable non-medical interventions such as sex-selection and the marketing of testing for trait-selection, including intelligence and appearance;
(v) the commodification of the body and its parts, including the buying and selling of eggs, sperm, and embryos; and, of course,

(vi) the fact that IVF involves the creation, screening, transfer, storage, and sometimes destruction of a living human being at the earliest stages of development. Facing these risks are uniquely vulnerable and desperate patients, feeling betrayed by their own bodies in the effort to become what they most want to be, namely, parents of their beloved children.

For all of these reasons, governing on IVF is not a simple matter, and lawmakers would be well advised to proceed with caution.

Here are a few points for consideration, enlarging briefly upon the concerns set forth above.

Twenty-one years ago, the President's Council on Bioethics report titled *Reproduction and Responsibility: The Regulation of New Technologies* declared that there 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." Our own research (including in Snead, *What It Means to be Human: The Case for the Body in Public Bioethics* (Harvard University Press 2020, especially Chapter 4), confirms that this is still the case.

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.

Make no mistake, elected officials who have committed themselves to protecting the unborn should have serious concerns about this total lack of oversight or protection for human beings at the embryonic stages of development in the IVF process.

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.

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.

For our elected officials on Capitol Hill, we respectfully suggest that Senators, Congress members, and their staffs carefully study all of the aforementioned risks and complexities carefully (including the irresponsible practices of the IVF industry itself) before moving forward with legislation in this fraught domain.

For Further Reading:

Snead, O. Carter, and Yuval Levin. "The Real Lessons of the Alabama IVF Ruling." *The Atlantic*, March 15, 2024. https://www.theatlantic.com/ideas/archive/2024/03/alabama-ivf-ruling-regulation/677747/.

Snead, O. Carter. *What It Means to be Human: The Case for the Body in Public Bioethics*. Cambridge, MA: Harvard University Press, 2022. (especially Chapter 4).

The President's Council on Bioethics Report, *Reproduction and Responsibility: The Regulation of New Biotechnologies*. Washington, D.C., 2004. https://bioethicsarchive.georgetown.edu/pcbe/reports/reproductionandresponsibility/index.html (especially Chapter 2).

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