IN THE SUPREME COURT OF ALABAMA

Case No. SC-2022-0515

JAMES LePAGE and
EMILY LePAGE
and
WILLIAM TRIPP FONDE
and CAROLINE FONDE,

Appellants

v.

THE CENTER FOR REPRODUCTIVE MEDICINE, P.C. and
MOBILE INFIRMARY ASSOCIATION d/b/a MOBILE INFIRMARY MEDICAL CENTER,

Appellees

ON APPLICATION FOR REHEARING

BRIEF OF AMICUS CURIAE AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Case:

Code:

Other Authorities:

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STATEMENT OF INTEREST OF AMICUS CURIAE

The American Society for Reproductive Medicine (ASRM) was founded in 1944 and today has more than 9,000 members, including scientists, OB/GYN physicians, and healthcare support personnel. ASRM is dedicated to advancing the science and practice of reproductive medicine and pursues this mission through educational and research efforts and advocacy on behalf of patients, physicians, and health care providers.

ASRM also has deep roots in the state of Alabama, where it was headquartered until 2019. Birmingham, Alabama remains the home of ASRM's administrative office and numerous ASRM staff.

The outcome of this Appeal will have a profound impact on fertility medicine providers and their patients. The Court's decision attaching potential wrongful-death liability to the disposal of *in vitro* embryos has already disrupted IVF treatment in Alabama by forcing fertility clinics to discontinue necessary medical treatments, threatening thousands of Alabamians' ability to access the safest and most effective form of fertility treatments and to fulfill their goals of becoming parents.

BACKGROUND

The Wrongful Death of a Minor Act, enacted in 1872, creates a cause of action for damages for parents of a deceased child "[w]hen the death of a minor child is caused by the wrongful act, omission, or negligence of any person." ALA. CODE § 6-5-391(a). On February 16, a majority of this Court concluded that the term "minor child" in that 1872 statute applies to frozen embryos.

Justices Sellers and Cook dissented in part. As they explained, the drafters of the Wrongful Death of a Minor Act could by no means have intended to protect a frozen, untransferred embryo within the ambit of the statute; the concept of in vitro fertilization was, after all, a hundred years in the future. See Slip Op. at 72 (Partial Dissent of Sellers, J.); id. at 83-91 (Dissent of Cook, J.,); see also Slip Op. at 56 (Mendheim, J., concurring only in the result) (noting that "the main opinion's view . . . is problematic because when the Wrongful Death of a Minor Act was first enacted in 1872, and for 100 years thereafter, IVF was not even a scientific possibility"). Justice Cook also pointed out that "[n]o court—anywhere in the country—has reached the conclusion the main opinion

reaches. And, the main opinion's holding almost certainly ends the creation of frozen embryos through [IVF] in Alabama." Slip Op. at 80. As he explained, "[n]o 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." Id. at 123-124.

Justice Cook is correct. The main opinion has indeed given rise to "unfortunate consequences," to put it mildly. Slip Op. at 69 (Mendheim, J., concurring in the result). Among other seismic impacts, IVF facilities across the State are pausing or cancelling scheduled treatments, leaving people without the hope or prospect of carrying and bearing children.

Appellees accordingly are seeking rehearing. They will explain in detail the legal deficiencies in the majority Opinion, and the grave consequences the majority's untenable reasoning has wrought. The ASRM submits this brief to further elaborate on the significant medical and scientific mistakes the majority committed in service of the outcome it reached.

SUMMARY OF THE ARGUMENT

To reach the conclusion that wrongful-death liability may extend to the destruction of cryogenically frozen embryos, the Court's Opinion uses a purportedly textualist analysis to conclude that the term "minor child" in Alabama Code § 6-5-391—enacted one hundred years before the first IVF baby was born—includes frozen embryos. And to buoy that flawed textual analysis, the Court relies on medically and scientifically inaccurate information to support its reasoning.

The Court's majority Opinion insists that it does not wish to engage in judicial policymaking. But by expanding the scope of the Wrongful Death Act far beyond its text and context, the decision did exactly that: Multiple IVF clinics across Alabama have ceased offering IVF treatments as a direct consequence of this Court's Opinion.

ASRM calls on this Court to grant the Application for Rehearing and restore access to vital care to Alabamians experiencing fertility challenges.

ARGUMENT

I. THE MAJORITY OPINION COMMITS MULTIPLE MEDICAL AND SCIENTIFIC ERRORS AND IGNORES BEST PRACTICES IN REPRODUCTIVE MEDICINE.

In both the majority Opinion and Chief Justice Parker's Concurrence, the Justices invoke purely hypothetical technology and commit multiple medical and scientific errors, ignoring best practices in reproductive technology. Those errors, omissions, and exaggerations are regrettable and should be corrected on rehearing.

A. The Majority Opinion Makes Critical Scientific Errors.

The majority bolstered its flawed statutory analysis by observing that if the Court were to rule in defendants' favor, "even a full-term infant or toddler conceived through IVF and gestated to term in an in vitro environment would not qualify as a child or person because such a child would both be unborn and not in utero." Id. at 9 (internal quotes, numbering, and quotation marks omitted).

As Justice Mendheim explained, however, "it is not now—or for the foreseeable future—scientifically possible to develop a child in an artificial womb so that such a scenario could somehow unfold." Id. at 65.

The majority responds that the impediments to artificial wombs are mere "practical limitations[,]" which are "shrinking each year due to technological advances." Id. at 10 n.2 (internal quotation marks and references omitted). But, as Justice Mendheim observes, "[t]hat is simply untrue." Id. at 65 n.29. Any "artificial womb" technology existing today is focused on developing an environment for premature babies to *continue to develop after birth*.[1]

The majority's use of this hypothetical also confuses two distinct medical concepts: fertilization and gestation. IVF treatments do not include *gestation* outside the uterus; rather, the technology is premised on *fertilization* outside the body and subsequent implantation in a human uterus for the gestation period. By erasing the boundaries between

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[1] Cassandra Willyard, Everything You Need To Know About Artificial Wombs, MIT TECHNOLOGY REVIEW (Sep. 29, 2023), https://www.technologyreview.com/2023/09/29/1080538/everything-you-need-to-know-about-artificial-wombs/ (last visited Feb. 27, 2024); see also FDA Briefing Document, Pediatric Advisory Committee 8, Sep. 19, 2023, https://www.fda.gov/media/172183/download?attachment#:~:text=The%20Food%20and%20Drug%20Administration%20(FDA)%20is%20convening%20the%20Pediatric,premature%20infants%20(EPls)%2C%20including (last visited Feb. 27, 2024).

fertilization and gestation and hypothesizing about hypothetical future developments in human gestation, the majority strays far both from the facts of this case, and from reality.

B. Chief Justice Parker's Special Concurrence Makes Medical and Scientific Mistakes.

Chief Justice Parker's special Concurrence also relies on medical and scientific inaccuracies to bolster his position. Chief Justice Parker maintains that "many other Westernized countries have adopted IVF practice or regulations that allow IVF to continue while drastically reducing the chances of embryos being killed." Slip Op. at 44 (Parker, C.J., specially concurring). He suggests that 90% of embryo transfers occur one-at-a-time in Australia and New Zealand and that many European Union countries limit the number of embryos transferred in one cycle. Id. at 45-46. He also points to a 2004 Italian law banning cryopreservation of embryos except under certain circumstances as an example of a potential way to reduce the number of embryos needed to be preserved. Id. at 46.

The Chief Justice is, regrettably, incorrect. Australia and New Zealand do not mandate single transfers.[2] Italy *repealed* parts of its 2004 law after concluding that the law "violated women's rights to have access to the best possible treatment with [] lower health risks for her and [her] future children."[3] And any disparity in the average number of transfers per country likely reflects differences in health care systems, not a disagreement over best practices.[4] The use of false, or selectively chosen,

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[2] ETHICAL GUIDELINES ON THE USE OF ASSISTED REPRODUCTIVE TECHNOLOGY IN CLINICAL PRACTICE AND RESEARCH § 4.2.9, Australian Government, National Health and Medical Research Council (updated 2023), https://www.nhmrc.gov.au/about-us/publications/art.

[3] See Paolo Emanuele Levi Setti, and Pasquale Patrizio, The Italian Experience of A Restrictive IVF Law: A Review, 2 JOURNAL OF FERTILIZATION: IN VITRO – IVF-WORLDWIDE, REPRODUCTIVE MEDICINE, GENETICS & STEM CELL BIOLOGY 1000e108, 1000e108, https://www.longdom.org/open-access/the-italian-experience-of-a-restrictive-ivf-law-a-review-6216.html#:~:text=In%20detail%2C%20the%20Law%20obliged,or%20oocytes%20donation%20were%20forbidden (last visited Feb. 28, 2024).

[4] In the United States, most patients pay out of pocket for treatment, and the cost-per-cycle makes multiple cycles prohibitive for many patients. Gabriela Weigel et al., Issue Brief: Coverage and Use of Fertility Services in the U.S., Kaiser Family Foundation (Sep. 15, 2020), https://www.kff.org/womens-health-policy/issue-brief/coverage-and-use-of-fertility-services-in-the-u-s/ (last visited Feb. 28, 2024). In Europe, "most countries have established coverage limits of three or four cycles." K. Berg Brigham et al., The Diversity of Regulation and Public

data presents a correspondingly false picture of the current state of IVF regulation in the United States as compared to the rest of the world.[5]

The Chief Justice also erroneously conflates multiple distinct aspects of reproductive technology. IVF involves the use of medication to stimulate ovulation, surgically removing a patient's eggs, fertilizing them with sperm, and transferring the embryos to the patient's uterus for implantation.[6] IVF is often combined with cryopreservation, a method of freezing embryos in order to postpone or delay transfer until the patient is prepared to start, or expand, a family.[7] The medical criteria for the appropriate number of embryos to transfer depends on a variety of

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Financing of IVF in Europe and its Impact on Utilization, 28 Human Reproduction 666, 670 (2013), https://doi.org/10.1093/humrep/des418.

[5] The Chief Justice's selective reliance on other countries' health systems also is troubling, given that the Court majority wholly ignores pertinent information far closer to home. As Justice Cook notes, "not a single state has held that a wrongful-death action . . . can be brought for the destruction of a frozen embryo." Slip Op. at 123. In fact, "a number of jurisdictions have rejected such causes of action." Id.

[6] In Vitro Fertilization (IVF), MAYO CLINIC, https://www.mayoclinic.org/tests-procedures/in-vitro-fertilization/about/pac-20384716 (last visited Feb. 27, 2024).

[7] Embryo Freezing (Cryopreservation), CLEVELAND CLINIC, https://my.clevelandclinic.org/health/treatments/15464-embryo-freezing-cryopreservation (last visited Feb. 27, 2024).

factors, including the age of the patient, the quality of the gametes, and the stage of the embryo.[8] Single-transfers of euploid blastocysts[9] are recommended for patients regardless of age.[10] Patients between 35 and 37 years old are strongly recommended to consider single-embryo transfers; patients between 38 and 40 should receive no more than 3 cleavage-stage embryos or two blastocyst.[11]

These differing recommendations reflect the medical reality that patients of differing ages and other factors will respond divergently to IVF treatment. Younger patients will more likely become pregnant with only one transfer; older patients may never become pregnant if restricted only to single transfers. Thus, Chief Justice Parker's advocacy of single transfers overlooks the extent to which the number of transfers medically recommended for a patient varies according to critical factors. The

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[8] Guidance on the Limits to the Number of Embryos to Transfer: A Committee Opinion, American Society for Reproductive Medicine, 166 FERTILITY AND STERILITY 651, 651 (2021), https://www.asrm.org/practice-guidance/practice-committee-documents/guidance-on-the-limits-to-the-number-of-embryos-to-transfer-a---committee-opinion-2021/ (last visited Feb. 28, 2024).
[9] Euploid embryos have the best prognosis for pregnancy. Id. at 653.
[10] Id. at 652.
[11] Id.

widespread negative impact of the Court's Opinion is not, as Chief Justice Parker suggests, mitigated by use of single transfers; it will persist as long as multiple transfers remain financially out of reach to many patients.

If access to cryopreservation is eliminated, patients using IVF have two remaining options, neither of them advisable. The first is to immediately implant *all* fertilized eggs in one transfer in a patient's uterus.[12]

However, multiple gestation is linked to higher-risk pregnancies, including greater risk of pre-term delivery and long-term complications associated with prematurity.[13]

The second option is to fertilize only one egg. But the percentage of embryo transfers that result in live-birth delivery of one or more babies varies by patient age and embryo source (patient or donor). The odds of

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[12] In Vitro Fertilization (IVF), MAYO CLINIC, https://www.mayoclinic.org/tests-procedures/in-vitro-fertilization/about/pac-20384716 (last visited Feb. 27, 2024).
[13] Complications of Multiple Pregnancy, JOHNS HOPKINS MEDICINE, https://www.hopkinsmedicine.org/health/conditions-and-diseases/staying-healthy-during-pregnancy/complications-of-multiple-pregnancy (last visited Feb. 27, 2024).

carrying a pregnancy to term conceived by an embryo transfer is not above 50% for women of any age.[14] If the patient does not become pregnant, she will lose her opportunity to become pregnant in the future if she cannot undergo another IVF cycle. Relying on this second option will also lead to unnecessary risks for patients forced to undergo multiple rounds of egg retrieval and hormone therapy, which can involve serious complications (and huge financial outlays).[15] It is because of awareness of the risks associated with egg retrieval that expert opinion suggests a maximum of six cycles per egg donor.[16] It is safer, more effective, and

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[14] 2019 Assisted Reproductive Technology Fertility Clinic and National Summary Report, CENTERS FOR DISEASE CONTROL AND PREVENTION 29 (2019), https://archive.cdc.gov/www_cdc_gov/art/reports/2019/pdf/2019-Report-ART-Fertility-Clinic-National-Summary-h.pdf (last visited Feb. 28, 2024) (reporting a 50.5% average embryo to live birth success rate).

[15] Prevention and Treatment of Moderate and Severe Ovarian Hyperstimulation Syndrome: A Guideline, American Society for Reproductive Medicine, 106 FERTILITY AND STERILITY 1634, 1634 (2016), https://www.asrm.org/globalassets/_asrm/practice-guidance/practice-guidelines/pdf/prevention_and_treatment_of_moderate_to_severe_ohss.pdf (last visited Feb. 28, 2024) (discussing prevention and treatment of ovarian hyperstimulation syndrome, a complication associated with IVF).

[16] Repetitive Oocyte Donation: A Committee Opinion, Practice Committee of the American Society for Reproductive Medicine and Practice Committee of the Society for Assisted Reproductive Technology, 113 FERTILITY AND STERILITY 1150-53, 1151 (2020),

better medicine for a woman undergoing IVF to undergo egg retrieval a single time and use cryopreservation to preserve embryos for future transfers.

* * *

The Justices are not medical experts. The speculations, mistakes, and omissions in the majority and Chief Justice's opinions are therefore perhaps understandable, but they are still unacceptable. The opinions relied on those medical and scientific errors to diminish the consequences of the Court's decision on the practice of IVF in Alabama. That was wrong and should be corrected.

II. THE MAJORITY FAILED TO ADEQUATELY CONSIDER THE REAL-WORLD IMPLICATIONS OF ITS LEGALLY AND SCIENTIFICALLY ERRONEOUS REASONING.

The majority Opinion states that it wishes to avoid judicial policymaking. But the serious legal, factual, and scientific shortcomings in the majority's quasi-textual reasoning invite the very discussion of policy implications the majority would otherwise seek to avoid. For to be

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https://www.asrm.org/globalassets/_asrm/practice-guidance/practice-guidelines/pdf/repetitive_oocyte_donation.pdf.

very clear: Allowing wrongful-death actions for loss of non-implanted frozen embryos will end IVF as it currently exists in the state of Alabama.

Before this Court's decision, it had been standard practice for Alabama couples to undergo IVF and freeze *in vitro* embryos in cryogenic storage. It is also standard practice for cryogenically frozen embryos to be discarded or donated if parents are unable or unwilling to undergo future transfers. Fertility clinics and other health care providers typically establish a procedure for when and how to donate or discard embryos in accordance with patients' direction and consent. Embryos are not stored in perpetuity; cryogenic storage is costly, and patients typically don't want to continue maintaining their frozen embryos indefinitely. Many clinics accordingly ask patients to sign contracts, including provisions related to use or disposal of embryos after a certain period. (This includes the Plaintiffs in this case, who all signed such contracts. Slip Op. at 4.) This practice of contracting related to length of preservation is a necessary reality for clinics and patients, neither of whom could shoulder this financial burden permanently.

Recognizing a wrongful death action for destruction of pre-implanted embryos would require fertility clinics to preserve these embryos in perpetuity. Indefinite preservation is impractical and would undermine fertility clinics' ability to offer IVF treatments. Storage fees for frozen embryos cost from $350 to $1,000 per year.[17] The costs would increase exponentially as increasing numbers of embryos are stored, and none are disposed of.[18]

But far worse than increasing costs of IVF for patients and clinics is the ruling's immediate, catastrophic impact on access to the safest and most effective method of IVF to Alabamians with fertility challenges. In the few weeks since this Court issued its decision, at least three fertility clinics have paused new IVF treatments.[19] This includes the largest clinic

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[17] Caroline A. Harman, Comment: Defining the Third Way – The Special-Respect Legal Status of Frozen Embryos, 26 GEO. MASON L. REV. 515, 521 (2018) (citing Embryo Storage Costs, REPROTECH LTD., https://reprotech.com/embryo-storage-costs/ (last visited Feb. 9, 2022)).
[18] Embryo Storage Costs, REPROTECH LTD., https://reprotech.com/embryo-storage-costs/ (last visited Feb. 9, 2022).
[19] Nomia Iqbal & Chloe Kim, Alabama Clinics Pause IVF Treatments After Frozen Embryo Ruling, BBC News, (Feb. 21, 2024), https://www.bbc.com/news/world-us-canada-68373901.

in the state.[20] Only days after the Court issued its Opinion, Alabama Fertility stated that it had made the "impossibly difficult decision to hold new IVF treatments due to the legal risk to our clinics and our embryologists."[21] The University of Alabama at Birmingham's IVF clinic also announced that it was pausing fertility treatments.[22] To make matters worse, patients who wish to transport their embryos to other facilities have been unable to do so. The University of Alabama at Birmingham Hospital stated that it has been unable to locate shipping companies "able and willing" to transport embryos.[23] Though the Hospital continues to search for a company, "at this time—there are no

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[20] Id.

[21] Alabama Fertility Specialists, FACEBOOK, (Feb. 25, 2024), https://www.facebook.com/alabamafertility/posts/dear-patients-of-afswe-have-made-the-impossibly-difficult-decision-to-hold-new-i/924664096329070/.

[22] El-Bawab, Nadine, Elizabeth Schulze, & Cheyenne Haslett, Alabama's Biggest Hospital to Suspend Transfer of Embryos After Court Ruling, ABC News (Feb. 23, 2024; 4:42 PM), https://abcnews.go.com/US/2-alabama-clinics-pause-ivf-fertility-treatment-after/story?id=107455469#:~:text=Alabama%27s%20biggest%20hospital%20announced%20it,frozen%20embryos%20are%20considered%20children.

[23] Id.

options available."[24] Even though the ruling has been in effect only for a matter of days, patients are already being denied access to treatments they are counting on to start or grow their families.[25]

The Opinion also fails to consider the reality of how IVF technology functions. It is common in the IVF process that some embryos do not develop. In nature as well as the lab, many, if not most, embryos do not result in a viable pregnancy. The freezing and thawing processes also impose some additional risk. Many embryos never develop and cannot be implanted. Indeed, the majority of "embryos stop developing and perish within days of fertilization."[26] The logical outgrowth of the Court's opinion, however, is that implanted embryos that fail to develop may also carry liability risks. That in turn would make IVF so legally risky that

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[24] Id.
[25] Iqbal, Alabama Clinics Pause IVF Treatments After Frozen Embryo Ruling, supra n.19.
[26] Study Finds Why Many IVF Embryos Fail to Develop, COLUMBIA UNIVERSITY (Jul. 19, 2022), https://www.cuimc.columbia.edu/news/study-finds-why-many-ivf-embryos-fail-develop#:~:text=In%20humans%2C%20a%20fertilized%20egg,an%20abnormal%20number%20of%20chromosomes (last visited Feb. 29, 2024).

most if not all fertility specialists would stop providing IVF treatments in the state *altogether*.

CONCLUSION

For these reasons, ASRM respectfully urges this Court to hold that "minor child" under Ala. Code § 6-5-391 does not include cryogenically stored embryos.

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