United States Senate

WASHINGTON, DC 20510

June 20, 2024

VIA ELECTRONIC TRANSMISSION

The Honorable Christi Grimm
Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
300 Independence Avenue, SW
Washington, D.C. 20201

Ms. Grimm:

We write to request that the Department of Health and Human Services Office of Inspector General (HHS OIG) audit the safety standards at fertility clinics and the quality of data collected by the Centers for Disease Control and Prevention (CDC) with respect to Assisted Reproductive Technology (ART) procedures to treat infertility. In-vitro fertilization (IVF) is an important tool for many American mothers who want to experience the joy of childbirth. Navigating the experience of needing IVF and the complex medical system in which it operates is a daunting endeavor. Mothers in this situation make a substantial emotional, financial, and personal investment, and rightly expect that fertility clinics will protect and respect human life—and keep treasured embryos safe.

Tragically, the recent case at the Center for Reproductive Medicine in Mobile, Alabama, in which a hospital patient wandered into the Center's cryogenic nursery through an unsecured doorway, attempted to remove human embryos from cryostorage, and dropped them—destroying five embryos[1]—is not unique. In March 2018, Pacific Fertility Center in San Francisco, California, suffered a cryogenic storage tank failure resulting in the death of 3,500 eggs and embryos.[2] That same weekend, a different cryogenic storage tank failed at University Hospitals Fertility Center in Cleveland, Ohio, resulting in the death of 4,000 eggs and embryos.[3]

In yet another example, in 2021, the California Center for Reproductive Health and In Vitrotech Labs in Los Angeles, California, "mixed up" two embryos and inserted them into the wrong women.[4] As a result, these mothers unwittingly gave birth to, and raised, the other's baby for

[1] *See LePage v. Ctr. for Reprod. Med., P.C.*, No. SC-2022-0515, 2024 WL 656591, at *1 (Ala. Feb. 16, 2024), *reh'g denied*, No. SC-2022-0515, 2024 WL 1947312 (Ala. May 3, 2024).
[2] *See In re Pac. Fertility Ctr. Litig.*, No. 18-CV-01586-JSC, 2021 WL 5283954 (N.D. Cal. Nov. 12, 2021); Verdict Form, *In re Pac. Fertility Ctr. Litig.*, No. 18-CV-01586-JSC, 2021 WL 2580263 (N.D. Cal. June 10, 2021).
[3] *See* Journal Entry, *Brickel et al. v. Univ. Hosps. Ahuja Med. Ctr. et al.*, No. CV-18-894332 (Ct. Com. Pl. Cuyahoga Cnty., Ohio, filed May 23, 2019).
[4] *See* Complaint, *Cardinale v. Cal. Ctr. for Reprod. Health et al.*, No. 21STCV41010 (Cal. Super. Ct. L.A. Cnty., filed Nov. 8, 2021).

months before DNA testing revealed the mistake.[5] A 2023 Bloomberg investigation into Kindbody, which operates 33 fertility clinics across the country, also revealed multiple instances of accidental embryo destruction, mislabeled embryos, and labs with faulty heating, ventilation, and air conditioning systems.[6] And, just this year, in April 2024, 11 couples filed lawsuits against Ovation Fertility in Newport Beach, California, for using hydrogen peroxide instead of distilled water during the incubation process and for relying on "inexperienced, cheap, unqualified, and untrained employees to cut corners and maximize profits."[7] The fertility clinic transferred more than two dozen embryos into would-be mothers despite knowing they were nonviable, and waited over a month to tell them something went wrong.[8] These tragedies, and many others not detailed, all stem from avoidable errors.

The Fertility Clinic Success Rate and Certification Act (FCSRCA) of 1992 is a federal statute governing ART programs and fertility clinics.[9] It requires each ART program to report data to CDC and directs CDC to develop a model certification program to be carried out voluntarily by interested states. Specifically, ART programs must annually report the rate of successful pregnancies, the identity of each embryology laboratory used by the program, and whether the embryology laboratory has applied for, or received, certification under the law. CDC is then required to publish this data annually in a public report. FCSRCA also gives the HHS Secretary the authority to revoke the approval of a state's certification program or the accreditation organization for failing to comply with these standards. While FCSRCA also requires state inspections, it authorizes, but does not require, federal inspections.

In 1999, CDC issued a notice setting forth the model certification program required by FCSRCA, which was informed by existing standards such as the Reproductive Laboratory Accreditation Program (RLAP), jointly developed by the College of American Pathologists (CAP) and the American Society for Reproductive Medicine (ASRM).[10] The notice states that CDC chose to "defer implementation of the approval of State certification programs or accreditation organizations, as well as Federal validation inspections of embryo laboratories certified by States adopting the model or accredited by an accreditation program for embryo laboratories."[11] Since these statutory requirements have not been implemented, in the annual report, CDC notes only that a fertility clinic has been accredited by CAP or the Joint Commission on Accreditation of

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[5] *See id.*
[6] *See* Jackie Davalos, *Kindbody Fertility Clinic Embryo Errors Spotlight IVF Business Risks*, BLOOMBERG (Oct. 13, 2023, 6:00 AM), https://www.bloomberg.com/news/articles/2023-10-13/kindbody-fertility-clinic-embryo-errors-spotlight-ivf-business-risks?sref=E9Urfma4&srnd=technology-vp.
[7] *See* Complaint, *Berger et al. v. Ovation Fertility et al.*, No. 30-2024-01395673-CU-PO-CXC (Cal. Super. Ct. Orange Cnty., filed Apr. 23, 2024); Complaint, *A.B. v. FPG Labs, LLC et al.*, No. 30-2024-01394273-CU-FR-CJC (Cal. Super. Ct. Orange Cnty., filed Apr. 18, 2024); Complaint, *E.F. v. FPG Labs, LLC et al.*, No. 30-2024-01394276-CU-FR-NJC (Cal. Super. Ct. Orange Cnty., filed Apr. 18, 2024).
[8] *Id.*
[9] Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, 106 Stat. 3146-52 (1992).
[10] Implementation of the Fertility Clinic Success Rate and Certification Act of 1992—A Model Program for the Certification of Embryo Laboratories, 64 Fed. Reg. 39,374 (July 21, 1999), https://www.govinfo.gov/content/pkg/FR-1999-07-21/pdf/99-18405.pdf.
[11] *Id.* at 39,382.

Healthcare Organizations (Joint Commission).[12] As a result, patients may be left uninformed about the safety standards of many of these clinics.

CDC's most recent annual report, published in 2023 and reflecting 2021 data, states that all of the facilities involved in the cases detailed above are certified embryo laboratories accredited by CAP through RLAP—presumably in good standing.[13] Though the federal statute does not specify that certification programs must include safety standards, RLAP "Focuses on areas to make laboratory processes more fail-safe and reduce risk of errors in patient identification, specimen labeling, handling of embryos and gametes and cryo storage conditions to protect your patients."[14] The Joint Commission's laboratory accreditation standards are not readily publicly available. As of 2021, 39 out of 453 ART clinics reporting to CDC had no accreditation, and 33 clinics still in operation did not comply with reporting requirements.[15]

CDC's annual report also fails to inform mothers that the Food and Drug Administration (FDA) has sent warning letters to numerous certified embryo laboratories due to "significant deviations" from federal regulations, including failure to properly test human reproductive material for communicable diseases (including Human Immunodeficiency Virus, hepatitis, West Nile virus, and others) and screen donors for risk factors that could increase the chance of transmitting a communicable disease.[16]

Women expect transparency with access to accurate pregnancy success rates and the certification status of the fertility clinics they are considering. It is unclear, however, whether CDC is implementing the law in such a manner as to maximally benefit the mothers it purportedly seeks to empower. As Congress considers legislation related to IVF, we respectfully request that HHS OIG provide an evaluation and assessment of how well ART clinic oversight is working to better enable Congress to evaluate what changes may need to be made. Thank you for your prompt attention to this request.

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[12] *2021 Assisted Reproductive Technology Fertility Clinic and National Summary Report*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (2023), https://www.cdc.gov/art/reports/2021/pdf/Report-ART-Fertility-Clinic-National-Summary-H.pdf.

[13] *Id.* at 34-71.

[14] *Reproductive Accreditation Program*, COLL. OF AM. PATHOLOGISTS, https://www.cap.org/laboratory-improvement/accreditation/reproductive-accreditation-program (last visited June 10, 2024).

[15] *2021 Assisted Reproductive Technology Fertility Clinic and National Summary Report*, *supra* note 12, at 34-74.

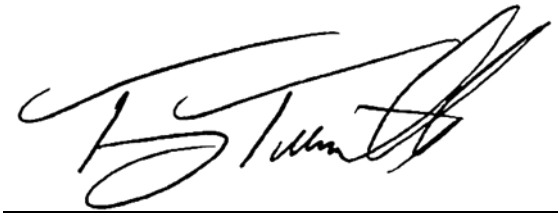
[16] The warning letters can be found in FDA's Warning Letter database, available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters. These warning letters are generally sent by the Office of Biological Product operations for violations of requirements that apply to human cells, tissues, and cellular and tissue-based products.

Sincerely,

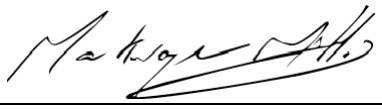
Bill Cassidy, M.D.
Ranking Member
U.S. Senate Committee on Health,
Education, Labor, and Pensions

James Lankford
U.S. Senator

Roger Marshall, M.D.
U.S. Senator



Tommy Tuberville
U.S. Senator



Markwayne Mullin
U.S. Senator