

January 29, 2024

**Via Federal eRulemaking Portal**

Tiffany Brown,  
Executive Secretary, Centers for Disease Control and Prevention.  
Division of Reproductive Health  
National Center for Chronic Disease Prevention and Health Promotion  
Centers for Disease Control and Prevention  
4770 Buford Highway NE,  
Mailstop S107-2,  
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Attention: Assisted Reproductive Technology Surveillance and Research Team

**Re: EPPC Scholar Comment on CDC’s Notice “Reporting of Pregnancy Success Rates From Assisted Reproductive Technology (ART) Programs; Proposed Modifications to Data Collection Fields and Data Validation Procedures; Request for Comment,” Docket No. CDC–2023–0093**

Dear Assisted Reproductive Technology Surveillance and Research Team:

My name is Natalie Dodson, and I am a scholar at the Ethics and Public Policy Center (EPPC), where I serve as a member of EPPC’s HHS Accountability Project. I write in response to the Centers for Disease Control and Prevention (CDC) notice “Reporting of Pregnancy Success Rates From Assisted Reproductive Technology (ART<sup>1</sup>) Programs; Proposed Modifications to Data Collection Fields and Data Validation Procedures; Request for Comment.”<sup>2</sup> I write to share my input with the CDC’s notice proposing changes to the reporting requirements for assisted reproductive technology (ART).

The HHS Accountability Project supports mothers and women, including those who struggle with infertility. We are also committed to upholding the dignity of human life from conception to natural death. Human life, including embryos created outside of the womb (unborn children), possesses invaluable dignity.

ART, the subject of this general notice, includes *in vitro fertilization* (IVF), surrogacy, egg donation, and sperm donation. These medical procedures raise serious ethical and moral questions, such as the commodification of women and children. Yet, the fertility industry is

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<sup>1</sup> As defined by the CDC, “ART includes all fertility treatments in which either eggs or embryos are handled.” <https://www.cdc.gov/art/whatis.html>.

<sup>2</sup> 88 Fed. Reg. at 83131 (Nov. 28, 2023).

largely self-regulated, with little to no government oversight. Without proper oversight, this industry has become the “Wild West of modern medicine.”<sup>3</sup> One of the only record-keeping requirements originates from the Fertility Clinic Success Rate and Certification Act of 1992, making the CDC’s reporting requirements obligatory and legally binding.

I am concerned with the CDC’s proposal to eliminate certain reporting requirements. Accurate data is the first step to protecting women’s health and children’s interests. As discussed below, rather than eliminating specific reporting requirements, the CDC should consider adding additional reporting requirements.

## **1. Background and Risks Associated with Assisted Reproductive Technology**

The Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA) requires reporting to the CDC for “pregnancy success rates” and “embryo laborator[ies].”<sup>4</sup> Throughout the years, the CDC has proposed updates to these reporting requirements. The last updated notice in June 2022 added additional reporting requirements to demographic reporting and donor information reporting.<sup>5</sup> The 2023 notice, however, proposes removing several reporting requirements and eliminating the CDC’s response requirements to data discrepancies.

Assisted reproductive technology (ART) is a primarily self-regulated industry. It addresses highly emotional, sensitive, and challenging reproductive situations such as infertility. Ethical and safety questions surrounding ART have historically been ignored by state and federal governments. As such, the CDC, via the FCSRCA, plays an essential role in the oversight of ART and ought to fulfill its duty to require adequate reporting.

ART, while expensive, is often one of the first suggested solutions to infertility. But ART is not without serious risks to both women and children. Many couples invest large portions of their finances into ART without proper understanding or knowledge of the risks associated with the treatments to the mother and child. The success rates for ART have also been artificially inflated, often misleading couples who view ART as the solution to their infertility.<sup>6</sup>

Consider IVF, one of the most commonly known parts of ART. Most embryos created through IVF do not make it to live births. Of the millions of embryos created in the last nearly thirty years, only 7% of lab-created children will be born alive.<sup>7</sup> Embryos that undergo genetic testing and are deemed undesirable will be thrown away. Some embryos “won’t survive the thaw or transfer, the few that do implant may be “selectively reduced” (aborted) or have their siblings

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<sup>3</sup> *Radical ‘Right to Build Families Act’ Would Unleash IVF and Commercial Surrogacy*, Daily Signal (January 12, 2023), <https://www.dailysignal.com/2023/01/12/radical-right-to-build-families-act-would-destroy-assisted-reproductive-technology-protections/>.

<sup>4</sup> Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. §263a-1–263a-7.

<sup>5</sup> 87 Fed. Reg. 112.

<sup>6</sup> Kallie Fell, *A Comprehensive Report on the Risks of ART*, Center for Bioethics and Culture Network, <https://cbc-network.org/wp-content/uploads/2023/05/Comprehensive-Paper-on-ART-Final.pdf>

<sup>7</sup> Steve Doughty, *1.7 million embryos created for IVF have been thrown away, and just 7 percent lead to pregnancy*, Daily Mail, Dec. 30, 2012, <https://www.dailymail.co.uk/news/article-2255107/1-7-million-embryos-created-IVF-thrown-away-just-7-cent-lead-pregnancy.html>.

“selected” for disposal. And many will spend their lives in a freezer.”<sup>8</sup> As of 2017, almost three-quarters of a million embryos had been frozen.<sup>9</sup> A fertility doctor commented on the ongoing misfortune when he shared, “Twenty-one percent of our embryos have been abandoned.”<sup>10</sup> The decision of what to do with these abandoned embryos is almost entirely left to these fertility clinics and doctors. For the embryos that are successfully thawed after freezing, the clinics are “performing a highly experimental procedure on human beings who cannot in any way consent to the procedure they are undergoing.”<sup>11</sup>

In addition to these concerns, donor conception (DC) for the use of IVF and surrogacy can lead to exploitation and disregard for a surrogate’s health. It also treats children as commodities. As one DC child described, children are essentially chosen from “a catalog.”<sup>12</sup> IVF practices commonly result in modern-day eugenics, as embryos with “desirable traits” are often prioritized over others.

ART has health risks for women seeking to become pregnant. The women involved in ART face “higher risks of adverse obstetric outcomes, and [it is recommended that] obstetricians should manage these pregnancies as high risk.”<sup>13</sup> From the first step of the ART process, egg donors are at risk of “ovarian Hyper Stimulation syndrome (OHSS) due to superovulation, loss of fertility, ovarian torsion, stroke, kidney disease, premature menopause, ovarian cysts, and in some rare cases, death.”<sup>14</sup> Unfortunately, not enough studies have been performed to understand the extent of the risks associated with ART, but incentivizing and requiring reporting may assist in these studies.

ART also impacts the health of children born through the intervention of these technologies in numerous ways. For example, “children conceived using ART were about two times more likely to be diagnosed with ASD [(autism spectrum disorder)] compared to children conceived without using ART.”<sup>15</sup> Similarly, “studies have found ART to be associated with a number of adverse health outcomes, including an increased risk of congenital malformations and perinatal mortality.”<sup>16</sup> An increased risk of childhood cancer has also been linked to ART.<sup>17</sup>

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<sup>8</sup> Them Before Us, *Fast Facts*, <https://thembeforeus.com/fast-facts/>.

<sup>9</sup> An Absurd Fate: What Happens to Abandoned Embryos?, *Public Discourse* (October 15, 2017), <https://www.thepublicdiscourse.com/2017/10/20180/>.

<sup>10</sup> Nation's fertility clinics struggle with a growing number of abandoned embryos, NBC News (August 12, 2019), <https://www.nbcnews.com/health/features/nation-s-fertility-clinics-struggle-growing-number-abandoned-embryos-n1040806>.

<sup>11</sup> An Absurd Fate: What Happens to Abandoned Embryos?, *Public Discourse* (October 15, 2017), <https://www.thepublicdiscourse.com/2017/10/20180/>.

<sup>12</sup> Them Before Us, <https://thembeforeus.com/fast-facts/>.

<sup>13</sup> Kallie Fell, *A Comprehensive Report on the Risks of ART*, Center for Bioethics and Culture Network, <https://cbc-network.org/wp-content/uploads/2023/05/Comprehensive-Paper-on-ART-Final.pdf>

<sup>14</sup> *Ibid.*

<sup>15</sup> Key Findings: The association between assisted reproductive technology and autism spectrum disorder, <https://www.cdc.gov/ncbddd/autism/features/artandasd.html>.

<sup>16</sup> Hargreave M. Fertility Treatment and Childhood Cancer Risk. *JAMA Netw Open*. 2022;5(8):e2230162. doi:10.1001/jamanetworkopen.2022.30162; Liang Y, Chen L, Yu H, Wang H, Li Q, Yu R, Qin J. Which type of congenital malformations is significantly increased in singleton pregnancies following after in vitro fertilization/intracytoplasmic sperm injection: a systematic review and meta-analysis. *Oncotarget*. 2017 Dec 25;9(3):4267-4278. doi: 10.18632/oncotarget.23689. PMID: 29423121; PMCID: PMC5790538.

Reporting requirements are all the more important for studies to accurately examine the risks associated with ART. Data is needed to provide women with informed consent. Children born via ART deserve to know their health profile and understand their predispositions to serious medical conditions and diseases.

## **2. The CDC Should Not Eliminate Reporting Requirements for Long-Acting FSH.**

The 2023 notice proposes removing the requirement for clinics to report dosage information for fertility medications, including Clomiphene, Letrozole, and long-acting FSH (follicle-stimulating hormones).<sup>18</sup> The proposal states that long-acting FSH “is no longer used in ART practice, [so] CDC proposes discontinuing the collection of information on this medication.”<sup>19</sup>

While long-acting FSH may not be as commonly used for ART, nothing prohibits clinics from using it in the future. Indeed, there is no guarantee that it will not regain its popularity or that it will not still be used in some practices. In fact, a 2020 research article asserted that “using long acting FSH ... should be the future of IVF.”<sup>20</sup> Indeed, the FDA still allows Elonva, the brand name for the drug, to be prescribed for three-month trials.<sup>21</sup> Even if, for the time being, long-acting FSH is not widely prescribed for ART, reporting is important so that the CDC and others can be informed if its usage increases again.

Further, it appears that long-acting FSH is still used prior to the production of the donor’s eggs and is closely connected to the ART process. A 2023 report on the risks of ART states:

In conjunction with Lupron®, egg donors begin taking Gonadotropins, which serve to stimulate the egg follicles to produce multiple eggs. These medications contain an active form of Follicle Stimulation Hormone (FSH), the main hormone responsible for producing mature eggs in the ovaries in a woman’s body.<sup>22</sup>

Documented side effects and risks of long-acting FSH include miscarriage, ovarian hyperstimulation syndrome, and ectopic pregnancy.<sup>23</sup> As such, it is important that the CDC continue to require reporting on the use of long-acting FSH, as prescriptions for the medication are still the established practice for egg donors. Data on long-acting FSH as it relates to the safety and well-being of these women is necessary for future oversight of its use.

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<sup>17</sup> *Ibid.*

<sup>18</sup> 88 Fed. Reg. at 83132.

<sup>19</sup> *Ibid.*

<sup>20</sup> Clinical and Experimental Obstetrics and Gynecology, ISSN: 2709-0094, Vol: 49, Issue: 3, Page: 78, 2022, <https://www.imrpress.com/journal/CEOG/49/3/10.31083/j.ceog4903078>.

<sup>21</sup> *IVF Pharmacy*. Accessed January 28, 2024. <https://www.ivfpharmacy.com/drug/>.

<sup>22</sup> Kallie Fell, *A Comprehensive Report on the Risks of ART*, Center for Bioethics and Culture Network, <https://cbc-network.org/wp-content/uploads/2023/05/Comprehensive-Paper-on-ART-Final.pdf>.

<sup>23</sup> Long-Acting FSH Useful for Assisted Reproduction, <https://www.contemporaryobgyn.net/view/long-acting-fsh-useful-assisted-reproduction>.

In short, the CDC tracks IVF cycles using donor eggs, and information about long-acting FSH would be valuable data to maintain and impose minimal reporting burdens, especially if it is not used (or used often) as the CDC claims.

### **3. The Assisted Reproductive Technology Industry is Largely Self-Regulated, so the CDC should Increase its Reporting Requirements.**

Besides medical licensing, very few states regulate the ART industry, leaving the federal government, particularly the CDC, in the preeminent position to regulate this space. Because serious medical and ethical dilemmas arise when handling genetic and embryonic materials, the CDC should require the relevant amount of clinical reporting possible.

Rather than eliminating reporting requirements for clinical data, I recommend adding requirements for tracking, data accumulations, and limits on how IVF is practiced, such as the number of embryos created, destruction, testing, etc.

I support the current reporting requirements for “cycle specific data,” which include the following<sup>24</sup>:

- Outcome of Treatment (Not Pregnant, Biochemical Pregnancy, Ectopic Pregnancy, Clinical Intrauterine Gestation, Heterotopic Pregnancy, Unknown);
- Maximum Number of Fetal Hearts;
- Ultrasound Date;
- If >2 Fetal Hearts, any Monochorionic Twins/Multiples;
- Outcome of Pregnancy (Live Birth, Stillbirth, Spontaneous Abortion, Induced Abortion, Maternal Death Prior to Birth, Unknown);
- Date of Pregnancy Outcome;
- Method of delivery (Vaginal, Cesarean section);
- Source for Outcome of Pregnancy (Verbal Confirmation Patient, Written Confirmation Patient, Verbal Confirmation Physician or Hospital, Written Confirmation Physician or Hospital);
- Method of Delivery (Vaginal, Cesarean section);
- Number of Infants Born;
- Birth Status (Live Birth, Stillbirth, Unknown);
- Gender of Infant (Each Live-born and Stillborn Infant);
- Birth Weight (Each Live-born and Stillborn Infant);
- Birth Defect (Each Live-born and Stillborn Infant) (Genetic Defect/Chromosomal Abnormality, Cleft Lip or Palate, Neural Tube Defect, Cardiac Defect, Limb Defect, Other Defect).

CDC should add the following reporting requirements in addition to the “cycle specific data,” including direct gaps in record collection identified by a 2023 Report “on the Risks of

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<sup>24</sup> 80 Fed. Reg. at 51815-51815.

ART”<sup>25</sup>:

- Number of Embryos from Each Clinic Donated to Research;
- SES Status and Race of Egg Donors and Adoptive Parents;
- Number of Embryos Injected in Uterus and Number of Embryos Successfully Implanted
- “Procedure-Associated and Short-Term Risks for Oocyte Donors;”<sup>26</sup>
- “Long-Term Follow-Up Studies of Egg Donors,” Especially on “Fertility, Cancer, and Other Potential Health Risks;”<sup>27</sup>
- Research on the Mental Health Outcomes of Egg Donors;
- Number of Embryos Injected in Uterus in Comparison with the Number of Live Births;
- Number of Embryos Successfully Implanted in Uterus in Comparison with the Number of Live Births;
- “Long-Term Medical, Social, Financial, [and] Psychological Effects on ... Surrogate Mothers;”<sup>28</sup>
- “Long-Term Data on the Health and Well-Being of Children Born from Surrogacy Contracts;”<sup>29</sup>
- “Rates of Complications Associated with Oocyte Retrieval Procedures;”<sup>30</sup>
- Rates of Ovarian Hyperstimulation Syndrome (OHSS) During Egg Retrieval.

#### **4. The Number of Research Cycles is not a Justification for Removing the Requirements to Report the Cycle Study Types.**

The notice proposes “to remove the requirement for clinics to report the research cycle study type, as only a small number of research cycles are performed each year.”<sup>31</sup> The study types the notice proposes to delete include “Device study, Protocol study, Pharmaceutical study, Laboratory technique, Other research.”<sup>32</sup> Most ART studies are performed via these clinics, especially the rising “3 parent embryo” research and practice.<sup>33</sup>

The CDC’s rationale to drop this reporting requirement is arbitrary and capricious. Just because there has been a limited number of research cycle studies in the past few years does not decrease the importance of the information being reported. Fewer research cycle studies should make it easier for clinics to report study types to the CDC. The number of studies could also change in the future. Indeed, this small number was possibly due to the limitation of COVID-19 in the last several years.

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<sup>25</sup> *Ibid*; Kallie Fell, *A Comprehensive Report on the Risks of ART*, Center for Bioethics and Culture Network, <https://cbc-network.org/wp-content/uploads/2023/05/Comprehensive-Paper-on-ART-Final.pdf>

<sup>26</sup> *Ibid*.

<sup>27</sup> *Ibid*.

<sup>28</sup> *Ibid*.

<sup>29</sup> *Ibid*.

<sup>30</sup> *Ibid*.

<sup>31</sup> 80 Fed. Reg. at 83132

<sup>32</sup> *Ibid*.

<sup>33</sup> *U.S. researcher says he’s ready to start four pregnancies with ‘three-parent’ embryos*, <https://www.statnews.com/2019/04/18/new-york-researcher-ready-to-start-pregnancies-with-three-parent-embryos/>.

In contrast to the CDC's current proposal, in 2015, the CDC announced a notice, "Reporting of Pregnancy Success Rates From Assisted Reproductive Technology (ART) Programs," that explained the requirements when reporting cycle data, including research cycle information.<sup>34</sup> This notice stressed the importance for clinics to maintain their records. Indeed, according to the notice, "each clinic is responsible for maintaining appropriate medical and laboratory records that contain information reported in NASS."<sup>35</sup> Included in the requirements for record-keeping in the 2015 notice was the cycle-specific data that "must be reported" for the following patients:

(1) All patients undergoing ART, (2) all patients undergoing ovarian stimulation or monitoring with the intent of undergoing ART but who did not proceed to oocyte retrieval or transfer of embryos for any reason, including patients whose cycles were canceled for any reason, (3) all patients providing donor oocytes, and (4) all patients undergoing monitoring and/or embryo (or oocyte) thawing with the intention of transferring cryopreserved embryos.<sup>36</sup>

The information in the above list is valuable not only to the CDC but also to the general public concerned with the ethical ramifications of embryonic material research and use. Concerns within the medical and bioethicist community about pre-implantation screening, such as how clinics test and select embryos, are prevalent.

When considering ART, clinics often experience monetary incentives to exhibit higher success rates.<sup>37</sup> Few state laws govern the practice or research studies on ART, so the only oversight on this part of the industry is through the CDC.<sup>38</sup> As such, the CDC plays a vital role in ensuring clinical studies that produce these higher success rates do not put any of the patients at risk: the women and children.

In addition to the reporting requirements under the FCSRCA, the CDC should consider developing an enforcement mechanism with proper incentives to ensure clinics report fairly and consistently. Since data discrepancies and success rate inflation are prevalent within this industry, the agency should consider thorough approaches to reporting requirements for these clinics in all matters.<sup>39</sup>

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<sup>34</sup> 80 Fed. Reg. at 51811 (Aug. 26, 2015).

<sup>35</sup> 80 Fed. Reg. at 51814.

<sup>36</sup> *Ibid.*

<sup>37</sup> Kallie Fell, *A Comprehensive Report on the Risks of ART 25*, Center for Bioethics and Culture Network, <https://cbc-network.org/wp-content/uploads/2023/05/Comprehensive-Paper-on-ART-Final.pdf> ("Brokers and clinics, who stand to profit most, resist calls to do the necessary studies and warn women of potential risks, putting the mental and physical health of women in the United States at risk.").

<sup>38</sup> *Id.* at 26 (Noting "the deceptive perception that the United States has regulated surrogacy in such a way that it is safe for all those involved. . . . The United States, has no federal policy governing commercial surrogacy as countries like Canada. A patchwork of state laws governs the practice in each state individually.").

<sup>39</sup> Data Validation, <https://www.cdc.gov/art/reports/2020/data-validation.html>.

## **5. Data Discrepancies Create More Grounds for Targeted Validation of Clinics, Not Less.**

In the notice, the CDC proposes no longer pursuing data validation. The reasoning behind this proposal is simply that “identifying major data discrepancies would require a review of a large number of clinic records at selected clinics, and it would increase the data collection burden on clinics.”<sup>40</sup> This reasoning is arbitrary and capricious.

Data discrepancies are a systemic problem within the industry, as evidenced by the CDC’s 2022 validation set, which found discrepancies in ovulatory dysfunction, cycle start dates, dates of pregnancy outcome, and cycle counts.<sup>41</sup> As such, why would less data validation targeting even be suggested in this proposal? Because clinics have the burden to report? Obviously, clinics have a burden to produce data, but the CDC fails to show how this data collection is unduly burdensome and not sufficient for its purpose of ensuring that the clinics report accurate numbers—numbers that are highly relevant for those pursuing ART.

In newer spaces like preimplantation genetic diagnosis (PGD) and polygenic embryo selection/screening (PES), these practices are “being offered despite ethical concerns and lack of data on accuracy.”<sup>42</sup> Especially when new ART practices arise, data accuracy and targeted validation of the data that the clinics provide become all the more necessary to collect. Therefore, I recommend targeted validation of the following data collections:

- Live Birth Rates in Comparison with Perinatal Mortality Rates;
- Rates of Ectopic Pregnancies;
- Oocyte Retrieval Complications; and
- Birth Weights.

The FCSRCA created a requirement for clinics to report their data to the CDC. The CDC’s proposal allows clinics to sidestep the oversight by the agency established by Congress in this law. Under the CDC’s proposal, clinics can decline to participate in reporting, and if they report their numbers in a way that results in discrepancies, they are not required to remedy the discrepancies because the CDC will not perform proper oversight by targeted data validation. Clinics rely on verification from the CDC to confirm that they are in good standing with the federal government. Without data validation, the self-regulation mentality that the clinics already portray will continue.

## **6. The CDC’s Proposal to Add Requirements for Clinics to Report the Date of Cryopreservation for Fresh Embryos**

I support the CDC’s proposal to add the requirement for clinics to report the date of cryopreservation for fresh embryos.

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<sup>40</sup> 88 Fed. Reg. at 83133.

<sup>41</sup> Data Validation, <https://www.cdc.gov/art/reports/2020/data-validation.html>.

<sup>42</sup> Kallie Fell, *A Comprehensive Report on the Risks of ART 13*, Center for Bioethics and Culture Network, <https://cbc-network.org/wp-content/uploads/2023/05/Comprehensive-Paper-on-ART-Final.pdf>.



**Conclusion**

Congress has, through the FCSRCA, created a mandatory duty for ART clinics to report data to the CDC. The CDC is tasked, therefore, with an obligation to perform adequate oversight of the fertility treatment industry by ensuring accurate data collection through reporting requirements. My recommendations above reflect the critical role of the CDC in delivering reliable ART data.

Sincerely,

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