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# In Vitro Fertilization and the "Right to IVF" Act: Ethical Considerations, Regulatory Failure, and Financial Impact

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#### **Executive Summary**

This issue centers on one of the deepest human desires: to have a child. Liberty Counsel Action first and foremost recognizes the inherent worth of every child born via in vitro fertilization (IVF) and celebrates the joy they bring to the world. We also have the utmost compassion for all couples who have faced or are facing challenges to conceive, including the author of this bill, and we cannot have this debate without first pausing to recognize the pain of so many. We likely all know someone who has, or we ourselves have experienced, the struggle to conceive.

Yet as one pundit noted, "A diagnosis or season of infertility does not mean that a couple will never have children; only that it may require more work and time than they initially expected." Unfortunately, the "Right to IVF Act," S. 4445, fails to address many of the root causes of infertility—which, if left unaddressed, can lead to harm for the mother and child.

The bill is also misleading. While claiming to be about IVF, the bill actually seeks to ensure that individuals (not just couples)—including those who do not have a medically diagnosed condition leading to infertility, e.g., those who are "socially infertile"<sup>4</sup>—can obtain "fertility treatment" by mandating insurance coverage for such treatments nationwide, "if such plan or coverage provides coverage for obstetrical services." The bill also mandates funding said procedures for service members and veterans.

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<sup>&</sup>lt;sup>1</sup> Tammy Duckworth, "Duckworth, Murray, Booker Unveil Sweeping Legislative Package to Establish a Nationwide Right to IVF and Lower IVF Costs for Families," June 3, 2024,

https://www.duckworth.senate.gov/news/press-releases/duckworth-murray-booker-unveil-sweeping-legislative-package-to-establish-a-nationwide-right-to-ivf-and-lower-ivf-costs-for-families. \*Tammy Duckworth authored this bill and "was the first Senator to give birth while serving in office." She also "had both of her children with the help of IVF."

<sup>&</sup>lt;sup>2</sup> Emma Waters, "A Christian's Practical Guide to Reproductive Technology," *The Heritage Foundation,* June 6, 2024, <a href="https://www.heritage.org/life/commentary/christians-practical-guide-reproductive-technology.">https://www.heritage.org/life/commentary/christians-practical-guide-reproductive-technology.</a>
<sup>3</sup> "S.4445 - Right to IVF Act," *Congress.Gov*, June 3, 2024, <a href="https://www.congress.gov/bill/118th-congress/senate-bill/44445">https://www.congress.gov/bill/118th-congress/senate-bill/44445</a>.

<sup>&</sup>lt;sup>4</sup> The bill explicitly includes coverage for individuals and LGBTQ+ individuals/couples, stating, "A group health plan and a health insurance issuer offering group or individual health insurance coverage that includes coverage for obstetrical services shall provide coverage for fertility treatment ... regardless of whether the participant, beneficiary, or enrollee receiving such treatment has been diagnosed with infertility as defined by the American Society for Reproductive Medicine." Furthermore, the American Society for Reproductive Medicine (ASRM) definition of infertility includes individuals/LGBTQI+ couples; see: "Definition Infertility: A Committee Opinion (2023)," American Society for Reproductive Medicine, <a href="https://www.asrm.org/practice-guidance/practice-committee-documents/denitions-of-infertility/">https://www.asrm.org/practice-guidance/practice-committee-documents/denitions-of-infertility/</a>. For more on the phrase "socially infertile," see: Weei Lo & Lisa Campo-Engelstein, "Expanding the Clinical Definition of Infertility to Include Socially Infertile Individuals and Couples" *Reproductive Ethics II*, August 21, 2018, <a href="https://link.springer.com/chapter/10.1007/978-3-319-89429-4">https://link.springer.com/chapter/10.1007/978-3-319-89429-4</a>.

"Fertility treatment" is defined to include the genetic testing of embryos, egg and sperm donation, the indefinite freezing and destruction of embryos, and Assisted Reproductive Technologies (ART) that go beyond IVF, such as the concerning practice of surrogacy.

This bill also claims to be about building families and protecting IVF. In fact, it is building the IVF industry, which does not need to be protected. As stated in the RESTORE Act findings, "In vitro fertilization and other assisted reproductive technologies are not under threat at the Federal level or in any State or territory of the United States."<sup>5</sup>

# Most notably:

- This bill props up the billion-dollar fertility industry, providing more protection for the industry than for the families it claims to help.
- The bill fails to address the tragic reality that for each live birth achieved, countless lives are lost. For example: In 2021, the CDC reported there were 413,776 assisted reproductive technology cycles performed, including 167,689 that were egg and embryo "banking." Presuming half of those cycles were for egg (vs. embryo) banking, that leaves 329,931 (413,776-83,845) ART cycles in which embryos were created. If one uses a conservative estimate that 10 embryos were created per cycle, that equates to approximately 3.3 million embryos yet there were only 97,128 live infants reported, translating to approximately 3.2 million embryos that were either frozen, discarded, failed to implant, or died at various stages of pregnancy. By way of comparison, in 2021, 625,978 abortions were reported to the CDC. Indeed, though these numbers are estimates, IVF is likely more destructive to human life than abortion.
- It treats children as commodities and fails to address the many harms and risks related to IVF and other fertility "treatments" (ARTs).
- The bill similarly fails to establish a uniform informed consent procedure that would ensure women are made aware of the many health risks (to mother and child) related to IVF and related ARTs (e.g. surrogacy), and, more notably, the alternatives available.
- This bill would allow for the transfer of multiple embryos at one time. Notably current guidance recommends between one and no more than five embryos be implanted at a

<sup>&</sup>lt;sup>5</sup> "S.4533 - RESTORE Act," *Congress.Gov*, June 13, 2024, <a href="https://www.congress.gov/bill/118th-congress/senate-bill/4533/text">https://www.congress.gov/bill/118th-congress/senate-bill/4533/text</a>.

<sup>&</sup>lt;sup>6</sup> "ART Success Rates," U.S. Centers for Disease Control and Prevention (CDC), 2021, https://www.cdc.gov/art/artdata/index.html.

<sup>&</sup>lt;sup>7</sup> Ibid., see also: Emma Waters, "Why the IVF Industry Must be Regulated," *The Heritage Foundation*, March 19, 2024, https://www.heritage.org/life/report/why-the-ivf-industry-must-be-regulated.

<sup>&</sup>lt;sup>8</sup> "Abortion Surveillance Findings and Reports," Centers for Disease Control and Prevention, 2021, <a href="https://www.cdc.gov/reproductive-health/data-statistics/abortion-surveillance-findings-reports.html">https://www.cdc.gov/reproductive-health/data-statistics/abortion-surveillance-findings-reports.html</a>. Note: Numbers based on 48 of 52 reporting areas.

time, pending the age of the woman and other factors,<sup>9</sup> though this is not an enforceable guideline and women who do carry multiples in pregnancy face a much higher rate of miscarriage, among other risks.<sup>10</sup> The risks to the developing children are also much higher in any pregnancy with multiples babies.

- The bill also fails to ensure conscience protections for employers who may be required to provide coverage for procedures that violate their sincerely held religious beliefs.
- It should not go unmentioned that Germany has some of the strongest IVF protections, largely because the history of eugenics under Nazism is very present in the national psyche. The German population understands fully the weight of creating human life—and the danger of choosing characteristics to suit one's own desires. (Specifically, the law requires all artificially fertilized eggs to be intended for pregnancy—that is, one cannot create numerous embryos to test for various characteristics and either discard or freeze the ones that don't make the cut. Furthermore, the law strictly prohibits egg donation, surrogacy, and embryo experimentation.<sup>11</sup>)
- Finally, this bill creates a situation in which ethically questionable scenarios are not only possible, such as the creation of three-parent embryos and human-animal chimeras, but if ushered in, they would be federally funded as outlined above. (In essence, this bill could drastically advance questionable medical and scientific practices, as well as the LGBTQ+ agenda, by using taxpayer dollars to provide, for example, a transgender-identifying individual access to "reproductive technologies" such as egg donation and surrogacy—among myriad other things.

#### Background: IVF, Reproductive Technologies, & the Alabama Controversy

#### I. What Is In Vitro Fertilization (IVF)?

Defined by the Mayo Clinic as "a complex series of procedures that can lead to a pregnancy." Specifically: "Mature eggs are collected from ovaries and fertilized by sperm in a lab. Then a procedure is done to place one or more of the fertilized eggs,

<sup>&</sup>lt;sup>9</sup> "Guidance on the Limits to the Number of Embryos to Transfer: A Committee Opinion," American Society for Reproductive Medicine, 2021, <a href="https://www.asrm.org/practice-guidance/practice-committee-documents/guidance-on-the-limits-to-the-number-of-embryos-to-transfer-a---committee-opinion-2021/">https://www.asrm.org/practice-guidance/practice-committee-opinion-2021/</a>.

<sup>&</sup>lt;sup>10</sup> "Complications of Multiple Pregnancy," John Hopkins Medicine, accessed November 14, 2024, https://www.hopkinsmedicine.org/health/conditions-and-diseases/staying-healthy-during-pregnancy/complications-of-multiple-pregnancy.

<sup>11 &</sup>quot;Act for the Protection of Embryos (The Embryo Protection Act)," Federal Law Gazette, December 13, 1990, https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3\_Downloads/Gesetze\_und\_Verordnungen/GuV/E/ESchG\_EN\_Fassung\_Stand\_10Dez2014\_01.pdf. See also: "Law on the Protection of Embryos (Embryo Protection Act - ESchG)," Federal law - consolidated daily - all versions since 2006, accessed November 14, 2024, https://www.buzer.de/gesetz/2831/index.htm.

called embryos, in a uterus ... One full cycle of IVF takes about 2 to 3 weeks. Sometimes these steps are split into different parts and the process can take longer." Its first successful use occurred in 1977 in Cambridge, England. 13

There are numerous risks associated with this series of procedures, which includes egg (oocyete) retrieval. During this process, women receive shots of fertility medicines that trigger ovulation. This can lead to ovarian hyperstimulation syndrome, which can develop into a serious condition and in rare instances lead to death (further risks are noted below).<sup>14</sup>

# II. Why Is IVF Controversial?

While the controversial nature of IVF goes beyond the following summary, at its core is the question of when life begins (see section on ethical foundations).

If one holds to the truth that life begins at fertilization, the unavoidable reality is the IVF process as it currently operates in the U.S. destroys countless of innocent lives annually, given most IVF clinics fertilize far more eggs than are necessary and only a fraction of the embryos are implanted in the womb—even fewer are subsequently born. Around 97% of embryos created in IVF are either "destroyed, frozen, or fail to implant". <sup>15</sup>

Specifically, a "grading" process determines which embryos will be implanted, frozen, or destroyed. A 2018 "Guide to IVF Embryo Grading" outlines that embryos graded as "excellent" have a 50% live birth rate, embryos graded as "average" have a 42.3% live birth rate, and those that receive a "poor" grade have a 25% live birth rate (that is, if they successfully implant in the first place). In other words, though there is not much difference in live birth rates, countless "less than excellent" embryos are frozen or discarded every year.

<sup>&</sup>lt;sup>12</sup> "In vitro fertilization (IVF)," Mayo Clinic, accessed October 18, 2024, <a href="https://www.mayoclinic.org/tests-procedures/in-vitro-fertilization/about/pac-20384716">https://www.mayoclinic.org/tests-procedures/in-vitro-fertilization/about/pac-20384716</a>.

<sup>&</sup>lt;sup>13</sup> "In Vitro Fertilization (IVF)," *UCSF Health*, accessed October 18, 2024, <a href="https://www.ucsfhealth.org/treatments/in-vitro-fertilization">https://www.ucsfhealth.org/treatments/in-vitro-fertilization</a>.

<sup>&</sup>lt;sup>14</sup> Swati Tyagi, Asit Ranjan Mridha, and Chittaranjan Behera, "Sudden death of an egg donor during oocyte retrieval due to ovarian hyperstimulation syndrome," *National Library of Medicine*, May 14, 2022, <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9212082/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9212082/</a>. See also: Ning Wang, et. al, "Sudden Death Due to Severe Ovarian Hyperstimulation Syndrome: An Autopsy-Centric Case Report," Am J Forensic Med Pathol, March 2021, <a href="https://pubmed.ncbi.nlm.nih.gov/33186129/">https://pubmed.ncbi.nlm.nih.gov/33186129/</a>.

<sup>&</sup>lt;sup>15</sup> Emma Waters, X, March 7, 2024, https://x.com/emlwaters/status/1765932136186392746.

<sup>&</sup>lt;sup>16</sup> "IVF Embryo Grading," Med Park Hospital, accessed October 18, 2024,

https://www.medparkhospital.com/en-US/disease-and-treatment/ivf-embryo-grading.

<sup>&</sup>lt;sup>17</sup> Halle Tecco, "Guide to IVF Embryo Grading," *Natalist*, February 18, 2024, https://natalist.com/blogs/learn/guide-to-ivf-embryo-grading.

This has, in part, led to an estimated 1.5 million human embryos being stored on ice nationwide (keep in mind this does not include the "excess" embryos destroyed). 18

Katy Faust, founder of the children's rights organization *Them Before Us*, summarizes the issue well: "The babies you do see who are born through IVF are built upon the bodies of dozens, hundreds of little IVF embryos that didn't make the grade." <sup>19</sup>

#### III. Assisted Reproductive Technologies (ART) & Concerning Language

The bill not only expands IVF, but more broadly expands all Assisted Reproductive Technologies (ART), which are defined as including "other treatments or procedures in which reproductive genetic material ... are handled, when clinically appropriate." It also states that fertility treatment can include "other ... treatments, procedures, medications, laboratory testing, technologies and services relating to fertility as the Secretary of Health and Human Services determines appropriate."

This is problematic for a myriad of reasons. Federal laws surrounding embryos are limited to two annual appropriations riders; one, known as the Dickey Wicker Amendment, prohibits federal funds for experiments involving creating or destroying embryos intended for research<sup>20</sup> (though said "research" does occur via private funding<sup>21</sup>). The other prohibits clinical trial applications that include genetically modified embryos, there are calls to remove this ban.<sup>22</sup> Specifically, the use of genetically modified embryos is indirectly banned by an annual appropriations bill rider which states, "This section prohibits the FDA from acknowledging applications for an exemption for investigational use of a drug or biological product in research in which a human embryo is intentionally created or modified to include a heritable genetic modification. Such a submission must be deemed to have not been received,

<sup>&</sup>lt;sup>18</sup> Joshua Sharfstein, "The Alabama Supreme Court's Ruling on Frozen Embryos," *John Hopkins Bloomberg School of Public Health*, February 27, 2024, <a href="https://publichealth.jhu.edu/2024/the-alabama-supreme-courts-ruling-on-frozen-embryos">https://publichealth.jhu.edu/2024/the-alabama-supreme-courts-ruling-on-frozen-embryos</a>.

<sup>&</sup>lt;sup>19</sup> Katy Faust, X, March 7, 2024, https://x.com/Advo\_Katy/status/1765823578312790366.

<sup>&</sup>lt;sup>20</sup> The Editors of The New Atlantis, "Take No for an Answer on Genetic Engineering," *The New Atlantis*, 2023, <a href="https://www.thenewatlantis.com/publications/take-no-for-an-answer-on-genetic-engineering">https://www.thenewatlantis.com/publications/take-no-for-an-answer-on-genetic-engineering</a>.

<sup>&</sup>lt;sup>21</sup> Kirstin R W Matthews, et. al., "Rethinking Human Embryo Research Policies," *Wiley Online*, February 25, 2021, <a href="https://pmc.ncbi.nlm.nih.gov/articles/PMC7986614/">https://pmc.ncbi.nlm.nih.gov/articles/PMC7986614/</a>.

<sup>&</sup>lt;sup>22</sup> Emily Mullin, "Patient advocates and scientists launch push to lift ban on 'three-parent IVF,'" *STAT*, April 16, 2019, <a href="https://www.statnews.com/2019/04/16/mitochondrial-replacement-three-parent-ivf-ban/">https://www.statnews.com/2019/04/16/mitochondrial-replacement-three-parent-ivf-ban/</a>. See also: Andrew Joseph, "Congress Revives Ban on Altering the DNA of Human Embryos Used for Pregnancies," Scientific American, June 5, 2019, <a href="https://www.scientificamerican.com/article/congress-revives-ban-on-altering-the-dna-of-human-embryos-used-for-pregnancies/">https://www.scientificamerican.com/article/congress-revives-ban-on-altering-the-dna-of-human-embryos-used-for-pregnancies/</a>.

and the exemption may not go into effect."<sup>23</sup> This language prevented researchers at Colombia University in New York from implanting "three-parent" embryos they had created with the use of private funding.<sup>24</sup> Similarly in 2017, the FDA sent a letter to the doctor who pioneered the "three-parent" procedure in the U.S., saying he could not market it in the U.S. (said doctor went to Mexico to implant the embryo).<sup>25</sup>

While the Right to IVF Act states it would not supersede this current ban, stating, "Nothing in this title shall have the effect of superseding, negating, or limiting provisions of Federal law, including the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.), and regulations promulgated under such statutes, with respect to the regulation of drugs, devices, biological products, human cells, tissues, or cellular or tissue-based products used in fertility treatment", should the current ban on this troubling research fail to be reinstated, the bill's language permitting the Secretary of Health and Human Services to determine what is "appropriate" could make the following permissible nationwide:<sup>26</sup>

• Commercial gestational surrogacy,<sup>27</sup> which is legal in some states though laws and regulations vary widely across the nation.<sup>28</sup> (Surrogacy allows strangers to hire a woman of child-bearing age to gestate an embryo. The couple or individual who arranges for the surrogate mother may use donors for the sperm, egg, or both. The "purchase" of a womb by a stranger is ethically questionable and detailed below.)

<sup>&</sup>lt;sup>23</sup> Kirstin R W Matthews and Daniel Morali, "Can we do that here? An analysis of US federal and state policies guiding human embryo and embryoid research," *Journal of Law and the Biosciences*, June 9, 2022, <a href="https://academic.oup.com/jlb/article/9/1/lsac014/6604445">https://academic.oup.com/jlb/article/9/1/lsac014/6604445</a>. For the most recent ban, see The Consolidated Appropriations Act, 2024, section 737, <a href="https://www.congress.gov/bill/118th-congress/house-bill/4366/text">https://www.congress.gov/bill/118th-congress/house-bill/4366/text</a>. <sup>24</sup> Emily Mullin, "U.S. researcher says he's ready to start four pregnancies with 'three-parent' embryos," *STAT*, April 18, 2019, <a href="https://www.statnews.com/2019/04/18/new-york-researcher-ready-to-start-pregnancies-with-three-parent-embryos">https://www.statnews.com/2019/04/18/new-york-researcher-ready-to-start-pregnancies-with-three-parent-embryos</a>.

<sup>&</sup>lt;sup>25</sup> Emily Mullin, "FDA Cracks Down on Pioneering Doctor Who Created a Three-Parent Baby," *MIT Technology Review*, August 7, 2017, <a href="https://www.technologyreview.com/2017/08/07/68027/fda-cracks-down-on-pioneering-doctor-who-created-three-parent-baby/">https://www.technologyreview.com/2017/08/07/68027/fda-cracks-down-on-pioneering-doctor-who-created-three-parent-baby/</a>.

<sup>&</sup>lt;sup>26</sup> See also the following post by Tony Perkins on X, September 17, 2024, https://x.com/tperkins/status/1836023723926634997.

<sup>&</sup>lt;sup>27</sup> Gestational surrogacy means "the surrogate mother has no biological link to the child she is carrying." See "What is Surrogacy?" *Global Surrogacy*, December 9, 2021,

https://globalsurrogacy.baby/what-is-surrogacy/. Commercial surrogacy, as opposed to altruistic surrogacy, involves compensating the woman carrying the child, "beyond reimbursement of medical expenses." See "About Surrogacy: What is Commercial Surrogacy?"

https://surrogate.com/about-surrogacy/types-of-surrogacy/what-is-commercial-surrogacy/.

<sup>&</sup>lt;sup>28</sup> "Surrogacy Laws by State," *Legal Professional Groups of the American Society for Reproductive Medicine, accessed October 22, 2024, https://connect.asrm.org/lpg/resources/surrogacy-by-state.* 

- Creation of, and the sale or purchase of, genetically modified embryos for implantation purposes, including three-parent embryos<sup>29</sup> and embryos created with animal DNA (also known as human-animal chimeras, which have already been created by scientists in China<sup>30</sup> and cultured for 20 days, well beyond the long-accepted standard practice of the 14-day rule, which unofficially limits embryo experimentation to 14 days<sup>31</sup>).
- Human cloning, including reproductive cloning.<sup>32</sup>
- Other forms of genetic modification (also prohibited under law).

In other words: this bill opens the door to buying and selling genetically modified children—and numerous other concerning scenarios. As Senator Cindy-Hyde Smith stated, "It would legalize human cloning. It would legalize commercial surrogacy, including for young girls without parental involvement. It would legalize gene edited designer babies . . ."<sup>33</sup>

# IV. The Alabama Issue: Why the Court Was Right and How the State Legislature Missed the Mark

The Alabama Supreme Court ruled 7-2 in *LePage v. Mobile Infirmary Clinic, Inc.*, that frozen embryos created through in vitro fertilization (IVF) are children under Alabama law. Specifically, Alabama Supreme Court Justice Jay Mitchell outlined that "unborn

<sup>&</sup>lt;sup>29</sup> The creation of three-parent embryos is legal in some countries and has led to live births, but evidence shows there are concerning risks; see: Jessica Hamzelouarchive, "Three-parent baby technique could create babies at risk of severe disease," *MIT Technology Review,* March 2, 2023,

https://www.technologyreview.com/2023/03/02/1069296/three-parent-baby-technique-risk-of-disease/; see also: Joanna Poulton, "World's first three-parent baby raises questions about long-term health risks," *The Conversation*, September 28, 2016,

https://theconversation.com/worlds-first-three-parent-baby-raises-questions-about-long-term-health-risks-66189. The long-term effects are unknown.

<sup>&</sup>lt;sup>30</sup> Alice Park, "Scientists Report Creating the First Embryo With Human and Non-Human Primate Cells," *Time*, April 15, 2021, <a href="https://time.com/5954818/first-human-monkey-chimera-embryo/">https://time.com/5954818/first-human-monkey-chimera-embryo/</a>.

<sup>&</sup>lt;sup>31</sup> John B Appleby and Annelien L Bredenoord, "Should the 14-day rule for embryo research become the 28-day rule?" *National Library of Medicine*, August 7, 2018, https://pmc.ncbi.nlm.nih.gov/articles/PMC6127884/.

<sup>&</sup>lt;sup>32</sup> Kirstin R W Matthews and Daniel Morali, "Can we do that here? An analysis of US federal and state policies guiding human embryo and embryoid research," *Journal of Law and the Biosciences*, 9, No.1, 2022, <a href="https://academic.oup.com/jlb/article/9/1/lsac014/6604445">https://academic.oup.com/jlb/article/9/1/lsac014/6604445</a>.

<sup>&</sup>lt;sup>33</sup> Nathaniel Weixel, "Republicans block bill to protect access to IVF," *The Hill*, February 28, 2024, <a href="https://thehill.com/policy/healthcare/4494243-republicans-block-bill-to-protect-access-to-ivf/">https://thehill.com/policy/healthcare/4494243-republicans-block-bill-to-protect-access-to-ivf/</a>. Note: Senator Duckworth said this was a misinterpretation of the bill, though as outlined, the bill would open the door to these scenarios.

children are 'children'... without exception based on developmental stage, physical location, or any other ancillary characteristics."<sup>34</sup>

The Court therefore ruled that the parents of embryos killed at an IVF clinic in 2020 after someone tampered with the cryogenic nursery, destroying the frozen embryos inside, may proceed with a wrongful death lawsuit.

**They did not ban IVF.** Yet in response, Alabama lawmakers fast-tracked and overwhelmingly passed legislation to provide both civil and criminal immunity "to any individual or entity" involved in providing or receiving services related to IVF when death or damage to an embryo occurs.<sup>35</sup>

Despite the Court stating that an IVF embryo is a "minor child" and is no different under the law than an embryo in the womb, the new law will treat frozen IVF children differently and not allow legal consequences for their deaths.

The law provides (seemingly) little consideration to the mental anguish parents may undergo having their children, though in embryonic form, carelessly handled and subsequently perish, particularly given the often-painful process required to harvest eggs, not to mention the expense involved.

#### **Ethical Foundations & Concerns**

#### I. Ethical Foundation

A unique human being is created when a sperm and egg unite at fertilization to form an embryo. <sup>36</sup> Consider, for example, twins Lydia and Timohty Ridgeway, born to Rachel and Philip Ridgeway, who felt called to build a larger family and chose to do so through embryo donation (colloquially deemed "embryo adoption"). <sup>37</sup> Conceived in 1992 and born October 31, 2022, the twins were "kept in liquid nitrogen at nearly 200 degrees below zero, in a device that looks much like a propane tank" for nearly three decades before the Ridgeway's adopted them in 2022. <sup>38</sup> The couple

<sup>&</sup>lt;sup>34</sup> "LePage v. Center for Reproductive Medicine, P.C.," Justia US Law, accessed October 22, 2024, https://law.justia.com/cases/alabama/supreme-court/2024/sc-2022-0579.html.

<sup>&</sup>lt;sup>35</sup> The bill text is available here:

https://alison.legislature.state.al.us/files/pdf/SearchableInstruments/2024RS/V1YMPLL-1.pdf.

<sup>&</sup>lt;sup>36</sup> Alberts B, Johnson A, Lewis J, et al., *Molecular Biology of the Cell 4th edition,* (Garland Science, 2002), <a href="https://www.ncbi.nlm.nih.gov/books/NBK21052/#A5175">https://www.ncbi.nlm.nih.gov/books/NBK21052/#A5175</a>. Specifically, "Fusion of a male and a female gamete (both haploid) to form a diploid zygote, which develops into a new individual."

<sup>&</sup>lt;sup>37</sup> Jen Christensen and Nadia Kounang, "Parents welcome twins from embryos frozen 30 years ago," CNN, November 21, 2022, <a href="https://www.cnn.com/2022/11/21/health/30-year-old-embryos-twins/index.html">https://www.cnn.com/2022/11/21/health/30-year-old-embryos-twins/index.html</a>.

<sup>38</sup> Ibid.

intentionally sought embryos that "that had been waiting the longest."<sup>39</sup> Their father, Phillip, who was five years old when the embryos were frozen, shares: "There is something mind-boggling about it."<sup>40</sup>

Their story illustrates the following scientific truth, outlined by Maureen Condic, Ph.D., associate professor of neurobiology at the University of Utah School of Medicine: "The conclusion that human life begins at sperm-egg fusion is uncontested, objective, based on the universally accepted scientific method of distinguishing different cell types from each other and on ample scientific evidence. ... Moreover, it is entirely independent of any specific ethical, moral, political, or religious view of human life or of human embryos."<sup>41</sup>

Steven Andrew Jacobs, J.D., Ph.D., corroborates this, noting that 96% (5,337 out of 5,577) of biologists surveyed from 1,058 academic institutions affirmed that human life begins at fertilization.<sup>42</sup> The American College of Pediatricians asserts that the difference between an adult human and a human in its "zygotic stage" at conception is simply "one of form, not nature."<sup>43</sup>

In essence, the location of a human being at the moment of fertilization (in or outside the womb) does not change the fact that said individual is a human being, no matter the surrounding circumstances (how the fertilization occurs).

#### II. Ethical Concerns

- IVF clinics facilitate the fertilization of an egg that results in the creation of a human being.
- IVF practices are for the most part unregulated.
- IVF clinics typically fertilize many eggs and proceed to implant more than necessary, destroy or freeze others, and use others for research. There are

<sup>39</sup> Ibid.

<sup>&</sup>lt;sup>40</sup> David Nield, "These Record-Breaking Twins Are The 'Oldest' Babies Ever Born," *Science Alert,* November 24, 2022, <a href="https://www.sciencealert.com/these-record-breaking-twins-are-the-oldest-babies-ever-born">https://www.sciencealert.com/these-record-breaking-twins-are-the-oldest-babies-ever-born</a>.

<sup>&</sup>lt;sup>41</sup> Maureen Condic, "A Scientific View of When Life Begins," Charlotte Lozier Institute, June 11, 2014, <a href="https://lozierinstitute.org/a-scientific-view-of-when-life-begins/">https://lozierinstitute.org/a-scientific-view-of-when-life-begins/</a>.

<sup>&</sup>lt;sup>42</sup> Steven Andrew Jacobs, "The Scientific Consensus on When a Human's Life Begins," *Issues in Law and Medicine*, October 1, 2021, <a href="https://issuesinlawandmedicine.com/articles/the-scientific-consensus-on-when-a-humans-life-begins/">https://issuesinlawandmedicine.com/articles/the-scientific-consensus-on-when-a-humans-life-begins/</a>.

<sup>&</sup>lt;sup>43</sup> Fred de Miranda, MD, updated by Dr. Patricia Lee June, MD, "When Human Life Begins," *American College of Pediatricians*, March 2004, updated March 2017, <a href="https://acpeds.org/position-statements/when-human-life-begins">https://acpeds.org/position-statements/when-human-life-begins</a>.

numerous examples of children being born who were frozen for decades as embryos.<sup>44</sup>

• There are also probing questions to consider, for example, what happens if the eggs are abandoned? Or the donor dies?

Natural law and human rights guarantee the right to life of each human embryo from fertilization. This should be the "North Star" guiding IVF ethics and policy creation. The conclusion of the above points, however, demonstrate that this foundational truth and the current standard practice of the IVF industry are at odds, and human beings are the ones who get hurt. Strong guardrails are needed if this practice is to continue.

#### What This Bill Does

- I. The "Right to IVF Act" seeks to expand individuals' access to "fertility treatments," in part through increases in federal funding (see point III). These "fertility treatments" include, but are not limited to, assisted reproductive technologies (ARTs) such as in vitro fertilization (IVF), genetic testing of embryos, freezing embryos, and surrogacy.
  - The bill would allow single individuals, non-married couples, and individuals in polyamorous relationships access to technology that would enable them to "create" a child genetically related to at least one of the individuals involved.
  - The bill would continue to allow foreign nationals access to the largely unregulated surrogacy market in the United States, which many view as a "pathway to citizenship" (more on this below).
- II. This bill would exacerbate the current lack of regulations over the fertility industry by codifying language that, in essence, allows the fertility industry to self-regulate by giving the American Society for Reproductive Medicine (ASRM) (which consists of several board members, some of whom have a financial interest in the fertility

<sup>&</sup>lt;sup>44</sup> Paige Stables, "'I Felt Misled': Are Women Getting the Full Truth About Egg Freezing?" *Allure,* November 16, 2023, <a href="https://www.allure.com/egg-freezing-facts">https://www.allure.com/egg-freezing-facts</a>; Sarah Zhang, "A Woman Gave Birth from an Embryo Frozen for 24 Years," *The Atlantic,* December 21, 2017,

https://www.theatlantic.com/science/archive/2017/12/frozen-embryo-ivf-24-years/548876/ (24 years); Jen Christensen and Nadia Kounang, "Parents welcome twins from embryos frozen 30 years ago," CNN, November 21, 2022, https://www.cnn.com/2022/11/21/health/30-year-old-embryos-twins/index.html (27 and 30 years).

industry)<sup>45</sup> the authority to define medical standards of care. Specifically, the bill states<sup>46</sup>:

- "The enforcement of State health and safety law regarding medical facilities or health care providers does not constitute a violation of subsection (a) if— (1) such regulations are in accordance with widely accepted and evidence-based medical standards of care for providing fertility treatment; and (2) the safety or health objective cannot be advanced by a different means that does not prohibit, limit, interfere with, or impede the rights described in subsection."
- The bill goes on to state that "a State law, or the administration, implementation, or enforcement of a State law, constitutes a prohibition, limitation, interference, or impediment" if the law "imposes requirements or limitations that are inconsistent with providing, receiving, providing health insurance coverage for, or providing drugs or devices for fertility treatment in accordance with widely accepted and evidence-based medical standards of care ... which may include ... requiring that a health care provider provide, and patients undertake, medically unnecessary procedures and services."
- The term "widely accepted and evidence-based medical standards of care" is defined in the bill as "any medical services, procedures, and practices that are in accordance with the guidelines of the American Society for Reproductive Medicine."

In other words, if the ASRM decides something is medically unnecessary or inaccurate, states cannot require it. Giving the ASRM that much power would, in essence, allow this profit-making industry to self-regulate.

Moreover, the ASRM recently redefined infertility to include individuals, and stated that "Nothing in this definition shall be used to deny or delay treatment to any individual, regardless of relationship status or sexual orientation." That is, according the ASRM, infertile "could refer to any individual who needs medical

<sup>&</sup>lt;sup>45</sup> Board members have self-disclosed conflicts of interest, which include some grant recipients, paid consultants (one of whom is a paid consultant for a fertility clinic), and being a direct stockholder for a fertility startup. See "American Society for Reproductive Medicine Conflict of Interest Disclosure," November 27, 2023, <a href="https://www.asrm.org/globalassets/asrm/about-us/board/asrm-board-disclosures.pdf">https://www.asrm.org/globalassets/asrm/about-us/board/asrm-board-disclosures.pdf</a>. 
<sup>46</sup> "S.4445 - Right to IVF Act," *Congress.Gov*, June 3, 2024, <a href="https://www.congress.gov/bill/118th-congress/senate-bill/4445">https://www.congress.gov/bill/118th-congress/senate-bill/4445</a>.

<sup>&</sup>lt;sup>47</sup> "Definition Infertility: A Committee Opinion (2023)," American Society for Reproductive Medicine, <a href="https://www.asrm.org/practice-guidance/practice-committee-documents/denitions-of-infertility/">https://www.asrm.org/practice-guidance/practice-committee-documents/denitions-of-infertility/</a>.

aid to conceive simply by virtue of not having an available partner." This is also known as being socially infertile (e.g., LGBTQ+ individuals).

Under the authority of the ASRM, states would most likely be prohibited from requiring any helpful safeguards, such as limiting the number of embryos to be created.

Though state regulation of IVF and related ARTs are limited, this bill would also likely invalidate the few that do exist to provide proper safeguards; specifically:

- Parental rights of those involved in IVF are defined in "37 states and the District of Columbia," either through statute or case law.
- Eleven states have laws regulating "facilities that collect and transfer human gametes and embryos."
- Two states impose on medical providers a duty "to inform patients about the potential health hazards and success rates of IVF procedures."
- Ten states (at least) impose "laws or regulations related to the purchase, donation, transfer, solicitation and/or harvesting of human eggs."
- Four states (AZ, IN, KY, NE) ban surrogacy (or surrogacy contracts) in some form, but in each state, surrogacy can still occur via pre-birth parentage orders or based on the language of the law (which, for example, makes contracts void and unenforceable, but not illegal).<sup>48</sup>
- III. The bill requires federal funding for "fertility treatments" as it mandates that:
  - Group and individual plans cover ART, including IVF, if the plan also "provides coverage for obstetrical services."
  - Medicare and Medicaid include "fertility treatment" coverage.
  - Federal Employment Health Benefits plans cover ART.
  - Members of the armed services and veterans have ART procedures covered. Specifically, it states that the Secretary of Defense shall make fertility treatment "available" to a member of the uniformed services, or their "spouse, partner, or gestational surrogate" ... "without regard to the sex ... infertility diagnosis, or marital status of the member of the uniformed services or their partner." Furthermore, the Department of Defense may be required to assist a member in finding fertility preservation services, as the bill states: "The Secretary of Defense

<sup>&</sup>lt;sup>48</sup> "Surrogacy Laws By State," *Legal Professional Groups of the American Society for Reproductive Medicine*, accessed October 22, 2024, <a href="https://connect.asrm.org/lpg/resources/surrogacy-by-state?ssopc=1">https://connect.asrm.org/lpg/resources/surrogacy-by-state?ssopc=1</a>. Of note, LA has a strict surrogacy law.

shall ensure that employees of the Department of Defense assist members of the uniformed services ... in finding a provider that meets the needs of such members with respect to [fertility preservation] services."

In summary, this bill promulgates the concerning lack of proper safety and ethical regulations that should be considered for all IVF and related reproductive technologies.

Core Issue 1: Health and Safety Concerns – Increased Risk of Complications for Developing Children and Mothers

# I. Risks to the Developing Child

The bill does not adequately address risks to the children involved. A study on the physical and chemical factors present in creating mammalian embryo cultures and their importance in assisted human reproduction found:

"Development of the embryo outside the body means that it is constantly exposed to stresses that it would not experience in vivo [a woman's uterus] ... From the viewpoint of assisted human reproduction, a major concern with chemical and physical factors lies in their adverse effects on the viability of embryos, and from long-term effects on the fetus, even as a result of a relatively brief exposure." 49

Referring to the above study, expert Jennifer Lahl stated, "Sources of stress on the human embryo include changes in pH and temperature shifts, exposure to atmospheric (20%) oxygen (vs. 95% in the body) and the build-up of toxins in the media the embryo is in. When more than one stress is present in the laboratory, there is evidence that negative synergies can result, culminating in significant trauma to the developing embryo." Further specific and known risks of ARTs to the developing child include:

A higher risk of stillbirth.<sup>51</sup>

<sup>&</sup>lt;sup>49</sup> Petra L Wale and David K Gardner, "The effects of chemical and physical factors on mammalian embryo culture and their importance for the practice of assisted human reproduction," *National Library of Medicine*, January 2016, <a href="https://pubmed.ncbi.nlm.nih.gov/26207016/">https://pubmed.ncbi.nlm.nih.gov/26207016/</a>.

<sup>&</sup>lt;sup>50</sup> "Jennifer Lahl Speaks to U.S. Senate," *CBC*, July 23, 2024, <a href="https://cbc-network.org/2024/07/jennifer-lahl-speaks-to-us-senate/">https://cbc-network.org/2024/07/jennifer-lahl-speaks-to-us-senate/</a>.

<sup>&</sup>lt;sup>51</sup> Deepa Dongarwar and Hamisu Mohammed Salihu, "Risk of Stillbirth after Infertility Treatment in the United States: 2014-2017," *International Journal of Maternal and Child Health and Aids*, February 2020, <a href="https://mchandaids.org/risk-of-stillbirth-after-infertility-treatment-in-the-united-states-2014-2017/">https://mchandaids.org/risk-of-stillbirth-after-infertility-treatment-in-the-united-states-2014-2017/</a>; B Bay et. al., "Risk of stillbirth in low-risk singleton term pregnancies following fertility treatment: a national cohort study," *An International Journal of Obstetrics and Gynecology*, October 20, 2018, <a href="https://pubmed.ncbi.nlm.nih.gov/30341984">https://pubmed.ncbi.nlm.nih.gov/30341984</a>; K Wisborg et. al., "IVF and stillbirth: a prospective follow-up study," May 2010, *Human Reprod*, <a href="https://pubmed.ncbi.nlm.nih.gov/20179321/">https://pubmed.ncbi.nlm.nih.gov/20179321/</a>.

- Severe fetal morbidities if donor eggs are used. 52
- Fetal anomalies; such as congenital malformation "and epigenetic issues like Beckwith-Wiedemann and Angelman syndrome." 53
- A greater "risk of any type of childhood cancer."
- A higher risk of leukemia.55
- A higher risk of hepatic tumors.<sup>56</sup>
- Pre-term birth and low birth weight (notably, premature babies often "have other long-term health complications").<sup>57</sup>
- Cleft palate.<sup>58</sup>

Additionally, as the bill would allow for the transfer of multiple embryos at one time, there is a risk that women will conceive multiples (twins, triplets, or even—in one of the most extreme cases—octuplets) Given the risks to developing children, such as birth defects, "including neural tube defects (such as spina bifida), gastrointestinal, and heart abnormalities," is much higher in such pregnancies may lead some women to opt for "60" in other words, aborting of one or more of the developing children. Such situations need to be considered and prohibited (see *Alternative Policy Recommendations* below)

Moreover, the percentage of children born from IVF who die in the first year is also higher; a Swedish study found children conceived through ARTs had "higher infant mortality risks" in their first year of life when compared to those born without the use

<sup>&</sup>lt;sup>52</sup> "Jennifer Lahl Speaks to US Senate," The Center for Bioethics and Culture Network, July 23, 2024, <a href="https://cbc-network.org/2024/07/jennifer-lahl-speaks-to-us-senate/">https://cbc-network.org/2024/07/jennifer-lahl-speaks-to-us-senate/</a>.

<sup>53</sup> Ibid.

<sup>&</sup>lt;sup>54</sup> Shiue-Shan Weng et. al., "Assisted Reproductive Technology and Risk of Childhood Cancers," *JAMA Network*, August 31, 2022, <a href="https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2795793">https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2795793</a>.

<sup>&</sup>lt;sup>55</sup> Ibid. See also: Leah Lawrence, "Assisted Reproductive Technology Linked to Increased Risk of Leukemia," Cancer Therapy Advisor, May 6, 2024, <a href="https://www.cancertherapyadvisor.com/news/assisted-reproductive-technology-leukemia/">https://www.cancertherapyadvisor.com/news/assisted-reproductive-technology-leukemia/</a>.

<sup>&</sup>lt;sup>56</sup> Logan G Spector et. al., "Association of In Vitro Fertilization With Childhood Cancer in the United States," *Jama Pediatrics*, 2019, <a href="https://jamanetwork.com/journals/jamapediatrics/fullarticle/2729182">https://jamanetwork.com/journals/jamapediatrics/fullarticle/2729182</a>.

<sup>&</sup>lt;sup>57</sup> "Jennifer Lahl Speaks to US Senate," The Center for Bioethics and Culture Network, July 23, 2024, https://cbc-network.org/2024/07/jennifer-lahl-speaks-to-us-senate/.

<sup>&</sup>lt;sup>58</sup> Ying Liang et. al., "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*, 2018, <a href="https://www.oncotarget.com/article/23689/text/">https://www.oncotarget.com/article/23689/text/</a>; Emma Waters, "Babies Aren't Disposable, at Any Stage," *The Heritage Foundation*, February 15, 2023, <a href="https://www.heritage.org/life/commentary/babies-arent-disposable-any-stage">https://www.heritage.org/life/commentary/babies-arent-disposable-any-stage</a>.

<sup>&</sup>lt;sup>59</sup> Jessica Sager, "Where Is 'Octomom' Now? All About Nadya Suleman's Life After Welcoming Octuplets in 2009," *People*, September 23, 2024, <a href="https://people.com/where-is-octomom-now-nadya-suleman-8622332">https://people.com/where-is-octomom-now-nadya-suleman-8622332</a>.

<sup>&</sup>lt;sup>60</sup> Michael Bebbington, "Selective reduction in multiple gestations," *Best Practice & Research Clinical Obstetrics & Gynaecology, 28*, No. 2, February 2014,

https://www.sciencedirect.com/science/article/abs/pii/S1521693413001697.

of ARTs. <sup>61</sup> Similarly, a 2021 study found that "children conceived by assisted reproductive technology (ART) had statistically significantly worse outcomes in left ventricular heart function and structure." <sup>62</sup>

There are also notable emotional risks to children conceived via egg and sperm donation, as well as those who were donated and adopted as embryos. As one children's rights activist outlines: "Adoption mends a wound; donor conception creates the wound. . . . Adoption says, 'Let me help.' . . . Third-party reproduction says, 'Let me have.'"63 Similarly, a donor-conceived woman writes, "We risk rejection from our 'parent(s)' if we disagree with their decision. We grow up walking on eggshells, lest we hurt them. We grow up emotionally numb because everyone tells us that we shouldn't feel something for our biological parent(s), grandparents, aunts, uncles, cousins, siblings, language, culture. In so many ways, we parent our parents. . . . We exist for someone else's happiness. That's a very heavy burden to bear."64

Indeed, there are numerous examples of children conceived from donor sperm struggling to come to terms with their genealogical history, which can at times include the added complexity of siblings: In one case, a woman researching her ancestry learned she had over 200 hundred siblings.<sup>65</sup>

The above does not take into account any experimentation or genetic testing on embryos, which can exacerbate the issues.

Women deserve to know the risks to them as well as their children and the alternative options available (detailed below). Many women treated holistically have been able to conceive after seasons of infertility with the proper medical advice and care, avoiding an expensive, risky, and often traumatic procedure. Any legislation related

<sup>&</sup>lt;sup>61</sup> Kenny A Rodriguez-Wallberg et. al., "Mortality from infancy to adolescence in singleton children conceived from assisted reproductive techniques versus naturally conceived singletons in Sweden," *Fertility and Sterility*, 113, No. 3, March 2020, <a href="https://www.fertstert.org/article/S0015-0282(19)32488-4/fulltext">https://www.fertstert.org/article/S0015-0282(19)32488-4/fulltext</a>. <sup>62</sup> "Jennifer Lahl Speaks to U.S. Senate," *CBC*, July 23, 2024, <a href="https://cbc-network.org/2024/07/jennifer-lahl-speaks-to-us-senate/">https://cbc-network.org/2024/07/jennifer-lahl-speaks-to-us-senate/</a>.

<sup>&</sup>lt;sup>63</sup> Katy Faust, "A Children's Rights Perspective on Embryo Adoption," *Them Before Us*, Apr 11, 2024, <a href="https://thembeforeus.com/a-childrens-rights-perspective-on-embryo-adoption/">https://thembeforeus.com/a-childrens-rights-perspective-on-embryo-adoption/</a>.

<sup>64</sup> Ibid.

<sup>&</sup>lt;sup>65</sup> Katie Camero, "These women discovered they were siblings. Then, they found hundreds more. It has taken a toll," USA Today, January 23, 2024, <a href="https://www.usatoday.com/story/life/health-wellness/2024/01/23/dna-horror-story-women-discover-200-siblingssperm-donor/72305605007">https://www.usatoday.com/story/life/health-wellness/2024/01/23/dna-horror-story-women-discover-200-siblingssperm-donor/72305605007</a>.

to IVF and related ARTs must address these questions (see *Alternative Policy Recommendations* below).

#### II. Risks of IVF to Women

Most IVF cycles fail, meaning that a live birth is the exception rather than the rule.<sup>66</sup> Indeed, one study found only 33 percent of women experience a live birth following their first IVF cycle.<sup>67</sup> Such a low success rate leads to traumatic stillbirth and miscarriage experiences for many women.

This bill does not address these issues, nor the myriad health and safety concerns related to the IVF procedure. Moreover, while many clinics may require women sign consent forms, the bill fails to address the lack of a uniform informed consent procedure that would ensure all women are thoroughly informed of the risks related to IVF and related ARTs, which include but are not limited to an increased risk of the following:

- Ovarian hyperstimulation syndrome, which (as noted above) can develop into a serious condition and in rare instances lead to death.<sup>68</sup>
- A significantly higher risk of blood transfusion at delivery.
- A higher risk of vascular complications (e.g. irregular heartbeat and kidney injury).
- Placental separation.
- Cesarean delivery.
- Preterm birth.
- Severe maternal morbidities if donor eggs are used.<sup>69</sup>

<sup>&</sup>lt;sup>66</sup> Jennifer Lahl, "Fading Fertility, Ready or Not," *The Heritage Foundation*, 2017, <a href="https://www.heritage.org/sites/default/files/2017-07/03%202017\_IndexofCultureandOpportunity\_Fertility.pdf">https://www.heritage.org/sites/default/files/2017-07/03%202017\_IndexofCultureandOpportunity\_Fertility.pdf</a>.

<sup>&</sup>lt;sup>67</sup> Georgine Chambers, "Women now have clearer statistics on whether IVF is likely to work," UNSW Sydney, July 24, 2017, <a href="https://www.unsw.edu.au/newsroom/news/2017/07/women-now-have-clearer-statistics-on-whether-ivf-is-likely-to-wo">https://www.unsw.edu.au/newsroom/news/2017/07/women-now-have-clearer-statistics-on-whether-ivf-is-likely-to-wo</a>. See also: Halle Tecco, "What are the 2024 Fertility Statistics I Need to Know About?" Family by CO, part of Cofertility, September 16, 2022; updated October 31, 2024, <a href="https://www.cofertility.com/family-learn/fertility-statistics">https://www.cofertility.com/family-learn/fertility-statistics</a>.

<sup>&</sup>lt;sup>68</sup> Swati Tyagi et. al., "Sudden death of an egg donor during oocyte retrieval due to ovarian hyperstimulation syndrome," *Pub Med Central*, May 27, 2022, <a href="https://pubmed.ncbi.nlm.nih.gov/33186129/">https://pubmed.ncbi.nlm.nih.gov/33186129/</a>.

<sup>&</sup>lt;sup>69</sup> Most of the risks are outlined by expert testimony provided by Jennifer Lahl (founder of The Center for Bioethics and Culture Network) to the U.S. Senate in July, 2024, <a href="https://cbc-network.org/2024/07/jennifer-lahl-speaks-to-us-senate/">https://cbc-network.org/2024/07/jennifer-lahl-speaks-to-us-senate/</a>. See also "Common infertility treatments may increase risks for pregnancy, vascular complications," *Journal of the American Heart Association Report*, February 22, 2022, <a href="https://newsroom.heart.org/news/common-infertility-treatments-may-increase-risks-for-pregnancy-vascular-complications">https://newsroom.heart.org/news/common-infertility-treatments-may-increase-risks-for-pregnancy-vascular-complications</a>.

Furthermore, as noted above, should multiple embryos be transferred leading to a pregnancy of multiples, the increased risk of complications may cause providers to recommend selective reduction (abortion), which also carries great risk to the mother and child. <sup>70</sup> Such situations should be prevented yet are currently permissible.

Overall, women should be given ample opportunity to consider not only these increased risks, but the alternatives available to them (see *Alternative Policy Recommendations* below).

# III. Physical, Mental, and Emotional Health Risks for Egg Donors and Surrogates

The bill similarly does not adequately address the harms experienced by surrogate mothers, who have a higher risk for medical complications like the above, as well as:

- Higher severe maternal morbidity rates (a measure that indicates potentially life-threatening problems; specifically, one study found rates of 7.8% among surrogates versus 4.3% among those who underwent IVF themselves. Notably, both rates are drastically higher than the 2.3% rate among the unassisted conception group).<sup>71</sup>
- Higher risk of hypertension (high blood pressure). From what we do know, "Studies show that women pregnant with donor eggs have a more than three-fold risk of developing pregnancy induced hypertension and pre-eclampsia."<sup>72</sup>
- Higher risk of gestational diabetes.<sup>73</sup>
- Higher risk of postpartum depression.74

Regarding postpartum depression, surrogate mothers often miss the "bonding, attachment, breastfeeding, and healing" that occurs post-birth, which is typically viewed as important and good. Tragically, this post-birth experience is "often ignored

<sup>&</sup>lt;sup>70</sup> "Complications of Multiple Pregnancy," John Hopkins Medicine, accessed November 14, 2024, https://www.hopkinsmedicine.org/health/conditions-and-diseases/staying-healthy-during-pregnancy/complications-of-multiple-pregnancy.

Maria P. Velez, et. al., "Severe Maternal and Neonatal Morbidity Among Gestational Carriers: A Cohort Study," *Annals of Internal Medicine*, September 24, <a href="https://www.acpjournals.org/doi/10.7326/M24-0417">https://www.acpjournals.org/doi/10.7326/M24-0417</a>.
 "Three Things You Should Know About Third Party Assisted Reproduction," *The Center for Bioethics and Culture Network*, accessed October 23, 2024, <a href="https://cbc-network.org/wp-content/uploads/2022/02/3">https://cbc-network.org/wp-content/uploads/2022/02/3</a> Things You Should Know About Third Party Reproduction-Center for Bioethics and Culture.pdf.

<sup>&</sup>lt;sup>73</sup> "Jennifer Lahl Speaks to U.S. Senate," *CBC*, July, 2024, <a href="https://cbc-network.org/2024/07/jennifer-lahl-speaks-to-us-senate/">https://cbc-network.org/2024/07/jennifer-lahl-speaks-to-us-senate/</a>.

<sup>&</sup>lt;sup>74</sup> Ibid., and N Lamba et. al., "The psychological well-being and prenatal bonding of gestational surrogates," *Human Reproduction*, February 23, 2018, <a href="https://academic.oup.com/humrep/article/33/4/646/4941810">https://academic.oup.com/humrep/article/33/4/646/4941810</a>.

and wiped away as unimportant in the context of the gestational surrogate pregnancy."<sup>75</sup>

Regarding egg donation specifically, substantial anecdotal evidence suggests an increased risk of breast cancer for egg donors.<sup>76</sup> It is furthermore important to note that the lack of "major peer-reviewed medical research on the long-term effects of egg harvesting on the health of the young women who provide their eggs" makes it impossible for women to provide "true meaningful informed consent relative to the health and psychological risks involved."<sup>77</sup>

It should also be noted that surrogates are also often presented with a financial incentive; as one study highlights, "Women's economic disadvantage was a major contributor to the decision to proceed with surrogacy." This presents important ethical, social, political, and economic questions that this bill does not address. Indeed, the bill would likely lead to further exploitation of women with an existing financial disadvantage. As one expert highlights:

"The use of donor eggs and surrogates to have children also involves the commodification of women, and exposes them to significant physical and psychological harm. The high sums of money offered, especially for elite egg donors (who are often college students or young professionals with student loans hanging over their heads), can be very hard to pass up, and many argue that offering so much money is exploitative. Indeed, the idea of 'selling' such an intimate part of oneself is arguably in itself a threat to human dignity; that's why we use the language of donation, even though most donors admit that they wouldn't do it without the financial incentive."

<sup>&</sup>lt;sup>75</sup> "Surrogacy Needs to be Regulated, Not Prohibited: A Response to the British Medical Journal," The Center for Bioethics and Culture Network, August 26, 2024, <a href="https://cbc-network.org/2024/08/surrogacy-regulation-bmi/">https://cbc-network.org/2024/08/surrogacy-regulation-bmi/</a>.

<sup>&</sup>lt;sup>76</sup> Jennifer Schneider et. al., "Long-term breast cancer risk following ovarian stimulation in young egg donors: a call for follow-up, research and informed consent," *Reprod Biomed Online*, May 2017, <a href="https://pubmed.ncbi.nlm.nih.gov/28473127/">https://pubmed.ncbi.nlm.nih.gov/28473127/</a>; see also "Jennifer Lahl Speaks to US Senate," *CBC*, July, 2024, <a href="https://cbc-network.org/2024/07/jennifer-lahl-speaks-to-us-senate/">https://cbc-network.org/2024/07/jennifer-lahl-speaks-to-us-senate/</a>.

<sup>&</sup>lt;sup>77</sup> "Three Things You Should Know About Third Party Assisted Reproduction," *The Center for Bioethics and Culture Network*, accessed October 23, 2024, <a href="https://cbc-network.org/wp-content/uploads/2022/02/3">https://cbc-network.org/wp-content/uploads/2022/02/3</a> Things You Should Know About Third Party Reproduction-Center for Bioethics and Culture.pdf.

<sup>&</sup>lt;sup>78</sup> Jennifer Lahl et. al, "A Comparison of American Women's Experiences with Both Gestational Surrogate Pregnancies and Spontaneous Pregnancies," *Dignity*, 2022, <a href="https://digitalcommons.uri.edu/dignity/vol7/iss3/1/">https://digitalcommons.uri.edu/dignity/vol7/iss3/1/</a>.

<sup>&</sup>lt;sup>79</sup> Dr. Melissa Moschella, "Reproductive Technologies and Human Dignity," *Public Discourse*, November 17, 2019, <a href="https://www.thepublicdiscourse.com/2019/11/57961/">https://www.thepublicdiscourse.com/2019/11/57961/</a>.

This same expert goes on to say:

"The same is true of gestational surrogacy. This has led many countries, such as France, Germany, Italy, Spain, Portugal, and Bulgaria to prohibit surrogacy entirely. Others, like Canada, Australia, the UK, Ireland, Denmark, and Belgium prohibit paid surrogacy arrangements. The US, however, remains largely unregulated, leaving women extremely vulnerable to psychological, physical, and financial harm."

Surrogate mother Crystal Kelley presents a key example of the harms that can be inflicted through this process:

- Kelley provided surrogate "services" and was eventually asked to abort after a five-month ultrasound showed "a number of medical problems, including a cleft palate, a brain cyst, and a heart condition."
- She refused and was subsequently offered \$10,000.
- She refused again and was threatened by being told the child would be placed in an institution.
- After seeking legal help, she was advised to go to Michigan, "One of the few states in which custody is automatically granted to the gestational mother."
- After finding a family to adopt the baby, she did so.<sup>81</sup>

There are other examples of surrogate mothers being asked to abort, which can be emotionally taxing and draining, if not traumatic, experiences for the birth mother.

Finally, in addition to the financial exploitation, there are cases of surrogates being trafficked,<sup>82</sup> becoming infertile, and dying as a result of the process. <sup>83</sup>

#### Core Issue 2: Ethics Concerns

We believe it is vital to underscore and affirm that all children born via IVF and other artificial (assisted) reproductive technologies are valuable and a gift. We furthermore recognize that many IVF clinics and providers genuinely seek to help couples build a family and should be commended. However, intentionally or unintentionally, the lack of a strong regulatory

<sup>80</sup> Ibid.

<sup>&</sup>lt;sup>81</sup> Ibid. See also: Elizabeth Cohen, "Surrogate offered \$10,000 to abort baby," *CNN*, March 6, 2013, https://www.cnn.com/2013/03/04/health/surrogacy-kelley-legal-battle/index.html.

<sup>&</sup>lt;sup>82</sup> Special Rapporteur on the sale and sexual exploitation of children, "Report on safeguards for the protection of the rights of children born from surrogacy arrangements," July 15, 2019, <a href="https://www.ohchr.org/en/calls-for-input/report-safeguards-protection-rights-children-born-surrogacy-arrangements">https://www.ohchr.org/en/calls-for-input/report-safeguards-protection-rights-children-born-surrogacy-arrangements</a>.

<sup>&</sup>lt;sup>83</sup> Grace Melton and Melanie Israel, "How Surrogacy Harms Women and Children," The Heritage Foundation, May 5, 2021, <a href="https://www.heritage.org/marriage-and-family/commentary/how-surrogacy-harms-women-and-children">https://www.heritage.org/marriage-and-family/commentary/how-surrogacy-harms-women-and-children</a>.

structure has led to myriad harms both to couples and their children. Failing to consider the lifelong psychological implications of IVF and related technologies does a disservice to the couples seeking to build their families, who deserve the best care available. Unfortunately, this bill protects the fertility industry over the families it claims to be helping.

# I. The Commodification of Children and Risk of Exploitation to Women

The ART industry generally, and this bill specifically treats children (embryos) as commodities and fails to address pressing issues related to the exploitation of women, particularly surrogate mothers.

- Buying and selling reproductive material (sperm and eggs): While widely available and practiced already, egg and sperm donation and compensation can lead to great harm, particularly for women. Unfortunately, given a lack of proper regulations, it continues on a widespread scale and is commodifying the process of reproduction. One website, for example, advertises "elite" donors who can "elevate your plan to parenthood," <sup>84</sup> and John Hopkins notes that it will generously compensate women who participate in egg donation. <sup>85</sup>
- Commercial surrogacy: Surrogacy is often employed by individuals and LGBTQ couples who cannot biologically have a child, though anyone utilizing this service can "buy" an egg or a sperm, "rent" a womb, and "create" a child or "designer baby" with traits to their liking. This process necessarily creates a broken situation by purposefully removing a child from its birth mother and can submit a child to motherlessness or fatherlessness (as well as, similar to adoption, removal from both biological parents depending on the situation). There are also unique ethical and legal questions related to the rise in demand for commercial surrogacy, particularly from foreign nationals and celebrities (detailed further below).
- Freezing embryos: This bill promotes the continued, concerning practice of creating more embryos than necessary and freezing them, which is another form of "commodifying" children. Because an individual or couple want to have a child, they will pay to store them (indefinitely) for future use, or if discarded, allow them to be experimented on or destroyed. In the best-case scenario, these embryos can be donated and adopted by others, though the current process is not a legal

<sup>84</sup> Elevate, https://donors.elevatebaby.com/.

<sup>&</sup>lt;sup>85</sup> "Infertility Services: Egg Donation," *John Hopkins Medicine*, accessed October 23, 2024, https://www.hopkinsmedicine.org/gynecology-obstetrics/specialty-areas/fertility-center/infertility-services/egg-donor.

<sup>86 &</sup>quot;Fast Facts," Them Before Us, Accessed October 23, 2024, https://thembeforeus.com/fast-facts/.

adoption in the traditional sense of the word (rather it involves taking "embryos from one couple or individual" and transferring "them into another individual in order to build families" <sup>87</sup>). Notably, this emerging practice raises an entirely unique policy question that this bill does not adequately address. <sup>88</sup> Of note: Minors and adults undergoing sex transitions are sometimes offered the opportunity to freeze their reproductive material, given the fact that such transitions may forever impact their fertility. <sup>89</sup>

 Failing to comprehensively address the health and safety of women and children: Finally, as detailed above, IVF and related ARTs present numerous health and safety risks to children, mothers, and surrogate mothers. This bill generally fails to address the risks associated with such technology while simultaneously providing federal funding for these procedures, inclusive of surrogacy and donor egg or sperm IVF.

In summary, as Dr. Melissa Moschella highlights, "By moving the site of procreation outside of the mother's body and into the lab, the embryonic human being becomes subject to the logic of manufacture and production. This logic is about efficiency, quality control, maximizing profit, and giving customers what they want. These features are clearly present in assisted reproduction."<sup>90</sup>

In other words, the fertility industry, and in this case, the Right To IVF Act, are completely centered on the desire for children without thought to the impact this technology may have on said children and their families. It not only exploits one of the deepest human desires, but it also at times flagrantly disregards the harms (physical, emotional, and psychological) that can result in the pursuit of profit.

While this profit-maximizing business model has benefits in a capitalistic setting, IVF and other ARTs are not dealing with inanimate sales products. **Children are not a commodity, and any legislation on this matter must address the myriad issues that this technology presents.** 

<sup>&</sup>lt;sup>87</sup> Jen Christensen and Nadia Kounang, "Parents welcome twins from embryos frozen 30 years ago," CNN, November 21, 2022, <a href="https://www.cnn.com/2022/11/21/health/30-year-old-embryos-twins/index.html">https://www.cnn.com/2022/11/21/health/30-year-old-embryos-twins/index.html</a>.

<sup>&</sup>lt;sup>88</sup> There are differing opinions on what should be done with the currently frozen embryos, of which there are over a million. For a helpful discussion on this topic, see Katy Faust, "A Children's Right's Perspective on Embryo Adoption," accessed October 23, 2024, accessed October 23, 2024. <a href="https://thembeforeus.com/a-childrens-rights-perspective-on-embryo-adoption/">https://thembeforeus.com/a-childrens-rights-perspective-on-embryo-adoption/</a>.

<sup>&</sup>lt;sup>89</sup> Elizabeth A Dilday, et al., "Sperm Cryopreservation Outcomes in Transgender Adolescents Compared with Adolescents Receiving Gonadotoxic Therapy," November 29, 2022, *Transgender Health* 7, No. 6, <a href="https://pmc.ncbi.nlm.nih.gov/articles/PMC9829158/">https://pmc.ncbi.nlm.nih.gov/articles/PMC9829158/</a>.

<sup>&</sup>lt;sup>90</sup> Dr. Melissa Moschella, "Reproductive Technologies and Human Dignity," *Public Discourse*, November 17, 2019, <a href="https://www.thepublicdiscourse.com/2019/11/57961/">https://www.thepublicdiscourse.com/2019/11/57961/</a>.

- II. Eugenics Concerns: Genetic Testing, Modification, & Selection (Creating "Designer" Babies)
  - Genetic testing is most commonly done via preimplantation genetic diagnosis (PGD). 91 PGD "is a laboratory procedure used in conjunction with in vitro fertilization (IVF) to reduce the risk of passing on inherited conditions."92 However, "it is also used to test for nonmedical traits like the sex of the embryo, skin color, or eye color. 92% of ART clinics offer PGD; 73% of them offer it explicitly for sex-selection."93

Furthermore, after testing, if the embryos' doctors determine the embryos may "carry traits the parents deem undesirable," the embryos are often destroyed. For example, "if they're hoping for a male baby," the female embryos are destroyed, as well as those with treatable diseases (like cystic fibrosis).<sup>94</sup>

• Genetic modification / editing goes a step further. While currently illegal in the United States (if intended for pregnancy), gene editing "alters the very makeup of an embryo" and could "be used to change an embryo's IQ, physical ability, or the ability to contract a disease. As technology develops, the possibilities are endless." The first scientist to employ gene editing (earning himself a three-year prison sentence) did so in 2018 with twin girls in China. Using a technique called CRISPR, or "clustered regularly interspaced short palindromic repeats," he reportedly immunized the babies against HIV. So As one news source stated, "many expressed shock at the use of a risky, untested procedure in circumstances where there was no unmet medical need. He's unpublished data

<sup>&</sup>lt;sup>91</sup> Emma Waters, "Babies Aren't Disposable, at Any Stage," *The Heritage Foundation,* February 15, 2023, <a href="https://www.heritage.org/life/commentary/babies-arent-disposable-any-stage.">https://www.heritage.org/life/commentary/babies-arent-disposable-any-stage.</a>

<sup>&</sup>lt;sup>92</sup> "Pre-Implantation Genetic Diagnosis," UCSF Health, <a href="https://www.ucsfhealth.org/treatments/pre-implantation-genetic-diagnosis">https://www.ucsfhealth.org/treatments/pre-implantation-genetic-diagnosis</a>.

<sup>&</sup>lt;sup>93</sup> Emma Waters, "Babies Aren't Disposable, at Any Stage," *The Heritage Foundation,* February 15, 2023, <a href="https://www.heritage.org/life/commentary/babies-arent-disposable-any-stage">https://www.heritage.org/life/commentary/babies-arent-disposable-any-stage</a>; see also: Sarah M Capelouto et. al., "Sex selection for non-medical indications: a survey of current pre-implantation genetic screening practices among U.S. ART clinics," *Journal of Assisted Reproduction and Genetics*, October 28, 2017, <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5904054/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5904054/</a>.

<sup>94</sup> Ibid.

<sup>95</sup> Ibid.

<sup>&</sup>lt;sup>96</sup> Bartha Maria Knoppers and Erika Kleiderman, "'CRISPR babies': What does this mean for science and Canada?" January 28, 2019; *National Library of Medicine*,

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6342697/#b1-191e091. See also John Ruwitch, "Chinese scientist who went to prison for a gene-therapy experiment is back in the lab," NPR, May 26, 2023, https://www.npr.org/2023/05/26/1178332423/chinese-scientist-who-went-to-prison-for-a-gene-therapy-experiment-is-back-in-th.

indicated concerning evidence of 'off-target' effects, unwanted genetic changes that can carry a risk of heart defects, cancer and developmental problems."<sup>97</sup>

- Embryo selection: Given the bill currently states that an individual has a right to make decisions about genetic testing, eugenic practices are entirely permissible and likely given current industry practices. Particular traits already include sex, skin and eye color, and could include "height, weight, skin tone, and even intelligence of an IVF embryo." (It should not go unmentioned that abortion is legal in many states for similar purposes, particularly non-life-threatening disabilities.)
- "Designer" babies: The term first appeared in the *Oxford English Dictionary* in 2004.<sup>99</sup> The *Cambridge Dictionary* defines a designer baby as one "whose genes have been chosen by its parents and doctors so that it has particular characteristics."<sup>100</sup> Notably, in 2015, several media outlets shared the news that celebrity couple Kanye West and Kim Kardashian used only male embryos in their IVF selection process.<sup>101</sup> While the couple denied it, the reality is entirely possible. As one outlet summarized, "Even if it's not true, does it give anyone else pause that it's even possible that the gender of a child can be selected like an item off a menu? 'Designer babies' are discussed as some kind of future proposition, an ethical problem for our grandchildren. But they're happening now, with barely a peep of protest."<sup>102</sup> More recently it has come to light that a U.S. startup fertility clinic is marketing IQ screening to wealthy couples "using controversial technology that raises questions about the ethics of genetic enhancement."<sup>103</sup>

<sup>&</sup>lt;sup>97</sup> Hannah Devlin, "Scientist who edited babies' genes says he acted 'too quickly,'" *The Guardian*, February 4, 2023, <a href="https://www.theguardian.com/science/2023/feb/04/scientist-edited-babies-genes-acted-too-quickly-he-jiankui.">https://www.theguardian.com/science/2023/feb/04/scientist-edited-babies-genes-acted-too-quickly-he-jiankui.</a>

<sup>&</sup>lt;sup>98</sup> Antonio Regalado, "Eugenics 2.0: We're at the Dawn of Choosing Embryos by Health, Height, and More," *MIT Technology Review,* November 1, 2017,

https://www.technologyreview.com/2017/11/01/105176/eugenics-20-were-at-the-dawn-of-choosing-embryos-by-health-height-and-more/.

<sup>&</sup>lt;sup>99</sup> Sarah Ly, "Ethics of Designer Babies," *Arizona State University*, March 31, 2011, <a href="https://embryo.asu.edu/pages/ethics-designer-babies">https://embryo.asu.edu/pages/ethics-designer-babies</a>.

<sup>&</sup>lt;sup>100</sup> Cambridge Advanced Learner's Dictionary & Thesaurus, (Cambridge University Press), "Designer Baby," entry, <a href="https://dictionary.cambridge.org/us/dictionary/english/designer-baby#google\_vignette">https://dictionary.cambridge.org/us/dictionary/english/designer-baby#google\_vignette</a>.

<sup>&</sup>lt;sup>101</sup> Naomi Schaefer Riley, "'Designer babies' are an unregulated reality," *New York Post*, July 5, 2015, https://nypost.com/2015/07/05/designer-babies-are-an-unregulated-reality/.

Hannah Devlin, Tom Burgis, David Pegg, and Jason Wilson, "US startup charging couples to 'screen embryos for IQ,'" *The Guardian*, October 18, 2024, <a href="https://archive.is/urFkV">https://archive.is/urFkV</a>.

ASRM cites data from the European Society for Human Reproduction Preimplantation Genetic Diagnosis Consortium and states that trends elsewhere show "a consistent increase in the number of in vitro fertilization (IVF)/PGT-M Cycles [preimplantation genetic testing for monogenic conditions, which tests for chromosomal disorders]."<sup>104</sup> Its use has increased over time for various reasons. ASRM posits that the dramatic growth can likely be attributed to factors including the following: ". . . improved patient and provider awareness; higher IVF utilization; and broadening insurance coverage." In other words, ensuring people are more aware of available testing and providing insurance coverage for it has likely increased its popularity. The Right to IVF Act would do the latter and likely the Former.

The above testing and gene editing for the purposes of selecting "desirable" embryos is the very epitome of **eugenics**, which is defined as "the selection of desired heritable characteristics in order to improve future generations, typically in reference to humans."<sup>105</sup>

Though it was once accepted as a failed science, "particularly after Nazi Germany used eugenics to support the extermination of those it considered 'socially inferior,'"<sup>106</sup> scientists seem to be either ignorant of this dark history or unashamed in promoting the advancement of it. Though some seek to justify the current practice of eugenics by distinguishing the reasons for it (parental desire for certain outcomes vs. state desire to improve the species), the outcomes are the same: individuals die if they don't make the grade.<sup>107</sup>

#### III. Conscience Protections for Health Care Providers and Employers

This bill provides no conscience clause protections for employers or health care providers who may hold beliefs contrary to what the bill requires, and may, in fact, require an employer to provide coverage for procedures that violate their sincerely

<sup>&</sup>lt;sup>104</sup> "Indications and management of preimplantation genetic testing for monogenic conditions: a committee opinion," *ASRM*, May 10, 2023, <a href="https://www.asrm.org/practice-guidance/practice-committee-documents/indications-and-management-of-preimplantation-genetic-testing-for-monogenic-conditions-accommittee-opinion-2023/">https://www.asrm.org/practice-guidance/practice-committee-committee-conditions-accommittee-opinion-2023/</a>.

<sup>&</sup>lt;sup>105</sup> "Eugenics," *Britannica*, accessed October 17, 2024, <a href="https://www.britannica.com/science/eugenics-genetics">https://www.britannica.com/science/eugenics-genetics</a>.

<sup>106</sup> Ibid.

<sup>&</sup>lt;sup>107</sup> Vera Lúcia Raposo, "From Public Eugenics to Private Eugenics: What Does the Future Hold?" *National Library of Medicine*, October 2022, <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9635610/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9635610/</a>.

held beliefs (e.g., so a single male employee can hire a surrogate to have a child, among other things).

# IV. Failure to Properly Address Current and Plausible Ethically Questionable Scenarios

Under this bill, the following (and other) scenarios are possible and would be federally funded through group or individual insurance plans including Medicare/Medicaid, as well as for service members and veterans:

- Lesbian couples having a child together with a sperm donor.
- Homosexual couples hiring a surrogate to have a child.
- Individual LGBTQ+ and other persons would be able to have a child via surrogacy or via sperm donors.
- While currently prohibited under federal law, as previously stated, there are calls to remove the ban on embryo modification for pregnancies, 108 which could lead to multi-person parenthood (where an embryo is developed with DNA from more than two persons. As noted above, the technology already exists for "three parent babies." This procedure is legal in the United Kingdom and has led to at least one birth there). This would enable polyamorous "throuples" to have a child related to all parents. It would also likely lead to genetically modifying embryos in pursuit of the "perfect" child.

With advancing technology, one also needs to consider the following plausible scenarios:

- Single-person parenthood, where an embryo is developed from a single person's DNA (detailed below).
- Genetically modifying an embryo to include animal DNA.
- Reproductive/human cloning; that is, "the deliberate production of genetically identical individuals. Each newly produced individual is a clone of the original."

These situations may seem rather "sci-fi," but some are already possible, and some are close to being possible. For example, advancements in stem cell technology include a process known as in vitro gametogenesis (IVG), "which involves custom-

<sup>&</sup>lt;sup>108</sup> See footnote 16; see also Rob Stein, "House Committee Votes to Continue Ban on Genetically Modified Babies," NPR, June 4, 2019, <a href="https://www.npr.org/sections/health-shots/2019/06/04/729606539/house-committee-votes-to-continue-research-ban-on-genetically-modified-babies">https://www.npr.org/sections/health-shots/2019/06/04/729606539/house-committee-votes-to-continue-research-ban-on-genetically-modified-babies</a>.

National Academy of Sciences (US), National Academy of Engineering (US), Institute of Medicine (US) and National Research Council (US) Committee on Science, Engineering, and Public Policy, "Scientific and Medical Aspects of Human Reproductive Cloning," *National Library of Medicine*, 2002, <a href="https://www.ncbi.nlm.nih.gov/books/NBK223960/">https://www.ncbi.nlm.nih.gov/books/NBK223960/</a>.

making human eggs and sperm in the laboratory from any cell in a person's body."<sup>110</sup> A reproductive biology specialist from Brown University recently stated of IVG, "It is on the precipice of materialization."<sup>111</sup> If it does materialize as some are seeking to ensure, IVG could:

- Enable lesbian, homosexual, and transgender couples to have babies that are genetically related to both partners.
- Enable a single person to have a "uni-baby." Specifically, a professor of obstetrics and gynecology, Dr. Paula Amato, states, "In theory you could reproduce with yourself." 112

In other words, this means we could see a sperm and egg developed from the cells of a single individual to create an embryo. With further technological advancements of artificial wombs, <sup>113</sup> theoretically, a male could self-procreate without the assistance of a biological woman.

While this bill does not explicitly address these scenarios, it could permit them (if the ban on genetically modifying embryos for implantation is not renewed via a rider in the annual appropriations bill) and federally fund them. Without a permanent statute regarding this matter, it is vital the ban is renewed during each appropriations season, or a permanent law is passed to prohibit these possibilities.

While this may sound extreme, so did castrating children (that is, performing surgical procedures on minors struggling with gender identity)—and yet, if technology continues to progress without society fully considering its ethical implications, we could easily find ourselves funding what many view as a dystopian nightmare. We must slow down and seriously consider where all of this is headed.

<sup>&</sup>lt;sup>110</sup> Rob Stein, "Creating a sperm or egg from any cell? Reproduction revolution on the horizon," *NPR*, May 27, 2023, <a href="https://www.npr.org/sections/health-shots/2023/05/27/1177191913/sperm-or-egg-in-lab-breakthrough-in-reproduction-designer-babies-ivg">https://www.npr.org/sections/health-shots/2023/05/27/1177191913/sperm-or-egg-in-lab-breakthrough-in-reproduction-designer-babies-ivg</a>.

<sup>&</sup>lt;sup>111</sup> Ibid.

<sup>112</sup> Ibid.

<sup>&</sup>lt;sup>113</sup> See Rob Stein, "An Artificial Womb Could Build a Bridge to Health for Premature Babies," NPR, April 12, 2024, <a href="https://www.npr.org/sections/health-shots/2024/04/12/1241895501/artificial-womb-premature-birth">https://www.npr.org/sections/health-shots/2024/04/12/1241895501/artificial-womb-premature-birth</a>.

#### Core Issue 3: Allowing a For-Profit Industry to Self-Regulate

"Big Fertility" is a multibillion-dollar industry often referred to as the "The Wild Wild West" due to the inadequate regulation of assisted reproductive technologies. 114 This bill not only fails to address this, doing nothing substantive to address the need for regulation in the IVF and related ARTs industry, but exacerbates it by allowing the ASRM to determine best practices.

#### I. Financial Incentives

As it now stands, the fertility industry in the U.S. profits from unethical, eugenic, and life-destroying practices that are inconsistent with the fact that life begins at fertilization.

- Globally, the IVF industry was valued at \$40 billion in 2023.<sup>115</sup>
- Anecdotal evidence suggests medical practitioners are pressured to offer IVF, demonstrating how the profit-making culture of the fertility industry has penetrated the practice of medicine. For example: an OBGYN surgeon who spends hours in the operating room to treat endometriosis was pressured by hospital administrators to offer IVF services because the time spent trying to heal the root cause was not as profitable.

#### II. Self-Regulation

The fertility industry is, for the most part, "self-regulated through membership with and recommendations from organizations such as the American Society for Reproductive Medicine (ASRM) and the Society for Assisted Reproductive Technology." Their current "regulations," or guidelines, permit several concerning practices, namely gene testing, creating multiple embryos, freezing embryos indefinitely, and more.

As noted above, the bill outlines that the ASRM would determine best medical practices (that is, "widely accepted and evidence-based medical standards of care").

<sup>&</sup>lt;sup>114</sup> Beth Kowitt, "Fertility Inc.: Inside the big business of babymaking," Fortune, January 21, 2020, <a href="https://fortune.com/longform/fertility-business-femtech-investing-ivf/">https://fortune.com/longform/fertility-business-femtech-investing-ivf/</a>.

<sup>115 &</sup>quot;Fertility Services Market Report by Cause of Infertility (Male Infertility, Female Infertility), Procedure (In Vitro Fertilization with Intracytoplasmic Sperm Injection (IVF with ICSI), Surrogacy, In Vitro Fertilization Without Intracytoplasmic Sperm Injection (IVF without ICSI), Intrauterine Insemination (IUI), and Others), Service (Fresh Non-Donor, Frozen Non-Donor, Egg and Embryo Banking, Fresh Donor, Frozen Donor), End-User (Fertility Clinics, Hospitals, Surgical Centres, Clinical Research, Institutes, Cryobanks), and Region 2024-2032," *Imarc*, accessed October 23, 2024, <a href="https://www.imarcgroup.com/fertility-services-market">https://www.imarcgroup.com/fertility-services-market</a>. See also: Emma Waters, "Why the IVF Industry Must be Regulated," The Heritage Foundation, March 19, 2024, <a href="https://www.heritage.org/life/report/why-the-ivf-industry-must-be-regulated">https://www.heritage.org/life/report/why-the-ivf-industry-must-be-regulated</a>.

<sup>&</sup>lt;sup>116</sup> Emma Waters, "Taming IVF's Wild West," *Heritage Foundation*, May 13, 2024, <a href="https://www.heritage.org/marriage-and-family/commentary/taming-ivfs-wild-west">https://www.heritage.org/marriage-and-family/commentary/taming-ivfs-wild-west</a>.

It should be of concern that (as noted previously) several ASRM board members have self-disclosed conflicts of interest and a financial interest in ART.

Tragically, there are numerous testimonies from women and doctors underscoring the frustration experienced by couples engaging with the fertility industry, in part due to the lack of proper regulation. While there are also numerous IVF providers that are operating with the best of intentions, the "bad actors", and the unfortunate truth that IVF and related ART procedures regularly lead to disappointment (miscarriage, stillbirth, or death of the child post-birth), necessitate proper regulations, which this bill fails to provide. Rather, this bill would codify the current reality that ART operates at the whim of a profit-making industry.

## III. Current State of Affairs: The Results of a Loose (nonexistent) Regulatory Regime

In summary, "regulations" are sparse. As previously stated, nationwide, "only 11 states have statutes that regulate facilities that collect and transfer human gametes and embryos." As it pertains to the commodification of reproductive material, "at least ten states have laws or regulations related to the purchase, donation, transfer, solicitation, and/or harvesting of human eggs," and only a few states have strict surrogacy laws. 119

Furthermore, there is no uniform informed consent procedure for women (though two states require "medical providers to inform patients about the potential health hazards and success rates of IVF procedures"). <sup>120</sup> This presents great risks to women's health, particularly surrogates (detailed above).

This lack of regulations has also likely contributed to the negligence shown by the industry. For example:

- The Alabama case was entirely centered on the wrongful death of embryos who died after someone tampered with the cryogenic nursery in 2020.
- In 2018, over 150 families filed suit against University Hospitals in Ohio after a freezer malfunctioned, leading to the loss of 4,000 eggs and embryos.

<sup>&</sup>lt;sup>117</sup> Robert Klitzman, "How much is a child worth? Providers' and patients' views and responses concerning ethical and policy challenges in paying for ART," *National Library of Medicine*, February 16, 2017, <a href="https://pmc.ncbi.nlm.nih.gov/articles/PMC5313146/">https://pmc.ncbi.nlm.nih.gov/articles/PMC5313146/</a>.

<sup>&</sup>lt;sup>118</sup> "Assisted Reproductive Technologies Disclosure (ART) and Risk Reduction Act," Americans United for Life Model Legislation and Policy Guide, August 2023, <a href="https://aul.org/wp-content/uploads/2024/02/Assisted-Reproductive-Technologies-Disclosure-and-Risk-Reduction-Act\_FINAL-2-2024.pdf">https://aul.org/wp-content/uploads/2024/02/Assisted-Reproductive-Technologies-Disclosure-and-Risk-Reduction-Act\_FINAL-2-2024.pdf</a>.

<sup>&</sup>lt;sup>119</sup> Ibid.

<sup>&</sup>lt;sup>120</sup> Ibid.

- According to one news source, "Temperatures rose in a cryopreservation tank, rendering the embryos and the eggs of more than 900 families nonviable." <sup>121</sup>
- In 2018, a California freezer tank failed, killing more than 3,500 human embryos and eggs. Over 140 federal lawsuits were filed against the tank manufacturer.<sup>122</sup>
- In 2019, a New Jersey couple filed suit against the "Institute for Reproductive Medicine and Science for an alleged mistake of putting the wrong egg with the wrong sperm." The couple noticed Asian features developing in the child at around the two-year mark, and after a DNA test show the father had a 0% chance of being biologically related, the stress and tension that ensued led to divorce.<sup>123</sup>
- Similarly, in recent years numerous "fertility fraud" cases have come to light; specifically, the cases "claim dozens of women unknowingly gave birth to children fathered by more than 50 doctors," some of whom are accused of illegally using "their own sperm to artificially inseminate patients." 124
- A lawyer whose firm has represented hundreds of people with fertility industry claims summarized the issue well: "Tragically we see very serious errors on a daily basis. These are the wild west days of the American fertility industry. It operates behind closed doors, and under a veil of secrecy. It can do, basically, whatever it likes, and that's no way for an industry that is so important to operate."125

<sup>&</sup>lt;sup>121</sup> John Caniglia, "UH freezer malfunction update: More than 150 families settle lawsuits in loss of embryos," September 29, 2019, Cleveland.com, <a href="https://www.cleveland.com/news/2019/09/uh-freezer-malfunction-update-more-than-150-families-settle-lawsuits-in-loss-of-embryos.html">https://www.cleveland.com/news/2019/09/uh-freezer-malfunction-update-more-than-150-families-settle-lawsuits-in-loss-of-embryos.html</a>.

<sup>&</sup>lt;sup>122</sup> Edward Helmore, "Five fertility clinic patients awarded \$15m after failure of freezing tank," *The Guardian*, June 12, 2021, <a href="https://www.theguardian.com/us-news/2021/jun/12/fertility-clinic-freezing-tank-failure-california">https://www.theguardian.com/us-news/2021/jun/12/fertility-clinic-freezing-tank-failure-california</a>; see also: Nicholas Iovino, "Jurors Asked to Award \$30 Million for Lost Eggs and Embryos," Courthouse News Service, June 9, 2021, <a href="https://www.courthousenews.com/jurors-asked-to-award-30-million-for-lost-eggs-and-embryos/">https://www.courthousenews.com/jurors-asked-to-award-30-million-for-lost-eggs-and-embryos/</a>.

<sup>&</sup>lt;sup>123</sup> "NJ couple sues fertility clinic, saying wrong sperm used to conceive child," *ABC News*, September 12, 2019, <a href="https://abc7news.com/fertility-clinic-mixup-new-jersey-lawsuit/5532537/">https://abc7news.com/fertility-clinic-mixup-new-jersey-lawsuit/5532537/</a>.

<sup>&</sup>lt;sup>124</sup> Mary Whitfill Roeloffs, "Doctors Impregnating Patients: Major Cases In 2023 Allege 'Fertility Fraud' Lead To 'Secret Children,'" *Forbes*, December 15, 2023,

https://www.forbes.com/sites/maryroeloffs/2023/12/15/doctors-impregnating-patients-major-cases-in-2023-allege-fertility-fraud-lead-to-secret-children/.

<sup>&</sup>lt;sup>125</sup> Edward Helmore, "Five fertility clinic patients awarded \$15m after failure of freezing tank," *The Guardian*, June 12, 2021, <a href="https://www.theguardian.com/us-news/2021/jun/12/fertility-clinic-freezing-tank-failure-california">https://www.theguardian.com/us-news/2021/jun/12/fertility-clinic-freezing-tank-failure-california</a>.

In summary: this bill fails to address basic matters of health and safety, and the prevention of exploitation of women. Rather, it exacerbates these issues by providing federal funding for them and allows the industry to continue regulating itself.

IV. The Growing Demand for Commercial Surrogacy from Foreign Nationals (Pathway to Citizenship) and Celebrities

Given the high cost of commercial surrogacy, it is a luxury not many can afford; hence it is not surprising to learn that wealthy foreign nationals and celebrities are providing much of the demand. The reasons vary but can include fertility issues, as well as (for the former) gaining a pathway to citizenship.

• "Reproductive tourism": From 2014-2020, 32% of surrogate embryo transfers "were for international intended parents." Of these, 41.7% come from China, many are men (41.3%) and 33.9% are over the age of 42 (compared to 26.2% of domestic intended parents). They are also far more likely to utilize genetic testing, and reports suggest a driving factor "is the desire for citizenship." Notably, "75 percent of foreign intended parents used facilities in California" which confirms the reality that "Chinese nationals are taking advantage of an unregulated market in the United States . . . that deals with the creation and selection of human life itself. What's more, we have no idea who these children or their parents are." This is particularly concerning given the Chinese Communist Party is known for "coercive tactics abroad" as well as human rights abuses—consider, for example, the CCP pressuring a Chinese couple with a child who holds U.S. citizenship to gain intelligence for them. Indeed, while it

<sup>&</sup>lt;sup>126</sup> Alexandra Herweck et. al, "International gestational surrogacy in the United States, 2014–2020," *Fertility and Sterility,* revised December 26, 2023, <a href="https://www.fertstert.org/article/S0015-0282(23)02142-8/abstract.">https://www.fertstert.org/article/S0015-0282(23)02142-8/abstract.</a>
Also of note, "Gestational carriers for international intended parents were more commonly younger than 30 years (42.8% vs. 29.1%) and identified as Hispanic race (28.6% vs. 11.7%)."

127 Ibid

<sup>&</sup>lt;sup>128</sup> Emma Waters, "America's Rent-A-Womb Industry Lures an Alarming Number of Chinese Nationals," *The Federalist*, December 14, 2024, <a href="https://thefederalist.com/2023/12/14/americas-rent-a-womb-industry-lures-an-alarming-number-of-chinese-nationals/">https://thefederalist.com/2023/12/14/americas-rent-a-womb-industry-lures-an-alarming-number-of-chinese-nationals/</a>.

<sup>&</sup>lt;sup>129</sup> Ibid. See also: Emma Waters, "California's New Handmaid's Tale," *The American Mind*, November 28, 2022, <a href="https://americanmind.org/salvo/california-new-handmaids-tale/">https://americanmind.org/salvo/california-new-handmaids-tale/</a>, which states "As one Chinese man said in an interview with NPR, 'as long as you know what you want and you have the money, having children in the U.S. will always bring advantages.'"

<sup>&</sup>lt;sup>130</sup> "The Chinese Communist Party: Threatening Global Peace and Security," U.S. Department of State, accessed October 23, 2024, <a href="https://2017-2021.state.gov/the-chinese-communist-party-threatening-global-peace-and-security/">https://2017-2021.state.gov/the-chinese-communist-party-threatening-global-peace-and-security/</a>.

<sup>&</sup>lt;sup>131</sup> Testimony to the Committee on Oversight and Accountability from June 2024 notes, "Beijing maintains an unofficial presence in our country, often cloaked as civil society organizations or community-based

is illegal in China to have dual citizenship, as one surrogacy agent (who gave a pseudonym for fear of retribution) notes, "many of her clients were 'high-level Communist Party officials and celebrities' with money and power who wanted their children to have American citizenship."<sup>132</sup>

• "Celebrity babies": numerous celebrities have utilized the unregulated surrogacy market, including Kim Kardashian, Khloe Kardashian, Paris Hilton, Maria Menounos, Chrissy Teigen, Rebel Wilson, Tan France, Anthony Rapp, Adrienne Bailon, Erin Andrews, Casey Wilson, and others. <sup>133</sup> Actress and producer Elizabeth Banks had two children via surrogacy in 2011 and 2012, respectively. Understanding the controversy inherent in IVF and surrogacy, she spoke on her experience years later in 2019; in a telling comparison, Banks noted "women's reproductive issues were things you would whisper about in small circles." Now, "there's #ShoutYourAbortion and IVF Facebook groups." <sup>134</sup> Surrogates carrying celebrity children have uniquely emotional and at times traumatic experiences. Aria Simuela, who runs a surrogacy agency in California, stated, "When a high-profile person comes with business managers, assistants, head of security, that can be very intimidating for a surrogate." <sup>135</sup>

In summary, the commercial surrogacy market's unique demand lines for celebrities and foreign nationals are another consequence of an unregulated fertility industry. This bill will continue to permit and likely promote "reproductive tourism" and "celebrity babies."

# Core Issue 4: Financial Impact

Funding this will create a massive federal expense. While it is challenging to provide an estimated cost for services under this bill, given particularly it allows individuals to access services, it will, no doubt, lead to an increase in federal spending.

associations that ultimately report to and receive money from the Party and in some cases, instructions from China's Ministry of Public Security." See "Congressional Testimony of Mary Kissel, Former Senior Advisor to the U.S. Secretary of State," U.S. House of Representatives Committee on Oversight and Accountability, June 26, 2024, https://oversight.house.gov/wp-content/uploads/2024/06/Kissel-Testimony.pdf.

<sup>&</sup>lt;sup>132</sup> Emily Feng, "Chinese families navigate a maze of laws and COVID rules to have babies in the U.S.," *NPR*, October 22, 2022, <a href="https://www.npr.org/2022/10/22/1128837495/surrogacy-birth-tourism-china-california">https://www.npr.org/2022/10/22/1128837495/surrogacy-birth-tourism-china-california</a>.

<sup>133</sup> Sophie Schillaci, "Hollywood's Surrogacy Spotlight: What to Know About the Process Used by Paris Hilton and More Stars," *ET*, November 27, 2023, <a href="https://www.etonline.com/hollywoods-surrogacy-spotlight-what-to-know-about-the-process-used-by-paris-hilton-and-more-stars">https://www.etonline.com/hollywoods-surrogacy-spotlight-what-to-know-about-the-process-used-by-paris-hilton-and-more-stars</a>.

<sup>&</sup>quot;Woman on a Mission," *Net-a-Porter*, accessed October 23, 2024, <a href="https://www.net-a-porter.com/en-us/porter/article-27979f432011eedc/cover-stories/cover-stories/elizabeth-banks">https://www.net-a-porter.com/en-us/porter/article-27979f432011eedc/cover-stories/cover-stories/elizabeth-banks</a>.

<sup>&</sup>lt;sup>135</sup> Megha Mohan, "The joy and the trauma of carrying a celebrity's baby," *BBC*, January 28, 2023, https://www.bbc.com/news/world-us-canada-64421478.

- According to the U.S. Department of Health and Human Services, "costs for a single cycle of IVF have recently been estimated to range from \$15,000 to \$20,000 and can exceed \$30,000"; combined with the fact that most women undergo 2.5 cycles, costs can easily exceed \$40,000 per woman.<sup>136</sup>
- While we do not have robust data on the number of individuals seeking IVF, according to the HHS, in 2021, approximately 413,776 assisted reproductive technology cycles were performed,<sup>137</sup> equating to \$6.2 billion.
- 1 in 6 women experience infertility.<sup>138</sup> In 2023, the Census Bureau estimated there were 61.5 million women in the U.S. between ages 18-45.<sup>139</sup> Using these estimates, there are at least 10.3 million women in the U.S. who struggle with infertility. Assuming just half of these would seek treatment under this bill (5.15 million), and using the cost of \$15,000 for *just one* IVF cycle, the cost could easily be in the billions (and this does not consider the men who would be eligible to hire surrogates).

## Core Issue 5: Failure to Address Underlying Health Conditions

Infertility itself is often a side effect of one or multiple underlying condition(s). **The bill largely dismisses these underlying conditions, which can affect the woman and baby in pregnancy.** Rather, it advances a risky procedure (IVF), which itself is a work-around for those who are experiencing infertility.

In essence, this bill treats a symptom (like giving someone with a fever a cool washcloth), rather than addressing the root of infertility. Underlying causes of infertility include (but are not limited to):

- Endometriosis.
- Adenomyosis.
- Polycystic ovary syndrome.
- Uterine fibroids.

<sup>&</sup>lt;sup>136</sup> "Fact Sheet: In Vitro Fertilization (IVF) Use Across the United States," U.S. Department of Health and Human Services, <a href="https://www.hhs.gov/about/news/2024/03/13/fact-sheet-in-vitro-fertilization-ivf-use-across-united-states.html#footnote35\_8g1x7d5">https://www.hhs.gov/about/news/2024/03/13/fact-sheet-in-vitro-fertilization-ivf-use-across-united-states.html#footnote35\_8g1x7d5</a>.

<sup>137</sup> Ibid

<sup>&</sup>lt;sup>138</sup> "Hope After IVF: Restorative Reproductive Medicine," International Institute for Restorative Reproductive Medicine, September 1, 2018, <a href="https://iirrm.org/hope-after-ivf-rrm/">https://iirrm.org/hope-after-ivf-rrm/</a>. See also, "1 in 6 people globally affected by infertility: WHO," World Health Organization, April 4, 2023, <a href="https://www.who.int/news/item/04-04-2023-1-in-6-people-globally-affected-by-infertility">https://www.who.int/news/item/04-04-2023-1-in-6-people-globally-affected-by-infertility</a>.

<sup>&</sup>lt;sup>139</sup> "National Population by Characteristics: 2020-2023; Annual Estimates of the Resident Population by Single Year of Age and Sex for the United States: April 1, 2020 to July 1," United States Census Bureau, 2023, https://www.census.gov/data/tables/time-series/demo/popest/2020s-national-detail.html.

- Blocked fallopian tubes.
- Hormone imbalances.
- Hyperprolactinemia.
- Thyroid conditions.
- Ovulation dysfunctions.<sup>140</sup>

Taking just one example, endometriosis ("an especially painful condition") is present in **63**% **of unexplained infertility** cases for women. Notably it is often a "primary contributor to infertility," affecting at least 10% of the reproductive-age female population. Tagically, it takes 11 years, on average, to receive a diagnosis. Many women turn to IVF, perhaps because "conventional treatments focus on symptom control but may not always be effective or suitable for pregnancy. Aconversely, "Some integrative treatments, for example traditional Chinese medicine (TCM), show promise in addressing the infertility symptom of endometriosis; specifically some studies that suggest TCM . . . can achieve effectiveness rates of 90 percent or higher in relieving symptoms like dysmenorrhea and infertility.

Looking at the issue more widely, a 2022 study published in the Oxford Academic journal *Human Reproduction Open* shows couples struggling with infertility collectively have an average of four or more underlying reproductive health conditions. <sup>146</sup> This same study points out that there are several single-clinic studies that **show "adjusted cumulative live birth rates ranging from 29% to 66%" when "subfertile couples" receive "restorative"** 

<sup>&</sup>lt;sup>140</sup> Emma Waters, "To Address Infertility, It's Time to Give Real Reproductive Health Options," *The Heritage Foundation*, June 17, 2024, <a href="https://www.heritage.org/marriage-and-family/commentary/address-infertility-its-time-give-real-reproductive-health-options/">https://www.heritage.org/marriage-and-family/commentary/address-infertility-its-time-give-real-reproductive-health-options/</a>.

<sup>&</sup>lt;sup>141</sup> Terri Ward, "Endometriosis: Symptoms, Causes, Treatments, and Natural Approaches," *Epoch Times*, September 15, 2024, <a href="https://www.theepochtimes.com/health/endometriosis-symptoms-causes-treatments-and-natural-approaches-5720724">https://www.theepochtimes.com/health/endometriosis-symptoms-causes-treatments-and-natural-approaches-5720724</a>.

<sup>&</sup>lt;sup>142</sup> Emma Waters, "To Address Infertility, It's Time to Give Real Reproductive Health Options," *The Heritage Foundation*, June 17, 2024, <a href="https://www.heritage.org/marriage-and-family/commentary/address-infertility-its-time-give-real-reproductive-health-options">https://www.heritage.org/marriage-and-family/commentary/address-infertility-its-time-give-real-reproductive-health-options.</a>

<sup>&</sup>lt;sup>144</sup> Terri Ward, "Endometriosis: Symptoms, Causes, Treatments, and Natural Approaches," *Epoch Times*, September 15, 2024, <a href="https://www.theepochtimes.com/health/endometriosis-symptoms-causes-treatments-and-natural-approaches-5720724">https://www.theepochtimes.com/health/endometriosis-symptoms-causes-treatments-and-natural-approaches-5720724</a>.

<sup>&</sup>lt;sup>145</sup> Ibid; see also Haiying Huang et. al., "A Meta-analysis of the Efficacy and Safety of Traditional Chinese Medicine in Treating Endometriosis," *Alternative Therapies in Health and Medicine*, March 2024, <a href="https://pubmed.ncbi.nlm.nih.gov/38551430/">https://pubmed.ncbi.nlm.nih.gov/38551430/</a>.

<sup>&</sup>lt;sup>146</sup> Joseph B Sanford et. al, "International Natural Procreative Technology Evaluation and Surveillance of Treatment for Subfertility (iNEST): enrollment and methods," *Oxford Academic*, August 9, 2022, <a href="https://academic.oup.com/hropen/article/2022/3/hoac033/6659100">https://academic.oup.com/hropen/article/2022/3/hoac033/6659100</a>.

reproductive medicine, mostly natural procreative technology . . . for up to two years."147

Conversely, the success rate for the expensive, risky IVF procedure is minimal, with most IVF cycles failing and costing tens of thousands; and for those that do succeed, the children are (as detailed above) at much higher risk for pediatric cancers, among other things.

In short, as Senior Research Associate with The Heritage Foundation Emma Waters highlights, this "means doctors and patients need to understand how to treat each of the conditions involved... Women should not spend years in pain struggling with 'unexplained infertility' when restorative treatments could alleviate their pain and remove barriers to successfully conceiving and carrying children. Such methods may also increase a couple's success rates if they decide to still use IVF, too." 148

Finally, failing to deal with these issues while still seeking IVF may lead to a greater chance of miscarriage. For example, one study found women with endometriosis had a 76% higher risk of miscarriage and an ectopic pregnancy rate was three times higher than those without.<sup>149</sup> A 2016 study similarly found an increased chance of miscarriage.<sup>150</sup>

While many couples seeking to get pregnant want to be healthy, this bill does nothing to address that. Rather than treat a symptom, the government should seek to facilitate paths to healing the underlying causes of infertility, including promoting holistic health. It should assume people want to be healthy.

In summary: "Democratic lawmakers want to lure Republicans—and the public at large—into bad-faith arguments over IVF. In doing so, they treat couples struggling with infertility as pawns to score political wins. Lawmakers should instead be empowering people with more

<sup>&</sup>lt;sup>147</sup> Ibid.

<sup>&</sup>lt;sup>148</sup> Emma Waters, "To Address Infertility, It's Time to Give Real Reproductive Health Options," *The Heritage Foundation*, June 17, 2024 <a href="https://www.heritage.org/marriage-and-family/commentary/address-infertility-its-time-give-real-reproductive-health-options">https://www.heritage.org/marriage-and-family/commentary/address-infertility-its-time-give-real-reproductive-health-options</a>.

<sup>&</sup>lt;sup>149</sup> Darin Swainston, MD, "Can Endometriosis Cause a Miscarriage?" GYN Robotic Surgery, accessed October 23, 2024, <a href="https://www.lasvegasgynsurgery.com/blog/can-endometriosis-cause-a-miscarriage">https://www.lasvegasgynsurgery.com/blog/can-endometriosis-cause-a-miscarriage</a>. 
<sup>150</sup> "Increased rate of spontaneous miscarriages in endometriosis-affected women," *National Library of Medicine*, May 2016, <a href="https://www.endofound.org/can-endometriosis-increase-your-risk-for-miscarriage">https://www.endofound.org/can-endometriosis-increase-your-risk-for-miscarriage</a>; 
<a href="https://pubmed.ncbi.nlm.nih.gov/26965434/">https://pubmed.ncbi.nlm.nih.gov/26965434/</a>.

options to diagnose and treat their reproductive health conditions, including the conditions that cause infertility."<sup>151</sup> Notably, the RESTORE Act does just that (detailed further below).

#### Alternative Policy Options and Recommendations

We suggest the administration and Congress urgently address the lack of, and need for, regulations related to IVF and other ARTs in the United States. More broadly, we propose the risks faced by embryos created through IVF procedures (increased pediatric cancer rates, congenital heart defects, etc.) deserve serious consideration in any public policy.

States certainly should, and some have, passed legislation to regulate IVF and ARTs. Given the current practice of selling reproductive material, as well as hiring surrogates both internationally and across state lines, Congress has an interest in legislating on this matter.

Some concerns related to the issues outlined above would be addressed by current proposed legislation. Other policy concerns require new legislation. Below are four policy proposals we believe legislators should be aware of, either to support or oppose (in addition to the Right To IVF Act), some of which closely mirror model legislation from Americans United for Liberty.<sup>152</sup>

#### I. Support / Advance the RESTORE Act

Introduced by Senator Hyde-Smith (R-MS) and co-sponsored by six other Republicans, the RESTORE Act seeks to "expand and promote research and data collection on reproductive health conditions" as well as "provide training opportunities for medical professionals to learn how to diagnose and treat reproductive health conditions." <sup>153</sup>

Research for most underlying reproductive health conditions is sorely lacking, leading to the current situation many couples experiencing infertility face, that is, medical professionals (who themselves may lack the proper training on these underlying causes) simply point them to IVF as a solution to their desire for children. Specifically, as the RESTORE Act findings state, "Women are worthy of the highest standard of medical care, including the opportunity to assess, understand, and

<sup>&</sup>lt;sup>151</sup> Natalie Dodson and Emma Waters, "To Address Infertility, It's Time To Give Real Reproductive Health Options," Cindy Hyde-Smith, June 13, 2024, <a href="https://www.hydesmith.senate.gov/address-infertility-its-time-give-real-reproductive-health-options-opinion">https://www.hydesmith.senate.gov/address-infertility-its-time-give-real-reproductive-health-options-opinion</a>.

<sup>&</sup>lt;sup>152</sup> "Assisted Reproductive Technologies Disclosure (ART) and Risk Reduction Act," Americans United for Life Model Legislation and Policy Guide, August 2023, <a href="https://aul.org/wp-content/uploads/2024/02/Assisted-Reproductive-Technologies-Disclosure-and-Risk-Reduction-Act\_FINAL-2-2024.pdf">https://aul.org/wp-content/uploads/2024/02/Assisted-Reproductive-Technologies-Disclosure-and-Risk-Reduction-Act\_FINAL-2-2024.pdf</a>.

<sup>&</sup>lt;sup>153</sup> "S.4533 - RESTORE Act," Congress.Gov, June 13, 2024, <a href="https://www.congress.gov/bill/118th-congress/senate-bill/4533/text">https://www.congress.gov/bill/118th-congress/senate-bill/4533/text</a>.

improve their reproductive health. Unfortunately, many women do not receive adequate information about their reproductive health and do not have access to restorative reproductive medicine."<sup>154</sup>

This takes the first steps to address those gaps.

# II. Introduce Legislation to Ensure Life Is Protected

At a minimum, regulations are required to rein in the harms being caused by "Big Fertility." As outlined by Americans United for Liberty, allowing the ART industry to self-regulate "is ineffective." Indeed, setting aside the fact that not all ART programs are members of the professional organizations that create recommended guidelines (e.g. the Society for Assisted Reproductive Technology (SART) or the American Society for Reproductive Medicine (ASRM)), even for those that are there is no guarantee they follow them.<sup>155</sup>

The following model offers a basic regulatory approach that ensures life is respected and protected, and mitigates the damage being caused by the lack of regulations.

# a. Limit the number of embryos created and transferred and prohibit freezing embryos. Specifically:

- No more than [one-two] [viable] embryos should be created in one reproductive cycle.
- All [viable] embryos should be implanted as soon as clinically appropriate.
- If two embryos are transferred, selective reduction should be expressly prohibited.
- Prohibit freezing embryos. For couples whose circumstances change, such that they no longer desire to have embryos created implanted, an exception to the prohibition on freezing should be permitted to allow for embryo adoption (see point (b)).

**Rationale:** As noted above, transferring multiple embryos at one time can lead to a pregnancy of multiples, which increases the risks of complications. Notably, in a 2021 Data Brief the CDC, citing ASRM, stated "Reducing the number of embryos transferred and increasing the use of single embryo transfer procedures, when

<sup>155</sup> "Assisted Reproductive Technologies Disclosure (ART) and Risk Reduction Act," Americans United for Life Model Legislation and Policy Guide, August 2023, <a href="https://aul.org/wp-content/uploads/2024/02/Assisted-Reproductive-Technologies-Disclosure-and-Risk-Reduction-Act\_FINAL-2-2024.pdf">https://aul.org/wp-content/uploads/2024/02/Assisted-Reproductive-Technologies-Disclosure-and-Risk-Reduction-Act\_FINAL-2-2024.pdf</a>.

<sup>154</sup> Ibid.

clinically appropriate, can help reduce multiple births and related adverse health consequences for both mothers and infants."<sup>156</sup>

The above recommendation allows couples to consider whether a higher risk (twin) pregnancy is clinically appropriate while remaining life-affirming and prevents the long-term / indefinite freezing of embryos.

Finally of note, several jurisdictions, including the state of Louisiana, as well as Australia, France, Germany, Italy, and New Zealand, have laws limiting or prohibiting "the wanton transfer, production, and destruction of human embryos."<sup>157</sup>

# b. Permit and create a regulatory structure for embryo adoption.

**Rationale:** For embryos currently frozen and those that may be created in the future and abandoned, the most life-affirming solution is to permit embryo adoption. As with most ART practices, the regulatory structures required to ensure the parents and children involved in embryo adoption are fully protected have not been developed and are needed.

For currently frozen embryos, parents should be notified of their options, including embryo adoption, and all decisions related to currently frozen embryos should require parental consent.

#### c. Prohibit genetic testing and selection.

**Rationale:** While the above would by implication prevent future testing of and selection of embryos, for embryos already created, Congress should ensure embryo testing does not become a tool of modern-day eugenics by prohibiting its further use. The immutable characteristics of sex, race, non-threatening life disability, or other known or anticipated traits should not be a sole reason for selecting certain embryos over others.

# d. Prohibit egg donation to third parties and surrogacy.

**Rationale**: As outlined above, women who donate eggs face myriad risks to their health. Similarly, there is a greater risk of complications in pregnancies involving

<sup>&</sup>lt;sup>156</sup> "State-Specific ART Surveillance," Center for Disease Control and Prevention, 2021, https://www.cdc.gov/art/state-specific-surveillance/2021/index.html.

<sup>&</sup>lt;sup>157</sup> Emma Waters, "Why the IVF Industry Must Be Regulated," *The Heritage Foundation,* March 19, 2024, <a href="https://www.heritage.org/life/report/why-the-ivf-industry-must-be-regulated">https://www.heritage.org/life/report/why-the-ivf-industry-must-be-regulated</a>.

donor eggs, which includes surrogacy. Furthermore, given the many health and psychological risks associated with surrogacy, its ties to human trafficking and concerns related to foreign nationals utilizing U.S. surrogates to obtain citizenship for their children, surrogacy should be expressly prohibited.

Notably, several nations have laws prohibiting commercial surrogacy, and surrogacy in all forms is banned in Bulgaria, France, Germany, Italy, Portugal, Taiwan, and Spain.<sup>158</sup>

# e. Prohibit genetic modification of embryos.

Congress should expressly prohibit genetically modifying embryos, including but not limited to the creation of three-parent embryos, creation of chimeras (human-animal hybrids), and any that could be created through advancements in in vitro gametogenesis.

**Rationale:** As outline above these are deeply controversial practices. The long-term effects of such modifications are unknown, and the ethical questions tied to such practices outweigh any arguments seeking to allow their continued practice.

# III. Require Regulation of ART Providers, Reporting (Data Collection), & Comprehensive Informed Consent

Notably, "there's no federal law, no state law, no enforced professional guideline that licenses [ART] facilities," which is entirely different from other fields that closely regulate medical facilities. Such licensing and regulation is particularly needed to mitigate the risk of 'never events;' that is, "major, avoidable mistakes" <sup>159</sup>—like placing the wrong egg and sperm together. Indeed, regulations are needed to prevent such tragedies, as well as advance our understanding of the nature and extent of ART procedures, and to ensure informed consent.

To the former point, without robust data, making policy recommendations is difficult. To the latter point, as Americans United for Liberty model state legislation on this matter outlines, "Informed consent is one of the core principles of ethical medical practice, and every patient has a right to information pertinent to an invasive medical

<sup>&</sup>lt;sup>158</sup> "Which countries allow commercial surrogacy?" Reuters, April 5, 2023, https://www.reuters.com/world/which-countries-allow-commercial-surrogacy-2023-04-05/.

<sup>&</sup>lt;sup>159</sup> Doha Madani and Jo Ling Kent, "Couple says fertility clinic that mixed up their embryos put them 'through living hell'," July 10, 2019, *NBC News*, <a href="https://www.nbcnews.com/news/us-news/couple-says-fertility-clinic-mixed-their-embryos-put-them-through-n1028396">https://www.nbcnews.com/news/us-news/couple-says-fertility-clinic-mixed-their-embryos-put-them-through-n1028396</a>.

procedure. Further, ART is unique because it produces a third party—the prospective child—who must also be considered and protected."<sup>160</sup>

As outlined by Mary E Harned, J.D., preexisting legislation, the Fertility Clinic Success Rate and Certification Act ("FCSRCA") which was passed in 1992, <sup>161</sup> could be amended to address some of these needs. Specifically, legislation is needed to:

- a. **Require Comprehensive Reporting.** Specifically, require (by providing states an incentive or penalty for adopting or failing to adopt it, respectively) ART providers and clinics to report to the CDC:
  - The information outlined in the FCSRCA, namely, pregnancy success rates achieved "through each assisted reproductive technology" and "whether the laboratory is certified," adding the specific rate of success per each ART cycle and the number of embryos created per cycle.
  - The number and type of adverse (or "never") events (both those affecting the woman and child).
  - o Any cases of negligent care of embryos resulting in destruction or injury.
  - o The costs of IVF and ARTs and related insurance payments.
  - Any lawsuits or similar actions taken against ART clinics and providers.
- b. Require Certification and Inspection of ART Clinics and Providers. Notably, the FCSRCA required development of a "model program for the certification of embryo laboratories" which states can adopt voluntarily; however, given the myriad issues related to the current practices of IVF, this or a similar model should be required (again by either providing states an incentive to adopt it or penalty for not adopting it). <sup>163</sup> If the FCSRCA model is used, it should be reviewed and updated as needed.

<sup>&</sup>lt;sup>160</sup> "Assisted Reproductive Technologies Disclosure (ART) and Risk Reduction Act," Americans United for Life Model Legislation and Policy Guide, August 2023, <a href="https://aul.org/wp-content/uploads/2024/02/Assisted-Reproductive-Technologies-Disclosure-and-Risk-Reduction-Act\_FINAL-2-2024.pdf">https://aul.org/wp-content/uploads/2024/02/Assisted-Reproductive-Technologies-Disclosure-and-Risk-Reduction-Act\_FINAL-2-2024.pdf</a>.

<sup>&</sup>lt;sup>161</sup> Mary E. Harned, "IVF Industry Regulation in the United States: Changes Are Needed to Protect Embryonic Children and their Families," Charlotte Lozier Institute, November 13, 2024, <a href="https://lozierinstitute.org/ivf-industry-regulation-in-the-united-states-changes-are-needed-to-protect-embryonic-children-and-their-families/">https://lozierinstitute.org/ivf-industry-regulation-in-the-united-states-changes-are-needed-to-protect-embryonic-children-and-their-families/</a>.

<sup>&</sup>lt;sup>162</sup> "42 USC 263a-1: Assisted reproductive technology programs," accessed November 19, 2024, https://uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=granuleid%3AUSC-prelim-title42-section263a-

 $<sup>\</sup>underline{1\&num=0\&saved=\%7CZ3JhbnVsZWlkOlVTQy1wcmVsaW0tdGl0bGU0Mi1zZWN0aW9uMjYzYS0z\%7C\%7C\%7C}\\ \underline{C0\%7Cfalse\%7Cprelim}.$ 

<sup>&</sup>lt;sup>163</sup> Ibid.

c. Require Uniform Informed Consent Procedures: Specifically this should include information on all risks and less invasive options available; including but not limited to those outlined in the RESTORE Act under the definition of the term "restorative reproductive medicine," which means "any scientific approach to reproductive medicine that seeks to cooperate with, or restore the normal physiology and anatomy of, the human reproductive system, without the use of methods that are inherently suppressive, circumventive, or destructive to natural human functions" and "may include ultrasounds, blood tests, hormone panels, laparoscopic and exploratory surgeries, examining the man's or woman's overall health and lifestyle, eliminating environmental endocrine disruptors, and assessing the health and fertility of the individual's partner, Natural Procreative Technology, fertility awareness-based methods, and fertility education and medical management." 164

Natural Procreative Technology should also be defined as it is under the RESTORE Act, as "an approach to health care that monitors and maintains a woman's reproductive and gynecological health, including laparoscopic gynecologic surgery to reconstruct the uterus, fallopian tubes, ovaries, and other organ structures to eliminate endometriosis and other reproductive health conditions."<sup>165</sup>

Related to this, consent from the parents should also be required regarding any decisions concerning currently frozen embryos.

As one researcher highlighted, "Women and men who may struggle with infertility deserve the highest standard of medical care, and this begins by offering them treatments to proactively assess and treat their reproductive health conditions before they are ready to have children. This is clearly more helpful than any political statement about IVF, which is already widely available." <sup>166</sup>

<sup>&</sup>lt;sup>164</sup> "S.4533 - RESTORE Act," Congress.Gov, June 13, 2024, <a href="https://www.congress.gov/bill/118th-congress/senate-bill/4533/text">https://www.congress.gov/bill/118th-congress/senate-bill/4533/text</a>.

<sup>&</sup>lt;sup>165</sup> Ibid.

<sup>&</sup>lt;sup>166</sup> Emma Waters, "To Address Infertility, It's Time to Give Real Reproductive Health Options," *The Heritage Foundation*, June 17, 2024, <a href="https://www.heritage.org/marriage-and-family/commentary/address-infertility-its-time-give-real-reproductive-health-options">https://www.heritage.org/marriage-and-family/commentary/address-infertility-its-time-give-real-reproductive-health-options.</a>

#### IV. Oppose the IVF Protection Act

This Act, while in many ways better than the "Right To IVF" Act, fails to address the myriad ethical questions surrounding IVF and other ARTs and therefore we recommend opposing it. Introduced by Senators Ted Cruz (R-TX) and Katie Britt (R-AL), The IVF Protection Act in essence treats IVF like abortion, allowing the states to regulate it as they determine best. Simultaneously, it seeks to ensure states do not ban access to IVF, with the alternative being a loss of Medicaid funds.<sup>167</sup>

# Assisted Reproductive Technologies and Life Affirming Regulations Are Not Mutually Exclusive

Couples and their prospective children deserve the best care available, including having access to the myriad resources available related to growing a family. The above recommendations seek to ensure the prior while providing life-affirming guardrails around the fertility industry.

Most importantly, we urge Members to avoid following the rash and reckless path of the Alabama legislature, whose knee-jerk reaction to the Alabama Supreme Court's decision (which permitted parents who lost their children to sue those who were negligent in their care of them) was to immunize fertility clinics from civil and criminal liability—an **immunity** "no other medical facilities or practitioners enjoy." It not only ignored the pain of the parents who lost children but also ignored the truth that "destroying or neglecting human embryos is not essential for IVF." 169

<sup>&</sup>lt;sup>167</sup> "S.4368 - IVF Protection Act," Congress.Gov, May 20, 2024, <a href="https://www.congress.gov/bill/118th-congress/senate-bill/4368/text">https://www.congress.gov/bill/118th-congress/senate-bill/4368/text</a>.

<sup>&</sup>lt;sup>168</sup> Mary E. Harned, "IVF Industry Regulation in the United States: Changes Are Needed to Protect Embryonic Children and their Families," Charolotte Lozier Institute, November 13, 2024, <a href="https://lozierinstitute.org/ivf-industry-regulation-in-the-united-states-changes-are-needed-to-protect-embryonic-children-and-their-families/">https://lozierinstitute.org/ivf-industry-regulation-in-the-united-states-changes-are-needed-to-protect-embryonic-children-and-their-families/</a>.

<sup>&</sup>lt;sup>169</sup> Emma Waters, "Why the IVF Industry Must be Regulated," The Heritage Foundation, March 19, 2024, <a href="https://www.heritage.org/life/report/why-the-ivf-industry-must-be-regulated">https://www.heritage.org/life/report/why-the-ivf-industry-must-be-regulated</a>.