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# THE CONTINUED ASSAULT ON REPRODUCTIVE FREEDOMS IN POST-DOBBS AMERICA

## HEARING

BEFORE THE

## COMMITTEE ON THE JUDICIARY
## UNITED STATES SENATE

ONE HUNDRED EIGHTEENTH CONGRESS

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# THE CONTINUED ASSAULT ON REPRODUCTIVE FREEDOMS IN POST-DOBBS AMERICA

**WEDNESDAY, MARCH 20, 2024**

UNITED STATES SENATE,
COMMITTEE ON THE JUDICIARY,
*Washington, DC.*

The Committee met, pursuant to notice, at 2:31 p.m., in Room G50, Dirksen Senate Office Building, Hon. Richard J. Durbin, Chair of the Committee, presiding.

Present: Senators Durbin [presiding], Whitehouse, Klobuchar, Coons, Blumenthal, Hirono, Booker, Padilla, Ossoff, Welch, Butler, Graham, Grassley, Lee, Cruz, Hawley, Kennedy, Tillis, and Blackburn.

Also present: Senator Duckworth, Congresswoman Fischbach.

## OPENING STATEMENT OF HON. RICHARD J. DURBIN, A U.S. SENATOR FROM THE STATE OF ILLINOIS

Chair DURBIN. This hearing will come to order. Todays hearing is the third of the Senate Judiciary Committee that we held since the Supreme Court over ruled *Roe v. Wade* eliminating a womens Constitutional right to reproductive freedom.

It was almost 2 years ago the court issued its decision of *Dobbs v. Jackson*. With a single ruling, the right-wing majority overruled nearly five decades of legal precedent, and revoked a constitutional right for the first time in history.

In the years leading up to *Dobbs*, we were warned about the dangers of overruling *Roe v. Wade*. Medical experts told us it would unleash a healthcare crisis across America. Legal experts warned us that it would establish a disastrous precedent under which unelected judges can recklessly eliminate fundamental freedoms. And women across the country warned that overruling *Roe* would insert politicians and judges into the most personal decision imaginable, taking away their right to choose whether and how to expand their family.

At the outset, I want to share a video on the state of our reproductive healthcare system in the post-*Dobbs* era.

[Video is shown.]

Chair DURBIN. The fallout of the *Dobbs* decision has been devastating. Women with non-viable, life-threatening pregnancies have been denied access to medical care as we heard from Amanda Zurawski under oath at our last hearing. Amanda's testimony is seared in my memory; forced to continue a non-viable pregnancy

due to Texas's extreme anti-abortion law, Amanda developed sepsis and nearly died. Amanda's healthcare providers wanted to provide the abortion she needed, but we now live in a nation where healthcare providers live in fear of civil and criminal liability for simply doing their jobs.

A Nation where women suffering from miscarriages have been threatened with jail time, and where access to FDA-approved medication used safely and effectively for more than two decades is threatened, and a nation in which just last month a State Supreme Court ruled that frozen embryos are children under a State law, which resulted in numerous IVF clinics in the State halting their services for those who desperately want a baby, but struggle with infertility, for cancer patients who must safeguard future reproductive options as they undergo treatment, for LGBTQ couples who use IVF to expand their families. This ruling in Alabama was heartbreaking.

Today, we will hear from Jamie Heard, one Alabamans affected by this decision. Despite State lawmakers' slapdash efforts to address the fallout after the Alabama Supreme Court decision, there remains significant concerns about the future of IVF in that State and others.

Fetal personhood bills have been introduced in at least a dozen other States, and 125 U.S. House Republicans have co-sponsored fetal personhood legislation with no carve out, carve out to protect access to IVF or birth control. And Justice Thomas showed us that constitutional right to birth control is at risk when, in his concurring opinion in *Dobbs*, he called for the court to reconsider its holding in *Griswold v. Connecticut*.

More than 25 million women of reproductive age now live in the States where abortion is banned, unavailable or restricted, and women's lives are in jeopardy. Women facing non-viable pregnancies are being denied emergency, life-saving medical treatment. Women suffering from miscarriages are being denied access to medication and procedures that can reduce emotional trauma and save their lives.

Rape and incest survivors are being victimized by a system that makes it harder for them to end an unwanted pregnancy. Healthcare providers can no longer be able to use their best medical judgment to treat patients. And those who desperately want to become pregnant, but need IVF are facing unnecessary barriers to parenthood.

Those of us who believe in a woman's right to bodily autonomy need to step up and stop this chaos. We must respect women's rights to make their own reproductive health decisions, but the question remains, will our Republican colleagues join us in this effort, and support legal access to abortion and reproductive freedom?

With that, I turn to Ranking Member Graham for his opening statement.

**OPENING STATEMENT OF HON. LINDSEY O. GRAHAM, A U.S. SENATOR FROM THE STATE OF SOUTH CAROLINA**

Senator GRAHAM. Thank you, Mr. Chairman. I appreciate it very much. So, we're having a hearing today about IVF treatments, and

the opening statement was about abortion. I think everybody on our side supports the idea of families being able to access this treatment. I know Senator Baldwin staff members on our side have had families through this procedure absolutely committed to making sure this is available.

The Alabama decision, I think, has been corrected by the Alabama legislature. There are a lot of questions around embryos and what status they should have, but I don't think you have any disagreement here on the Committee that IVF treatments should be made available. I mean, there should be reasonable regulation in this area, just like any other area of medicine.

The abortion debate is one worth having, really. I think it's very important. What kind of country do we want to be in 2024, and 2025, and beyond? I have been vocal about a national limitation; exceptions for rape, incest, life of the mother exceptions at 15 weeks. Fifteen weeks limitation process in line with the majority of the European nations. I think 47 to 52 nations in Europe limit abortion between 12 and 15 weeks.

The bottom line here is that you and others on your side have been supporting national laws that would override every State pro-life law on the books to replace it with rules that would not be *Roe v. Wade*. There'd be absolutely no limitations at all on the ability to get an abortion. Everybody in the media says Democrats are not for abortion on demand up to the moment of birth. Well, okay, what limitations do you have?

I challenge every Member of this Committee on the Democratic side, pick a week in the birthing process where you would limit abortion. Just any week. I don't care if it's the last week, just pick one you want, because you can't. Politically, all the energy on your side is to make America like China, and North Korea, and Iran when it comes to abortion, where you can have abortion literally right up to the moment of birth with no exceptions at all.

Most Americans reject that way of thinking. What States do after the *Dobbs* decision on abortion is up to them to a point. I always thought the pro-life movement to me was about the developing child. At 15 weeks, we know an unborn child can feel pain. You provide anesthesia to treat the child medically because they can feel pain, that's normal medical practices.

So, the debate about when to intervene, if at all, on behalf of the unborn child is worthy of a great nation. There is no effort by anybody I know of in the Republican Party in Washington, DC to shut down fertility clinics. Quite the opposite. We appreciate this as a form of way of bringing life into the world for couples that are having a very difficult time conceiving a child otherwise.

So, we will continue to have this debate, but I'm waiting to hear from one national Democrat in the Senate, let's just start with the Senate, that would tell the country at what point would you limit abortion on demand? Just pick a week, pick any exception at all, and the answer is deafening. Not one of you has come out that I know of with any limitation on abortion at all, anytime, anywhere, for any reason.

So I am waiting to hear what you have to say. I have been clear about what I think, and I look forward to this discussion, and thank you very much.

Chair DURBIN. Thanks, Senator Graham. We'll begin with our witnesses when we go to the witness panel, which is the second group. Each member will have 5 minutes to provide their statement, and then 5 minutes of questioning from each Senator.

But first, we begin with a statement from my colleague, Senator Tammy Duckworth, my fellow Senator from Illinois. She's an exceptional champion for reproductive rights and the people of Illinois, and I'm grateful for her joining us today.

Tammy brings a unique perspective to this. I remember when she called me, and said she had news to tell me. And I said, "What's up, Tammy?" She said, "I'm going to have a baby." I couldn't believe it after what that body of yours has been through that you were able to do. That was a remarkable, almost a miracle. Beautiful little girl, and another one following. It's a tribute to you, and your determination and courage throughout your life.

The floor is yours.

**STATEMENT OF HON. TAMMY DUCKWORTH,**
**A U.S. SENATOR FROM THE STATE OF ILLINOIS**

Senator DUCKWORTH. Thank you, Mr. Chairman and Ranking Member Graham. I am Tammy Duckworth, not Tammy Baldwin. Although I am honored to be mistaken for the Chairwoman of the Tammy Caucus, Senator Baldwin. Thank you for holding today's important hearing.

As a Senator who's dream of becoming a mother was made possible through the miracle of that is IVF, I am uniquely situated to remind this Committee of a basic principle; we can recognize the value of potential human life, acknowledge that fertilized eggs are incredibly precious and valuable, and we can also accept the fact that an embryo is not yet a human being.

No one, and I mean no one, better understands the hopes and dreams that viable embryos represent than an IVF patient struggling with infertility. No one better understands the pure unmitigated joy that flows when a successful transfer of embryos results in pregnancy.

And sadly, for us women who have lived through the soul crushing, bone-deep agony of having that hope destroyed after completing unsuccessful rounds of IVF or of suffering a miscarriage, we experience in the most painful manner possible, the fundamental reality that while every fertilized egg is unbelievably precious, unfortunately not all will become a living, breathing child whose laughter and joy will fill our hearts and enrich our lives.

Federal law wisely reflects this fact by defining the terms person, human being, child, and individual to only include, "every infant member of the species Homo Sapiens who is born alive at any stage of development." Section 8 of Title 1 of the United States Code is consistent with Ranking Member Graham's common-sense observation that, "Nobody's ever been born in a freezer."

Attempting to deny this reality, attempting to rewrite State constitutions and laws to define a fertilized egg as a human child, which is what the embryonic person would crusade achieved in Alabama is an affront to the millions of aspiring parents who struggle to conceive. It's a threat to the separation of church and

state. It's a betrayal of our great American spirit that reveres scientific discovery and progress.

Those seeking to ban IVF won't stop at one medical procedure. Their ultimate mission is to extinguish the legacy of American ingenuity that was born in the experiments of Benjamin Franklin, and continued through the groundbreaking IVF of conception and birth of Elizabeth Carr in December of 1981.

Look, every American has the right to personally believe that an embryo is a human child and to live their life in accordance with such beliefs by refusing to receive, provide, or offer IVF services just as every American should have the right to decide whether, when, and how to build their family. But Congress must draw a line against a person or movements with abuse of government power to force every American to live their life in accordance with that movement's moral beliefs.

Opponents of IVF are being dishonest and claiming that the Alabama Supreme Court never banned IVF. Defining the cluster of cells that comprise an embryo to be a human being, and even the single cell that is fertilized prior to becoming embryo, they're defining that as an extra-uterine child entitled to all the legal rights and protections of a person.

This may not be an explicit IVF ban, but makes no sense as we witnessed this in Alabama, it's an awfully effective way to ban IVF. After all, Alabama's criminal code defines murder as intentionally causing the death of a person. And just like that one plus one equals two.

When Alabama defined a fertilized to be a person, and their code defines intentionally causing the death of a person, the intentional disposal of an embryo, even a non-viable one that could cause a miscarriage if you were to implant it, which is a common practice in IVF, that disposal became a Class A felony.

The flawed solution to Alabama Republicans crafted to restore IVF validates this suspect by branding women and doctors that receive or provide IVF as de facto criminals in need of broad criminal and civil immunity simply because they require medical help to start a family.

So let me say again, the law that was passed by Alabama does not negate the fact that the destruction of an embryo is the destruction of a human being. All that law that was recently signed into law says is that we're just not going to prosecute you. The chaos, confusion, and outrage in Alabama was a chilling preview of the dystopian future that awaits us if Congress fail to pass IVF protections that are effective and enforceable.

That is why any Senator that claims to support nationwide IVF protections to join me and the 48 Senator co-sponsoring my bill in voting to pass the Access to Family Building Act. Our pro-family, pro-freedom bill would establish a nationwide right for patients to receive IVF. It would allow insurers to cover IVF, and it would also allow doctors to provide IVF in accordance with, and I make it clear that we state this in the bill, widely accepted and evidence-based medical standards of care.

Unfortunately, there's a bad faith effort to confuse the public about my bill using absurd hypotheticals that are an insult to struggling with infertility. So let's be clear, under S. 3612, no

healthcare provider would be forced to provide IVF, period. That's because my bill statutory definition of healthcare provider excludes providers that do not provide or do not or seek to provide IVF.

In addition, my bill only intends to protect IVF services provided in accordance with widely accepted and evidence-based medical standards of care. Wild-eyed hypotheticals like creating gene-edited designer babies, or—and I can't believe I have to say this, but it was brought up by my colleague who stood up to oppose my move for unanimous consent to pass the bill. She said that my bill would actually allow for the creation of human/animal chimera such as half human, half horse hybrids.

Neither are widely accepted or consistent with evidence-based medical standards of care for IVF, thus S. 3612 would not protect such procedures. Bottom line, Congress has the power to prevent what happened to those families in Alabama from ever happening again.

So, let's come together and achieve that goal. Let's pass the Access to Family Building Act, enshrine in Federal the law the right to receive, provide, and cover IVF so that more families like mine can hold their precious babies after all those long years of struggle of infertility, and finally have that child that they've dreamt of for decades. Thank you.

Chair DURBIN. Thank you, Senator Duckworth. Senator Graham, would you like to introduce your guest?

Senator GRAHAM. Yes, Mr. Chairman. And I also, I'd like to put into the record Senator Cindy Hyde-Smith's response to the bill in question if that's okay.

[The information appears as a submission for the record.]

Chair DURBIN. Without objection.

Senator GRAHAM. Okay. So, Congresswoman Michelle Fischbach—did I get that right?

Representative FISCHBACH. Yes.

Senator GRAHAM. Good. Welcome. The Representative of Minnesota's 7th District, which covers the western half of Minnesota. She joined the U.S. House in 2021 and serves on the House Ways and Means Committee, Rules Committee, Budget Committee, and Ethics Committee. In addition to her four committees, she serves as a Co-Chair of the Pro-Life Caucus. She introduced legislation that was passed in the House, Supporting Pregnant and Parent Pregnant Women Parenting Families Act in January.

During her 22 years in Minnesota State Senate, including four as the first woman Senate President, Representative Fischback led multiple legislative initiatives to protect mothers and their unborn children. She wrote the state's Women's Right to Know Law and carried a number of other pro-life bills, including abortion clinic licensing legislation to let to passage.

She continues to fight for the pro-life cause in Minnesota's 49th District. She received a BA in political Science from St. Cloud State University and a JD from William Mitchell College of Law. Welcome.

**STATEMENT OF HON. MICHELLE FISCHBACH, A U.S. REPRESENTATIVE FROM THE 7TH CONGRESSIONAL DISTRICT OF MINNESOTA**

Representative Fischbach. Thank you very, very much, Senator, and thank you for the opportunity to be here today.

You know, I have been representing Western Minnesota in Congress since 2021, and I represented on the State level, but I'm also pro-life, and have been part of the pro-life community helping women choose life for my entire life.

Senators, most Americans agree that there should be limitations on abortion. According to the 2023 Harvard/Harris National Poll, 73 percent of American voters oppose abortion after the 15th week. Meaning, most Americans agreed there should be limitations on abortions. The Republican position is not extreme. The position of many elected Democrats, however, is extreme.

Every Democrat on this committee voted for the Women's Health Protection Act, which would allow abortion on demand through all 9 months of pregnancy. Only 10 percent of voters support this position. The fact is that Democrats are catering to the voices of the extreme fringe, and are not listening to the American people.

Republicans care deeply about the unborn child and the mother. We are looking at every opportunity to empower women to choose life and introducing legislation to support that aim. For example, this Congress, I introduced the HOPE Act. This bill arms women with knowledge, and helps them access the resources they need to confidently carry their pregnancy to term, and provide resources for any expectant mother to support them throughout and after their pregnancy, and their children.

I also introduced legislation to ensure that TANF dollars could continue to go to pregnancy care centers. This bill passed the House, but Democrats fought against it, and it became clear they fought so hard because the only option they want women to have is abortion. The display was repugnant and frankly belittling to women everywhere.

Democrats can spin their stories and can confuse the issues all they want. They can trust to mislead Americans into thinking that *Dobbs* has anything to do with IVF or the Alabama Supreme Court decision. They can try to pretend like Republicans are launching an assault on reproductive rights, but they hide behind false narratives like this to drive their political agenda and to conceal deeply troubling features of their pro-abortion agenda.

We do not have to look any further than some of the bills being discussed here today, such as S. 701 and S. 3612. These bills would allow abortion on demand until birth. They permit things like human cloning and very problematic forms of genetic engineering. These bills also preempt all State laws, and completely destroy anyone's religious right not to participate in abortions or other practices they find to be morally objectionable. These measures are extreme. They put us in the same camp as countries like North Korea and China.

Senators, I understand the majority here today is looking to paint Republicans as monsters who want to take freedoms away from women in this country. I assure you nothing is further from the truth. My Republican colleagues and those in the pro-life com-

munity agree with most Americans, and we deeply understand the challenges expectant mothers face. We stand with them, and are doing everything we can to empower these women to confidently choose life for their children.

And I thank you for the time.

Chair DURBIN. Thank you very much, Congresswoman.

Representative FISCHBACH. Thank you.

Chair DURBIN. Our first panel will please approach the witness table.

We welcome Jamie Heard, who is from Alabama. She was told she had to put her IVF treatment on pause after the recent Alabama Supreme Court ruling.

We are joined by Lourdes Rivera, president of Pregnancy Justice, an advocacy organization focusing on the rights of pregnant people. Our final majority witness is Dr. Austin Dennard, who has joined us from Texas. She's here to speak about her personal experience of being denied healthcare she needed. She's an OB–GYN in Dallas.

Ranking Member Graham, would you like to introduce your two minority witnesses?

Senator GRAHAM. Thank you, Mr. Chairman. We have Dr. Monique—I'm going to call her Monique Wubbenhorst. Sorry, I'll get your name right in a minute. She's a board-certified OB–GYN with over 20 years of experience in patient care, teaching research, health policy, public health, global health, and bioethics.

She graduated from Mount Holyoke College, and received her medical degree from Brown University. She earned her master's degree in public health from Harvard. She completed her residency in OB–GYN at Yale New Haven Hospital, and her postdoctoral fellowship in health services research at Sheps Center for Health Services Research at the University North Carolina Chapel Hill.

She was a faculty member at Duke University School of Medicine from 2003 to 2018. She served as deputy assistant administrator in the Bureau for Global Health at the United States Agency for International Development.

Her clinical career is focused on caring for women, and underserved and disadvantaged populations, especially, African American, and Native American communities, with a focus on women with medical, social, and psychiatric problems. Currently, she is a senior fellow at the Center for Ethics and Culture, University of Notre Dame.

Next, Professor O. Carter Snead is a Charles E. Rice Professor of Law at the University of Notre Dame Law School, the director of Center for Ethics and Culture at the University of Notre Dame, and a concurrent professor of political science at the University of Notre Dame.

He's one of the world's leading experts on public bioethics, and his research explores issues relating to neuroethics enhancement, human embryo research, assisted reproduction, abortion, and end of life decisionmaking. He is author of "What It Means to Be Human: The Case for The Body in Public Bioethics," and has written more than 70 journal articles, books, chapters, and essays.

Prior to Notre Dame, he served as general counsel to President George W. Bush as counsel on bioethics under Dr. Leon Kass,

where he was the primary drafter of the 2004 report, "Reproduction and Responsibility: The Regulation of New Bio Technologies."

In 2008, Professor Snead was appointed by the director general of UNESCO to a 4-year term on the International Bioethics Committee, received the JD from George Washington University, and a bachelor of arts from St. John's College in Annapolis, Maryland.

Chair DURBIN. Thank you, Senator Graham.

I'd ask the witnesses to please stand to be sworn in.

[Witnesses are sworn in.]

Chair DURBIN. Let the record reflect that the witnesses answered in the affirmative, and our first witness is Ms. Heard. Could you proceed with your opening statement, please?

**STATEMENT OF JAMIE HEARD, BIRMINGHAM, ALABAMA**

Ms. HEARD. Thank you, Chairman Durbin, Ranking Member Graham, and Members of the Senate Judiciary Committee. Thank you for the opportunity to testify before you today.

My name is Jamie Heard and I am from Birmingham, Alabama. I am here to share how the Alabama Supreme Courts decision to declare personhood for frozen embroys has affected me and my family.

In 2012, I was diagnosed with Polycystic ovary syndrome, the most common cause of female infertility. I can remember my body feeling heavy as I listened to the doctor explain the challenges I would face in getting pregnant. Untimely news that not only changed the planned trajectory for my hopes of building a family of my own, but news that found me on the wrong side of time as we dealt with the loss of both my mother and my husband's father to cancer, and subsequently, the death of my only sibling. Our family's sorrow became the cornerstone of our inspiration to build and expand our family.

As my husband and I began the journey to grow our family, we were met with obstacles as the doctor had previously prepared me for. We discussed options for having kids, but at the time it seemed very far-fetched because we couldn't afford the out-of-pocket costs of the medical treatment the doctor said we needed.

But then, to our great surprise and luck, my employer expanded its health insurance to include fertility treatments, including In Vitro Fertilization. My heart was filled with so much joy and hope to finally have a chance to grow our family. This coverage was the answer to our prayers and the only way we would have access to the necessary medical care to treat my infertility.

We continued to encounter many obstacles and heartaches as we went through fertility treatments, from failed attempts at conception to the devastating loss of an ectopic pregnancy. After taking a pause on further treatments for a while due to the emotional and physical distress, we ultimately made the decision to begin the journey again.

We met with our doctor who explained that after trying other medical treatments that did not work, our best chance would be with IVF. We began with months of intensive tests and procedures. And while the journey through infertility treatments was not an easy one, we were finally blessed with our beautiful son through IVF. After taking our son on his first Disney trip, a truly magical

experience, we felt so inspired and ready to grow our family. We decided to start the IVF journey again to have our second child.

We began that process on February 14, 2024, when we met with our fertility doctor to put a plan together to begin that process, which again involves multiple tests and procedures. Just a few days later, we saw in the news the Alabama Supreme Court's ruling classifying frozen embryos as children. We later saw a statement from our clinic that they made the decision to pause new IVF treatments due to the legal risk to their clinic and their embryologists.

Our hopes broke hearing the news of our clinic pausing treatments. My heart breaks as I hear and read comments such as our health conditions are nature's way of telling us we shouldn't have kids. I've never been actively involved in politics or advocacy before. I'm truly an ordinary individual living an ordinary life. Even to appear before you today, with the support of my husband and very dear friend, has brought its own separate challenges.

Although I'm typically not on the front lines advocating for any particular cause or issue, I knew I needed to fight not only for my rights as a woman, but also fight for my future family and all those individuals who are too deep in emotional and physical trauma of infertility.

Now my husband and I are filled with so much uncertainty about how we move forward with expanding our family without the risk of being prosecuted. All these questions, all these decisions, regarding my body and my family, being decided by those that aren't here with me to fight the anguish of infertility.

IVF is hope for those of us struggling to conceive. IVF is medically necessary care due to my and many other people's circumstances. Access to medical treatments, without restrictions, is a basic human right. It is enough of a traumatic experience dealing with infertility and going through fertility treatments, to now have a basic human right being politicized, to further expand that trauma.

I'm asking you to truly put families first, which begins with having the fundamental right to build a family and the access to the needed resources to do so. You play a vital role in fostering compassion, understanding, and support, for those in your communities, your neighbors, who are confronting the hardships of infertility.

Daily, I look and just stare at my son, still in awe that I've been afforded the opportunity to be a mom to such a beautiful miracle. A dream that for a while I didn't think would come true. But it did, through IVF.

I ask the Committee to think about the hope that IVF means for patients like me. Protect that hope, do not restrict it, but instead nurture that hope.

Thank you again for letting me share my story.

[The prepared statement of Ms. Heard appears as a submission for the record.]

Chair DURBIN. Well, you shouldn't have been nervous or stressed. You did just fine. Thank you so much for being here. Professor Snead.

**STATEMENT OF O. CARTER SNEAD, CHARLES E. RICE PROFESSOR OF LAW, CONCURRENT PROFESSOR OF POLITICAL SCIENCE, DIRECTOR, DE NICOLA CENTER FOR ETHICS AND CULTURE UNIVERSITY OF NOTRE DAME, SOUTH BEND, INDIANA**

Professor SNEAD. Chairman Durbin, Senator Graham, thank you for inviting me to testify before you-all today.

When the Supreme Court decided in *Dobbs* that the Constitution does not preclude the people from governing themselves on the fraught question of abortion, it brought us into alignment with most nations around the world who have always addressed the issue through the political process, most of whom restrict purely elective abortion between 10 and 14 weeks of pregnancy.

After nearly 50 years of being deprived of the authority to meaningfully govern ourselves in this domain, the current political and legal landscape is widely varied, complicated, and a work in progress. But our system of federalism allows for divergent approaches to vexed questions.

Some States have enacted strict limits on abortion whereas others have dramatically increased access. Voters have supported abortion rights in every State referendum since *Dobbs*, going so far in Montana as to reject a proposed law protecting newborns who survive abortions. A similar proposal was rejected by this body.

I would like to, respectfully, make three suggestions for good governance in this difficult area. First, it is important to be clear about the complexity of the issue. It is not simply a variation of the health care debate, or even reducible to the important values of equality or bodily autonomy of women facing serious burdens on their health and future.

Rather, the issue challenges us to consider how these goods stand in relation to the life of the unborn child, a whole, living, distinct member of the human species who, if all goes well, will move herself along the trajectory of development from embryo, to fetus, to newborn, provided she has the necessary support and sustenance in her mother's womb, the first place of belonging for every human being. She is not a trespassing stranger; she is the biological child of this particular mother.

Our public debate is impoverished when those who support abortion rights fail to acknowledge, much less respond to this reality. On the other hand, our discourse suffers when pro-life elected officials fail to acknowledge and seek to alleviate the sometimes-crushing burdens of unwanted pregnancy and parenthood. To govern ourselves wisely, justly, and humanely, we must begin by articulating the problem before us in its full complexity, without question begging.

Second, we must fairly and accurately characterize the legal landscape. Here too, we have fallen short. A recent Alabama case has been widely misdescribed as a theocratic power grab heralding the demise of IVF. In fact, the victorious plaintiffs there were IVF patients suing a clinic for the negligent destruction of their frozen embryos, using a civil statute that already allowed such claims for the death of embryos in the womb.

The decision did not depend on and had nothing to do with *Dobbs*. In response, the conservative legislature and Governor

moved immediately to grant blanket civil and criminal immunity to IVF clinics for such misconduct. Popular accounts of women in Texas being denied life-saving medical care are similarly lacking. Texas abortion law allows exceptions to protect a mother's life or prevent her substantial bodily impairment. But many of these cases involved women seeking abortions because their unborn child was the one to receive a heartbreaking diagnosis of disability or terminal illness.

But, Texas does not authorize abortions soley because of an unborn baby's disability or poor prognosis. Regarding risks to mothers, Texas just passed a bipartisan law stating that previable, premature rupture of membranes and reaffirming ectopic pregnancies fall under the health exception. The same goes for miscarriage management.

The Texas Supreme Court just declared that serious health risks need not be imminent to justify abortion. And the "reasonable medical judgment" standard for clinicians invoking such exceptions has been in place without issue since the passage of Texas' 20-week abortion ban in 2013. Since then, there have been 238 abortions performed at or after 20 weeks or later with zero prosecutions. This week, the Texas Medical Board will meet to develop clinical guidelines in this area.

Finally, I would invite the members to reimagine the framing of the human context in which the question of abortion arises. Instead of a zero-sum conflict among strangers over the permissible use of lethal force, think of it instead as a crisis facing a mother and her child. Then, ask how we can work together across our differences to come to their aid not just during pregnancy, but throughout life's journey. Thank you.

[The prepared statement of Professor Snead appears as a submission for the record.]

Chair DURBIN. Thank you very much. Next is Dr. Lourdes—or Ms. Lourdes Rivera.

**STATEMENT OF LOURDES A. RIVERA, PRESIDENT, PREGNANCY JUSTICE, NEW YORK, NEW YORK**

Ms. RIVERA. Thank you, Chairman Durbin, Ranking Member Graham, and Senate Judiciary Committee Members, for the opportunity to testify today.

I'm Lourdes Rivera, President of Pregnancy Justice, a nonpartisan legal advocacy organization that for over 20 years has defended and advocated for the rights of pregnant people facing criminalization and other rights violations.

I want to first explain what is pregnancy criminalization and fetal personhood, and then discuss the path to Alabama's IVF decision. Pregnancy criminalization is charging pregnant women for conduct that would not be illegal except for the fact that they're pregnant and regardless of pregnancy outcomes. This includes being charged with murder for experiencing a still birth or for having a miscarriage, and not knowing what to do with the fetal remains as if there were an instruction manual for that.

We've documented over 1,800 cases of pregnancy criminalization in the years 1973 to 2022 from *Roe* to *Dobbs*. The majority, 1,400 of them, occurred in the last 15 years as fetal personhood had

gained traction in State law. Unsurprisingly, those targeted are overwhelmingly poor, and disproportionately, people of color. The stowing legal personhood status on fertilized eggs, embryos, and fuses is what underlies these prosecutions as well as abortion bans, and threatens IVF and birth control.

Attempts to define fetuses as legal persons have been rejected by voters in nearly every State in which it has been put on the ballot, including in Mississippi. Yet State legislatures in at least 11 States have passed broad fetal personhood laws before Dobbs. These laws could potentially be read to extend full rights to fertilized eggs. Constitutional protections provided by *Roe v. Wade*, however, meant that fetal personhood laws could not be fully enforced.

But there are significant exceptions. Ten years ago, the Alabama Supreme Court held that embryos and fetuses are the same as children under the state's criminal child abuse laws, and that pregnant women can be charged as child abusers from the moment of fertilization.

With over 600 women being charged, Alabama leads every State in the Nation on pregnancy criminalization. And while shocking, it is hardly surprising that the Alabama Supreme Court decided to extend its reasoning to frozen embryos. Alabama, along with Oklahoma, and South Carolina, whose Supreme Courts have also designated fetuses as children under their State criminal laws, accounts for two-thirds of arrests of pregnant people nationally, including those who experience miscarriage and stillbirth.

When conduct during pregnancy or pregnancy outcomes are punished, pregnant people in their families suffer irreparable harm. This includes dire consequences, health consequences, incarceration, and families torn apart. Our nation is facing a maternal and infant health crisis in pregnant and postpartum people, but especially, Black women face increased risks of death and severe complications, including due to mental health conditions.

The three States with the highest prevalence of pregnancy criminalization also have some of the highest rates of maternal mortality in the Nation. Alabama ranks fourth and has some of the worst infant health outcomes. Research shows that criminalizing pregnancy does absolutely nothing to improve maternal and infant health, and in fact, it does the opposite.

Every major medical and public health association in the Nation opposes criminalizing pregnancy because it interferes with the patient-provider relationship and deters access to needed healthcare.

Let me be clear. When anti-abortion lawmakers endow fertilize eggs with personhood rights, they seek to ban abortion, and IVF, and threaten contraception. As legal personhood advances, more pregnant people can face criminal charges for any conceivable risk to their pregnancies or to a fertilized egg before implantation. This is not hyperbole. Our clients are living this reality now.

When an anti-abortion movement talks about fetal and embryonic personhood, it is not about protecting babies, it's about controlling and punishing women, pregnant people, and communities that are already marginalized. And the Life at Conception Act, if ever adopted, would ban abortion nationally, eliminate the right to IVF, endanger access to birth control, and expand the government's abil-

ity to police pregnant people, and criminalize pregnancy, and pregnancy outcomes.

With these attacks and the crisis we are facing, we must remember that women and pregnant people must be treated as fully autonomous, rights-bearing persons who are entitled to healthcare and bodily integrity, and they must be allowed to make their own healthcare decisions.

[The prepared statement of Ms. Rivera appears as a submission for the record.]

Chair DURBIN. Thank you very much, Ms. Rivera. Dr. Monique Wubbenhorst. I hope I was close in pronunciation.

Dr. WUBBENHORST. It's phonetic. Thank you. That was good.

**STATEMENT OF MONIQUE C. WUBBENHORST, SENIOR FELLOW, DE NICOLA CENTER FOR ETHICS AND CULTURE UNIVERSITY OF NOTRE DAME, SOUTH BEND, INDIANA**

Dr. WUBBENHORST. Good afternoon, Chair Durbin, Ranking Member Graham, Members of the Committee. Thank you for the opportunity to testify at this hearing. It is an honor to be here.

Following the *Dobbs* decision, which returned decisionmaking regarding abortion to the people of the United States and elected representatives, there have been many opportunities to mitigate abortions harm to women, their children, their communities. And these laws protect women and children. Abortion is not healthcare. It not only poses risks to the mother, it is always lethal to an unborn child.

These opportunities have resulted in vigorous debate on abortion and the humanity of the embryo of the unborn child. At the heart of this debate is whether or not the unborn child is a human being, which science clearly demonstrates. An unborn child is therefore not a part of the mother's body in the way that her heart or her pancreas are.

Since embryos are human, they have fundamental human rights. One of these rights is the right to life. Yet, unborn children are subject to abortion even though they're the smallest, weakest, and most vulnerable members of the human family. Abortion is associated with harms to women. It is also not safe, and in childbirth, this false claim can be traced to papers published in leading OB–GYN journals, which contain methodological errors and did not consider the biology of fetal and uterine development.

When induced abortion is compared in context to childbirth, it is clear that it is not safer than childbirth. In addition, in the United States, African American women have the highest rates of abortion and the highest maternal mortality. Both cannot be true if abortion decreases maternal mortality.

Reproductive rights, so-called, are not human rights because they disappear as they dispose of the fetus. So-called reproductive justice is, in fact, reproductive injustice because it selectively destroys Black and brown babies who are 100 percent of the future of our ethnic groups. The same eugenic mindset that led to the sterilization of African American, Native American, and Hispanic women continues in disproportionate rates of abortion in Black and Hispanic women.

The issue of the humanity of the unborn child is also a topic of debate related to In Vitro Fertilization. And as noted, in 2022, three couples filed a wrongful death suit in Alabama regarding their frozen embryos, and the Alabama Supreme Court issued an opinion which has set up a national debate about In Vitro Fertilization. This ruling correctly assigns value to the embryo, but it does not prohibit IVF. It speaks only to whether embryos should be destroyed.

A 2019 study found that the majority of IVF practitioners dispose of embryos by placing them directly in a trash can. They often administer alcohol or other things to try to kill the embryos before disposing of them. Louisiana and Germany have established ethics and safety standards for IVF that prevent embryo destruction.

Since 1986, in Louisiana, for example, IVF protection of embryos has occurred side by side as embryos are recognized as human beings, not chattel property. In Germany, since 1990, the Embryo Protection Act has regulated how embryos may be handled. In procedures, the number of embryos fertilized or that develop into embryos may not exceed the number of those that are transferred to the woman during a treatment, no more than three embryos may be stored, sex selection is prohibited, and embryonic research is prohibited.

Embryo destruction can be addressed in part by reducing the creation of excess embryos. It's not IVF that is at issue, but rather whether embryos should be destroyed. People can be in favor of IVF without agreeing to the destruction of embryos.

The IVF industry has been described as the Wild, Wild West. These questions show the dilemmas associated with it and the need for its regulation. Anyone who knows, or has family member who has cared for or has undergone IVF can testify to its mental, emotional, and financial costs and burdens. Prospective parents embrace these to build their families. But are all aspects of the IVF process compassionate and just? There's a need to regulate the industry, protect children, protect mothers, and maintain parents' legals rights.

In addition, when we look at fetuses with anomalies, how do we treat them with dignity? A developmental accident that resulted in disability does not make these children subhuman. The value of a child's life has nothing to do with how long it is or how he or she was conceived.

How we treat mothers matters too. Multiple studies indicate that there is a psychological benefit to continuing a pregnancy following prenatal diagnosis of a lethal fetal defect, especially where there's compassion, palliative care for newborns with anomalies.

The rights of a mother and those of an unborn child with an abnormality, or was unexpected, or "unwanted" are not in opposition. They're intertwined. Both have inherent human dignity, both deserve not only compassion and justice, but love because love seeks the highest and best for another. Both deserve the best of care, which excludes abortion, because abortion is not healthcare. It violates the bodily integrity, autonomy, and rights of the mother, and kills her unborn child.

To conclude, the *Dobbs* decision has resulted in vigorous even fractious debate about abortion, but debate is positive. A similar

debate should ensue, ensue for IVF with the view to better regulation. The IVF industry is concerned with the deepest desires of parents, and with the most vulnerable human beings; unborn children. Our views of human dignity along with compassion, justice, and scientific and clinical data, should inform this process. Thank you.

[The prepared statement of Dr. Wubbenhorst appears as a submission for the record.]

Chair DURBIN. Thank you, Doctor. Dr. Austin Dennard.

**TESTIMONY ON AUSTIN DENNARD, DOCTOR OF OSTEOPATHIC MEDICINE, FELLOW OF THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS, DALLAS, TEXAS**

Dr. DENNARD. Chairman Durbin, Ranking Member Graham, and Members of the Senate Judiciary Committee. Thank you for having me here today.

My name's Austin Dennard. I'm a mother, a Texan, and a practicing OB–GYN. I'm here today to describe what life has been like in Texas since the Federal right to abortion was taken away by the Supreme Court, and the State began criminalizing and banning abortion care.

Nothing brings me more joy than being a mother to my three children, but a close second is being an OB–GYN. I get to be present for the most incredible moments. There's nothing quite like the moment when a baby is born and a family is created. I've delivered thousands of babies and it still takes my breath away.

But intertwined in these celebrations are also moments of complete heartbreak; pregnancy loss, a devastating diagnosis, infertility. Since SB8 was enacted and the *Dobbs* decision came down in 2022, those tough moments have become even more tragic. In Texas, where my husband and I both practice medicine, we live in fear, as physicians and as patients. I can speak to both of those perspectives because I am a Texan and OB–GYN who needed an abortion in Texas and could not get one.

After careful consideration and many prayers, my husband and I were delighted to find out that we were pregnant again in the summer of 2022. Between our two toddlers and growing surgical practices, we were feeling really busy, but also very blessed. But at 11 weeks of pregnancy, I had a routine ultrasound that changed the course of my family's life forever. The brain and skull had not formed. It was anencephaly. The most severe neural tube defect, 100 percent fatal.

I will never forget looking up at the ultrasound screen in complete disbelief and devastation. I needed an abortion, but would need to flee my State to get one, Texas, where I've lived for six generations, where I practice medicine and where I am raising my family.

My mind began to spin. Where would I go? Who would take care of me? Who will take care of my children? What about my patients? And what if this is the last time I ever get to be pregnant? Because of Texas's new laws, we were afraid to use credit cards or even tell people why we were traveling to the East Coast so suddenly. I was terrified my husband would be arrested for aiding and abetting my abortion just for traveling with me.

And under Texas's new laws, the penalties were so severe, a hundred years in prison, huge fines, a loss of our medical license. It was humiliating through it all. I felt so broken and abandoned by my home State. But at the same time, I had never seen my luck and privilege with more clarity. What would other people do in my place who could not afford the extensive costs and lost wages? No one should have to be lucky to access essential medical care.

As heartbreaking and traumatizing as that was for me, it is even more disturbing to be a working OB–GYN in Texas, trying to abide by these paralyzing punitive laws while still providing timely compassion, compassionate, and ethical care for my patients. Conversations in my office are different now. Couples arrive for their pregnancy confirmation visits filled with worry. They know how much is at stake. What if it's an ectopic? What if I start bleeding? What if I become really, really sick?

I have the same answer for all of them, that I will do everything in my power to keep them safe. But still, we collectively hold our breath as we pass the pregnancy milestones because my patients know that lawmakers have stripped away their rights to make decisions about their own health, their own body, and their own family.

So long as they remain on Texas soil, their pregnancies belong to the State. Exceptions are said to exist in the laws, but in reality, it's fiction. These bans have stolen so much from us. I have spent a greater part of my life dedicated to becoming the best doctor I know how to be. Yet, lawmakers are making decisions about my body and my practice as if they know better.

I've never wanted to be a public person, but I can't be silent anymore. The silence is too painful. These cruel laws have to change. Texas women deserve better, Americans deserve better, and my 4-year-old daughter deserves so much better. Thank you.

[The prepared statement of Dr. Dennard appears as a submission for the record.]

Chair DURBIN. Thank you, Doctor. We'll have 5-minute rounds of questions. I'm trying to resolve in my mind these two issues of abortion and IVF. I understand the premise. If you start with the premise that life begins at conception, that it certainly is reasonable, I suppose, to follow that through to the conclusion that no abortion is warranted, and to want to overturn *Roe v. Wade*, which is what one group of thinkers in this country arrived at.

But then for the same people to say, but, I'm all right with IVF. It seems to me to be inconsistent because we know during the IVF procedure, we run the risk, if not the reality, that there will be embryos created that will not be implanted. So, is this the end of a life? How can you reconcile those two positions? I find it difficult, very difficult.

Professor Snead said we're going through a work in progress since *Dobbs*. It sure is a work in progress when you hear Dr. Dennard and others, Ms. Heard, describe what they've been through. But it's a work in progress that I think is fundamentally ignoring the obvious. Ms. Rivera, this notion of personhood, how would you describe it?

Ms. RIVERA. Thank you for your question, Senator. I think you are absolutely right. These reproductive health issues do not exist

in silos. And the problem is that if you define fertilized eggs, embryos, and fetuses as legal persons with independent rights, it's going to affect everyone. It's going to affect abortion, it's going to affect access to IVF, it's going to affect contraception, and it's going to affect the quality of healthcare that pregnant women and pregnant people are entitled to. So, you are absolutely right.

Chair DURBIN. So, they wanted to overturn *Roe v. Wade* to take away the right of a woman to decide to end her pregnancy. Now, there are some who want to outlaw IVF and deny a woman the right to start a pregnancy. A common notion here is the woman is just a vessel, is not a participant in this decisionmaking process, either for her own health or the future of her own family. Dr. Dennard, is that what you discovered?

Dr. DENNARD. Thank you so much for bringing this up. When I was pregnant in my State, I felt exactly how you describe. I felt like a vessel. And when I looked up at that ultrasound screen and saw that I was growing a pregnancy that had no skull or brain, but had no way of making any decision on my health, it's exactly how I felt. And that's exactly how my patients feel when they're in similar situations. We've lost our ability to make any decisions about our bodies, and it is harming women, and it is harming families.

Chair DURBIN. There was a report on national public radio just yesterday that said, "The dangerous disruption of standard of care for pregnancy in the State of Louisiana in wake of the Louisiana abortion ban." The story noted that women in that State had been forced to undergo a cesarean section when their water breaks early in pregnancy before the fetus is viable instead of receiving an abortion procedure or a medication, which is standard medical practice.

One doctor explained the C-section was done to, "Preserve the appearance of not doing an abortion." And even more galling, the patients aren't even given a choice. As I understand it, a C-section is much more serious and not as safe procedure as ordinary vaginal abortion. Equally troubling, the NPR story reports that OB–GYNs in Louisiana are now delaying routine prenatal care until patients reach 12 weeks, a serious deviation from standard medical practice. Can you speak to how these restrictive abortion bans affect the ability of OB–GYNs to practice the standard of care that you learned in medical school?

Dr. DENNARD. Thank you for this question. At this point in my State, I feel like Ken Paxton himself is standing in each and every one of my office rooms when I see patients. Because now, individuals are having to change the way that they practice medicine. Individuals are having to change the way that they counsel patients due to all of the fear that has paralyzed our care. So much so that women who are living in Texas and other States where abortion bans exist, their lives are at stake and they are not receiving the same medical care that individuals are in States where the restrictions are not so severe.

There are so many rippling effects of this. There have been migrations of physicians to different States. Patients have been abandoned in certain States because of this, and we're losing physicians that have the ability to do procedures including abortion care because of these restrictions.

Chair DURBIN. Senator Graham.

Senator GRAHAM. Thank you, Mr. Chairman. Professor Snead, you mentioned something in your testimony that most western nations limited abortion from 10 to 14 weeks. Is that correct?

Mr. SNEAD. That's correct.

Senator GRAHAM. I think 47 or 52 European Union nations have a limitation below 15 weeks. Is that correct?

Mr. SNEAD. That is my understanding, Senator.

Senator GRAHAM. Why is that?

Mr. SNEAD. Well, one major difference between European nations is that they have resolved these questions through a political process in which they have come up with laws that balance the judgment of the people in an appropriate way, the important goods of autonomy, and health, and equality for women on the one side, but also respecting the intrinsic equal value of every human being for conception.

Senator GRAHAM. My point is, elected officials do this.

Mr. SNEAD. Absolutely. We are unique in that we are the only country that I'm aware of in which for 50 years, the Supreme Court set our national abortion policy as opposed to the people themselves.

Senator GRAHAM. Now, after the *Dobbs* decision, elected officials at every State level decide matters of when you can have abortion limits, if any. Is that correct?

Mr. SNEAD. That is correct.

Senator GRAHAM. And that's in line with most of the civilized world in terms of having elected officials do this.

Mr. SNEAD. In most cases, it's decided by the people through their elected officials. Yes, Senator.

Senator GRAHAM. So, let's talk a little bit about IVF treatment. Doctor, can I call you Monique? Great. And say Monique, you mentioned Germany. They have laws regulating IVF treatments. Is that correct?

Dr. WUBBENHORST. Yes, Senator.

Senator GRAHAM. Is that true of most Western Nations?

Dr. WUBBENHORST. I'm not as familiar with the overall landscape——

Senator GRAHAM. What about Professor Snead?

Professor SNEAD. Yes. It is the case, and the country that pioneered IVF, the United Kingdom, has an elaborate scheme of regulation of IVF and embryo research.

Senator GRAHAM. And we don't?

Professor SNEAD. We are unique in that way. We do not have an overarching scheme.

Senator GRAHAM. Okay. So, let's talk a little bit about the embryo. In Germany, there are limits on how many embryos you can create. Is that correct, Monique?

Dr. WUBBENHORST. That's correct.

Senator GRAHAM. All right. I guess the reason for that is this ethical debate we have. What is an embryo? Is it a person? I don't know of anybody who's been born that wasn't at one time an embryo, we all have that in common, to kind of deal with what we're talking about. Is that right, Professor Snead?

Professor SNEAD. Yes, that's correct, Senator.

Senator GRAHAM. Okay. So, I'm very open-minded about this in this regard. I want every family to be able to have a child, and if science can help, that great. IVF treatments have been a blessing to many families. The idea of what legal protection to provide when I think should be done by elected officials. So, I'd like to get us kind of in line with the rest of the world on this area, if that's even possible.

We have tax credits for children. Well, I think everybody up here is for tax credits for children. Should we have a tax credit for people trying to have a child through the IVF process because it's very expensive? Maybe we should. The point I'm trying to make is that all of us are for life. There's just a different opinion of when the law should intervene.

Some people say you have no rights until you are actually born. Other people believe that the day before you're born, you should have some rights. It's all a balancing act here. Right? And what I'm trying to do, Mr. Chairman, is if we don't have any national standards about IVF treatment, should we? Monique? What do you think?

Dr. WUBBENHORST. I think that it's very important to open the debate and to have national standards, as I've said even people related to the industry say it is like the Wild West.

Senator GRAHAM. Do you agree with that, Professor Snead?

Professor SNEAD. Yes, Senator. There's a statute that you-all passed in 1992, your colleague, Senator Wyden, called the Fertility Clinic Success Rate and Certification Act, which began as a sort of consumer protection law. But it's proven to be inadequate to even protect the interest of families that are seeking IVF.

And I think it would be a great opportunity as the President's Council on Bioethics recommended to take up the question to see how moms, and babies, and families can be best protected who are seeking fertility care.

Senator GRAHAM. So, I'd like to sit down with you and anybody else try to find out a way to see if we can get America united on this topic. Creating life is a good thing. IVF is a good thing. Like every other practice that needs to be regulated, what happens when the clinic negligently destroys an embryo that is yours, part of you. These are decisions that we need to talk about.

And Mr. Chairman, I'm hopeful that over the arc of time, maybe we can find a way to create an environment in this country where we support IVF, not only just through regulation. Make sure it's ethical, make sure it's done right, but maybe we should encourage people to use this process through tax credits. Somebody's got to pay my Social Security, the more children, the better.

Chair DURBIN. Senator Butler.

Senator BUTLER. Thank you, Mr. Chair. Thank you for having such a timely hearing. Thank you all for being witnesses here today to help us all learn and understand the very perspectives across a really rich issue environment.

Professor Snead, there's an exchange between you and Senator Graham about the state of IVF and other countries around the world where you talked about the regulatory framework that other countries around the world have relative to IVF and as well as like the gestational periods, and correct me if I'm getting any of your

testimony incorrect. Can you speak to the state of paid medical family leave or paid medical leave in those countries as well?

Professor SNEAD. That's an excellent question, Senator. And I think in many of those countries, there's more support for people who have families. And I've argued in print and elsewhere, that if a person wants to be comprehensively pro-life, that has to be part of the picture. You have to provide a safety net and support for moms, and babies, and families.

Senator BUTLER. Totally appreciate you raising that point because my next question is going to be about the State of childcare in those countries, and we can go down the list. All of those countries also have a higher minimum wage than $7.25. All of those countries also allow workers to unionize without intimidation from their employer. All of those countries also provide comprehensive healthcare and retirement security for the residents in those countries. Am I characterizing that accurately?

Professor SNEAD. It's obviously a complicated question because we're talking about a lot of countries, but I think that there are many instances in which they do better than we do in those respects. Yes, ma'am.

Senator BUTLER. I appreciate you helping me to bring this into perspective and really try to understand the juxtaposition of the tension that we find ourselves in this sort of uniqueness in spaces. I think that's the word we use, the sort of U.S. uniqueness, as there are many other ways in which the U.S. is unique in ways that it is not advancing the equivalent supports for families, for life, as those other countries that are being that are being compared to.

There's an interesting other sort of irony that I wanted to call forth in the sort of pro-life argument as it's being presented here. And that is the irony of that argument sort of juxtaposed with the criminalization of patients and physicians.

I find it ironic, and I direct this to you Dr. Dennard and Ms. Rivera, find it ironic that the folks who are doing their best by way of presenting as patients in need of a healthcare procedure, a full spectrum of healthcare procedures that women often need, that are different, that then the punishment is a criminal record, years in prison, and losing your livelihood to provide for the family that is a demonstration of this value of life.

You spoke a little bit, Dr. Dennard, about the trends that you're seeing in the OB–GYN space in Texas. I wonder if you could offer just quickly a little bit more of what you are seeing. What are OB–GYNs talking about? Are there more medical school students, for example, that are choosing to on match day practice in the OB–GYN space?

Dr. DENNARD. Thank you so much for bringing this up, and you speak so eloquently. You take the words out of my mouth, really, when it comes to the irony that we're all facing. We're seeing that States like Texas are less desirable for medical students that are coming out of their training because the training is different now in our State due to these ridiculous regulations, to be quite honest.

And when I went to medical school, I went because I wanted to take care of people. I didn't think I was going to have to worry

about being criminalized or being thrown in jail. I just want to take good care of my patients. They're like family.

I see patients who come to me in college wanting to talk about contraception, and then the next year they come back, they've met someone, they're getting married, they want to talk about starting a family. And then we go through pregnancy together, and it's a really, really important relationship that we have with our patients. But it's becoming really traumatizing.

Senator BUTLER. Thank you so much. And Mr. Chair, if I might just close. I do look forward to working with my colleagues to make sure that we repeal the Trump tax cuts for the wealthy so that we could actually do some of the things that other countries are doing to wrap around the kind of full service of life and protection of life that other countries around the world are doing.

Thank you all so much. Thank you, Mr. Chair.

Chair DURBIN. Thank you, Senator Butler. And Senator Kennedy.

Senator KENNEDY. Thank you, Mr. Chairman. Ms. Rivera, if you were queen for a day and you had unfettered discretion to establish a national rule on abortion for America, what restrictions, if any, would you implement with respect to abortion?

Ms. RIVERA. Thank you for your question, Senator. I would so the American College of Obstetricians and Gynecologists opposed restrictions that are not based on medicine, right? People need to be able to make their own reproductive healthcare decisions, and having arbitrary restrictions lead to the situations like we've been hearing about, like Kate Cox and others who are not able to get the healthcare they need during obstetric emergencies. We know the majority of people access——

Senator KENNEDY. Yes, ma'am. Maybe I wasn't clear because I've got to ask each of our witnesses here. Just tell me if you could implement any rule, what restrictions, if any, you would put on abortion?

Ms. RIVERA. Senator, arbitrary restrictions put women's health in danger.

Senator KENNEDY. So that means no restrictions?

Ms. RIVERA. Senator, healthcare needs to be driven by medical practice and medical standards of care.

Senator KENNEDY. I agree. You don't believe in any restrictions on abortion?

Ms. RIVERA. Healthcare needs to be driven by medical standards of care.

Senator KENNEDY. Well, your website says you support abortions at all gestations.

Ms. RIVERA. That is correct, because——

Senator KENNEDY. You support abortion——

Ms. RIVERA. Abortion needs to——

Senator KENNEDY [continuing]. Without any restrictions.

Ms. RIVERA [continuing]. Be based on medical standards of care.

Senator KENNEDY. How about could you give it if the mother's healthy and the baby's healthy? Would you support an abortion the day before birth?

Ms. RIVERA. Actually, that is not how abortion care works.

Senator KENNEDY. Would you support that. You say no restrictions.

Ms. RIVERA. That is called labor and delivery, Senator.

Senator KENNEDY. But you support no restrictions.

Ms. RIVERA. Senator that is not how abortion care works, Senator.

Senator KENNEDY. The question is really simple, would you have a rule saying that if a healthy mother or a healthy baby wanted to have an abortion the day before birth, would it be okay with you?

Ms. RIVERA. Senator that is not how abortion care works. And it's really dangerous. That rhetoric is really dangerous for the people who are coming——

Senator KENNEDY. It would be okay with you, wouldn't it?

Ms. RIVERA. That is called labor and delivery, sir.

Senator KENNEDY. It would be okay with you.

Ms. RIVERA. That is called labor and delivery, sir.

Senator KENNEDY. I find that astonishing.

Senator KENNEDY. On your website——

Ms. RIVERA. Senator, that is really offensive——

Senator KENNEDY [continuing]. You issued a press release. You don't refer to mothers. You say at your organization, you don't refer to mothers. You call them birthing people. Is that right?

Ms. RIVERA. That is among the language that we use, yes.

Senator KENNEDY. Now, what's the difference?

Ms. RIVERA. A birthing person is someone who's in labor and delivery.

Senator KENNEDY. Okay. That's a mother. Right?

Ms. RIVERA. So for sure, the majority of people who are pregnant are cisgender women. And at the same time, we have to acknowledge that trans people and non-binary people do and can become pregnant, and it's really important not to misgender them in law and health because it is really dangerous to them.

Senator KENNEDY. You were invited here by my Democratic colleagues today?

Ms. RIVERA. That is correct.

Senator KENNEDY. Okay. Dr. Dennard, if you were Queen for a day, what restrictions, if any, would you place on abortion?

Dr. DENNARD. Well, if I was Queen for a day, I would use shared decisionmaking between myself and my patients so I could take really, really good care of them.

Senator KENNEDY. So, you don't think there ought to be any restrictions?

Dr. DENNARD. You know, that's not really how abortion care works. We need to be able to take——

Senator KENNEDY. Yes, ma'am, but I'm trying to understand your position first. Do you support any restrictions in abortion?

Dr. DENNARD. I support my patients, I trust women, and I know that they're going to make the right decision for themselves.

Senator KENNEDY. Okay. And you were invited here today by the Democrats?

Dr. DENNARD. Correct.

Senator KENNEDY. Okay. Professor Snead—well, let me back up. I don't have much time left. How would you change Texas law? Are

you suggesting that Texas should adopt a law saying there should be no restrictions on abortion?

Dr. DENNARD. Are you asking me?

Senator KENNEDY. Yes, ma'am.

Dr. DENNARD. Yes. If I could change Texas' laws, I would be able to take care of my patients if they're in need without restrictions.

Senator KENNEDY. I just find it extraordinary that neither you nor Ms. Rivera are willing to say what you believe, which is clearly that you don't think there ought to be any restrictions on abortion. You think it's okay. You want society to adopt a rule that says if a healthy mother with a healthy child wants to have an abortion, maybe she wants a different gender the day before birth, that that's okay. It's clear that's what you believe. Why don't you say it?

Dr. DENNARD. With all due respect, I've been to medical school, I've done multiple years of training, delivered babies, and done thousands of surgeries for over a decade, and you are describing a clinical situation that just doesn't exist.

Senator KENNEDY. Ma'am, you're wrong. You are wrong, and you know you're wrong. Do you perform abortion, Dr. Dennard?

Dr. DENNARD. I'm not an abortion provider.

Senator KENNEDY. Okay. Have you ever done an abortion?

Dr. DENNARD. I have never done an abortion, but I take care of my patients who are actively having miscarriages.

Senator KENNEDY. Okay. I think I'm over. Thank you for your indulgence, Mr. Chairman.

Chair DURBIN. Senator Ossoff. Wait a minute, is it Ossoff? Senator Ossoff.

Senator OSSOFF. Thank you, Mr. Chairman. Senator Welch, if you are in a big hurry.

Senator WELCH. No, no.

Senator OSSOFF. Okay.

Chair DURBIN. Looks like my Chairmanship is in doubt. Proceed.

Senator OSSOFF. Dr. Dennard thank you for joining us and sharing your story with us. I want to talk about the availability of OB care, particularly in parts of the country with extraordinarily high rates of maternal mortality and shortages of qualified obstetric clinicians.

In the State of Georgia, just for context, half of our counties have no OB–GYN at all. We have one of the highest maternal mortality rates in the country, and I hear consistently in rural communities—and in fact just a few days ago on a defense installation in Georgia speaking with service members and military spouses—just how dire this lack of access to obstetric care is. And of course, it's not just OB–GYNs, it is obstetric nurses, it is midwives, with sometimes deadly consequences for women who are unable to access perinatal healthcare.

Georgia has passed one of the most extreme abortion bans in the country at 6 weeks before many women even know they're pregnant. One of the things that I'm hearing is that the fear of criminal prosecution of doctors deters OB–GYN residents from pursuing training in States with those kinds of extreme abortion bans. And I think as the clinicians here probably know from their experience,

my understanding is that doctors are much more likely to stay in practice where they've trained.

The question for you is, based upon your experience as a doctor, what's the impact on local communities when there are no OB–GYNs or the nearest qualified provider is 90-minute drive away?

Dr. DENNARD. Thank you for highlighting this really important issue. Personally, I practice in a large metropolitan area in Texas, but what I can say is that many medical journals will show, it's no surprise that when there's lack of access to care, there are very poor outcomes.

And patients have to travel. They have to travel around to get the care that they need, and that distance is becoming further and further for them. So, what happens is the areas that have lack of access to care, patients travel and overwhelm other areas where there is more access to care and there are bad outcomes. So, it's quite devastating to the women in our country, and it's negatively affecting my specialty significantly.

Senator OSSOFF. Thank you, Dr. Dennard. And Ms. Heard, I've heard, my office has heard in the last few weeks from a huge number of Georgians who are scared that the direction my State is on, the direction the country is on could deny Georgia families access to IVF. We saw what happened in Alabama. We see more and more extreme policies, a 6-week ban, for example, far out of the mainstream opposed by most Georgians deterring OB–GYNs from practicing in the State. We see more and more of this being pushed across the country since the *Dobbs* decision.

And so, families are afraid that they may not have access to IVF. They may not therefore have the opportunity to achieve the blessing and responsibilities of parenthood. What is your message for families in Georgia and across the country who feel fear right now that their path to conception and parenthood may be closed to them by political extremists?

Ms. HEARD. Thank you, Senator, for asking that question. I think I mentioned in my testimony that I've never advocated for anything before, and me being here today is completely new territory for me.

But when everything kind of took place in Alabama, I felt attacked. I felt like my family was being attacked, my future family was being attacked. And I know so many other women personally that are going through the process that, you know, unfortunately haven't had success as of yet.

But I knew that I needed to step up and let my voice be heard. Not just for me and my experience, but also for all those others that don't have the ability to let their voice be heard to fight for our rights and to continue to have access to those treatments that we need.

So, my message to them is, you know, I understand that infertility is such a personal trauma and it's hard to talk about. It's hard to speak about, but I empower them to get active. Let your voice be heard, let your story be shared because the more that we speak up, the more that we share our story, the more that we can bring awareness and understanding to what the IVF process is, the better, you know, hopefully that we can see change through that.

Senator OSSOFF. Thank you for your courage. Thank you all.

Senator COONS [presiding]. Senator Tillis.

Senator TILLIS. Thanks, Mr. Chair. Thanks, everybody, for being here. Ms. Heard, I know this is a unique experience for you, but thank you for being here. I'm sorry about the challenges you went through. And Dr. Dennard, did you not speak before a judiciary hearing in the past?

Dr. DENNARD. I did.

Senator TILLIS. I thought so. I remember your testimony. I think you were sitting at the far left in that hearing, if I recall. I'm Thom Tillis from North Carolina. I was Speaker of the House before I came up here to the Senate. And I remember when I decided to run for the Senate, I had been Speaker, and we'd passed some pro-life bills. They returned at the time, radical pro-life bills.

In North Carolina, they said now that you're running for Senator against the Democrat pro-choice incumbent how are you going to deal with your record? I said, you're asking a question as if I'm going to run from my record. I intend to run on my record.

And Ms. Heard, and Dr. Dennard, both, I'm very sorry for the experiences that you went through, but this hearing isn't about coming up with a common-sense solution or maybe striking balance that I heard in Professor Snead's comments. This is about it's about political points.

So I'm sorry that you have to be a part of this, but if you'll indulge me, I won't go over my time. But the reality is, the reason I wasn't concerned with my radical position on pro-life is because I was consistent with the majority of North Carolinians. It was even better numbers probably back at the time.

We're not talking about—we get into this argument and we shout over everyone because we talk about the extreme position as if I would have supported the extreme. What I argue was an extreme judgment in Alabama, but the fact of the matter is Professor Snead did a pretty good job of under of explaining how that whole process went into place. And then the Alabama legislature fixed that one.

Having said that, I for one, think that policies that the Alabama legislature proposed on abortion restrictions are a bit extreme. And ultimately, over time, I don't think that they will win the day in terms of public opinion. Maybe the same could be argued for some of Texas's policies, although they've addressed some of the concerns that may have made the experience that you went through go differently.

But when people go out of this Committee and they hear the narrative of a Republican's extreme policies, vast majority of the Republicans extreme policies are in alignment with the Western world. They would be out of alignment with countries like China and North Korea. They're not extreme. It's not extreme to say late trimester abortions have to have some reasonable limits, including exceptions that would not have been an impediment to Dr. Dennard's abortion.

I think that there's a happy middle ground that most Americans will accept, but they don't get a chance to have that discussion because what we have here are policy-driven hearings that really drowned out those in the middle who think that there probably is a common-sense middle ground. I think this is pretty close to it. Maybe we could have a debate about it.

Let me tell you what's not mainstream policy. A vote that we had on the floor that every Member who was in Congress, a Democrat Member, voted for. And every Member in this Congress has co-sponsored a Democrat Member. It's a pretty extreme policy. And I told my staff, you better fact check this three ways to Wednesday, because it is factually what was voted on the floor.

And I had somebody call into my office saying, Senator, tell us you have to support that vote on the floor because it's just codifying *Roe v. Wade*. He did not know who I was. I told my staff, if you get calls like this, tell them that the Democrats are voting on a policy that would use taxpayer dollars to compel a religious institution to perform an abortion on a minor, not necessarily with a doctor, a physician's assistant without the knowledge and consent of their parents.

That is not hyperbole, that is not exaggeration. That is the text of the bill that my colleagues voted on, and then they come to a hearing like this and suggest that we have the radical position. This is rejected by a vast majority of the American people. So, if we want to have a hearing, educating people on radical, that is radical. That is a law that was voted on the floor is now co-sponsored by my Democrat colleagues.

So, I look forward as somebody who's worked on a lot of bipartisan bills. I look forward to having an honest discussion where Ms. Heard's experience can be taken into account, Ms. Dennard's experience can be taken into account, and the extremes at either end which are preventing any sort of certainty that I think every expected mother deserves or any aspiring mother deserves.

You are collateral damage for the political games that we play here in these Committee hearings, and this is an example of one that has nothing to do with a reasonable bipartisan outcome. Thank you all for being here.

Chair COONS. Senator Whitehouse.

Senator WHITEHOUSE. First of all, thank you all for being here. I know these are very difficult issues, and very often, very personal issues. In my meetings with the OB–GYN community in Rhode Island, the doctors are horrified and furious at what they're hearing from their colleagues in other States who have to make the awful decision to not provide the standard of care that they are trained to because a bunch of characters in the State legislature wrote over what medical science knows to be best practices.

And that's particularly concerning when a pregnancy begins to be troubled, and now you've got the mother's health at risk as well. So, I am very, very sorry for your experience, Dr. Dennard, and I'm really grateful that you took the trouble to come here and share it.

Chair Durbin opened up with the observation that if you come to this with the belief that life begins at conception, not only is taking away women's rights to make a choice about abortion, something you want to get rid of, but IVF has to go too because it necessarily involves embryos. It's hard to have one theory apply in one case, but not in the other.

I'm a little bit concerned that that also would apply to mifepristone, a perfectly legal drug that is sold by regular pharmacies and can often be delivered through the mail. You are a doctor who practices in this area. Do you see the drug mifepristone as

being in the crosshairs of this theory that life begins at the moment of conception?

Dr. DENNARD. Thank you so much, Senator Whitehouse. Mifepristone has been so regulated and it's so difficult to obtain in the State of Texas that I really don't have personal experience administering it or prescribing it for patients. I think it's really important——

Senator WHITEHOUSE. You presumably don't take it until a pregnancy has commenced until there is an embryo, right?

Dr. DENNARD. I'm sorry, could you say that again?

Senator WHITEHOUSE. It presumably is prescribed once there is an embryo?

Dr. DENNARD. Correct?

Senator WHITEHOUSE. Yes. So, it would seem that mifepristone is next in the cross hairs of things to be taken away, and I don't know if contraception is next. That used to be an issue in this battle, and maybe that's where we go next. It just doesn't seem to make any sense any longer in this context of fetal personhood.

I just really hope that to follow Senator Tillis's remarks that as we go through this, we can bear in mind just what evil this has worked in the medical profession when hard family choices have to be made with the life and safety of the mother at risk, the life and safety of the fetus at risk, and a doctor doing their very best, using the very best standard of care that they've been trained to all their professional lives, trying to advise through that very, very difficult and painful situation.

And the notion that some force from the State legislature is suddenly in that room with that family and trying to give directions to the doctor and to the mom about all of this. I mean, talk about having the person who is least likely to make the right decision in that place. So, God bless you for what you've done, and thank you for being here today.

Chair DURBIN. Senator Blackburn.

Senator BLACKBURN. Thank you, Mr. Chairman, and thank you all for being here today. I appreciate it.

And I'm going to pick up kind of where Senator Tillis left off because this hearing today is really a distraction from the discussion that we ought to be having. And as he said, my colleagues across the dais have supported the Women's Health Protection Act is really something that goes so far beyond codifying *Roe v. Wade*.

It goes so far. It is that bill that is abortion on demand from conception to birth. That's what that bill does. Partial birth abortions, it permits. It even goes so far as to supersede State laws, Federal and State laws that are conscience laws, and that protect healthcare providers who choose not to perform abortions for moral or religious reasons.

And the policies that the Democrats have laid out hardly get covered by the mainstream media, but I can guarantee you that media will cover this hearing today because they want to say, Republicans are anti-IVF, and we know that's probably what they're going to say now. And we know they'll use fear tactics and try to paint Republicans as anti-IVF so that they can scare families.

Well, just for the record, and here's the reality. I support IVF. I support fertility-related services. I'm a mom and a grandmom.

Have plenty of friends that have used IVF and these services. I think that having children is one of the greatest blessings that God gives us. I want Tennesseans to have the right to rear that family, and I will always oppose efforts that are going to block IVF because it is a service that many people need.

So I think it is long past time that we hold our colleagues, our friends across the aisle to account for what the Women's Health Protection Act would actually do and the radical nature of that.

And Dr. Wubbenhorst, thank you for being here today. I spoke a little bit about that, Women's Health Protection Act, and how far it goes beyond codifying *Roe v. Wade*. And one of the most reprehensible provisions that is in that legislation is the ban on informed consent, and the fact that those requirements are banned. You couldn't give the woman the opportunity to view the image of an unborn child or to hear the heartbeat of an unborn child.

I am the sponsor of the Women's Right to Know Act. I think women need that opportunity to experience what that life in the womb is really about, and to know that. And I would just like for you to weigh in, in the minute I've got left, about what women have a right to know, about that, about the dangers that are there with abortion, the medical complications. So, I'd like for you to speak.

Dr. WUBBENHORST. Yes. Thank you so much for the opportunity to speak. I do think that the ability to see your baby's heartbeat and hear it is extremely important. And I think one of the reasons for the opposition is that there are some studies that show that about, at least, 60 percent of women who actually do that will choose to keep their baby and parent their baby. So that shows the power of what you see and what you hear as overcoming the idea that, okay, this is just a clump of cells. This is not really a human being.

I think that the other points that you're making are very important about the safety of abortion. Abortion is associated with significant harms to women. And I do want to correct something. You know, it's not true that abortions do not occur very, very late. Dr. Warren Hern does abortions very far into the third trimester. And that is not the same as labor and delivery, because the goal of labor and delivery is a living child. The goal of an abortion is a dead child. And in fact, if an abortion is not successful, that is called a failed abortion. So those two things are not equivalent.

In addition to that, both medical and surgical abortion are associated with complications and women deserve to know what those are. They need to understand that these procedures have important consequences for them, including hemorrhage, infection, damage to the uterus. I personally cared for women who had abortion complications, in particular, needing ICU stay, needing a couple of surgeries after their mid-trimester abortion.

Senator BLACKBURN. Thank you. Thank you, Mr. Chairman.

Chair DURBIN. Thank you. Senator Coons.

Senator COONS. Thank you, Chairman Durbin, and thank you to all of our witnesses, and my colleagues.

The Supreme Court's decision at *Dobbs v. Jackson Women's Health* 2 years ago overturned roughly 50 years of settled precedent, and was a forceful abrasion act of conservative judicial activ-

ism. As we've heard today from a number of my colleagues and several witnesses, the predictions about *Dobbs'* aftermath and its potential impact on women's health have unfortunately, in many cases, all too many cases come true.

Women across our Nation have lost the autonomy to make their own decisions about their body, their care, when and how to have a family. And the recent attack on fertility treatments proves that this issue may not stop at abortion. Contraception in different forms, IVF, IUDs are on the front lines. Every woman in America deserves the freedom to make her own reproductive choices regardless of where she lives, and every American family should have the right to decide whether when to become a parent.

Ms. Rivera, it's good to see you again. As President Biden said during the State of the Union, we've seen an assault on reproductive freedom. Unfortunately, the administration's taken action to protect reproductive care through litigation, challenging some of the State bans and executive orders. The administration has prioritized patient privacy protections and expanding access to contraception.

What additional actions should the Federal Government consider to protect women in States with significant barriers to reproductive care, and what rights and protections might be at risk under a future administration that doesn't share the same commitment to protecting access to reproductive health?

Ms. RIVERA. Thank you, Senator. I mean, I think one of the things that can be done is passing the Momnibus Act, which is, you know, to address maternal healthcare, particularly, for Black women who are facing maternal mortality at disproportionate rates.

The other one is making sure that States are actually expanding Medicaid so that people can get the healthcare they need. One of the alarming things that we're seeing right now is, you know, the attacks on mifepristone, and I just want to say that mifepristone, right now, and medication abortion, right now, is what's keeping America from looking like pre-*Roe* America, where our emergency rooms were filled with women who had to resort to unsafe abortion. But right now, they're able to access safe abortion, but mifepristone is being attacked right now in a current Supreme Court case. So that's one thing.

And I think that investing—I think there should be, you know, better time and resources spent investing in expanding access to services, expanding access to prenatal care, to substance use treatment for pregnant women because there's a dose of it right now. And this is the number one thing that I think can help us result in much better reproductive health outcomes.

Senator COONS. Thank you. I think all of us who support healthy families and healthy children should support the legislation, the expansion of access to care that you referenced.

But one of the issues that's been battered around quite a bit in today's hearing is the impact of the Alabama Supreme Court's decision in *LePage v. Center for Reproductive Medicine*, where they held that embryos are extra-uterine children.

Ms. RIVERA. Yes.

Senator COONS. The Alabama legislature says their new law protects, fully, access to IVF in their State. Is that true? Is the Alabama statute sufficiently comprehensive?

Ms. RIVERA. There are a lot of questions remaining. This legislative fix at, I think, at best is temporary and narrow. So, for example, it talks about protecting patients from liability. Well, what happens when somebody's no longer a patient? So, there's a big question there. And there's a big question about what happens when somebody else brings a challenge under the rationale of the State Supreme Court and under the State Constitution.

I really want to bring attention to the chief justice concurring opinion which people should read because it's very alarming just under religious freedom grounds. But the opinion basically says that the State legislature can do what it wants, but it has to comply with the State's constitutional language which includes the Sanctity of Life Act. So that's a really big concern. And, you know, there's a parallel with the life at Conception Act which Congress is considering right now, which can make nationally look like Alabama.

Senator COONS. Thank you. Ms. Heard, if I might briefly thank you for sharing how this Supreme Court decision in Alabama on fetal personhood affected you and your family. I joined my colleague Senators Duckworth, Murray, and others in introducing and supporting a bill to protect IVF nationwide. It was blocked on the floor. What would it mean for you personally and for families across our Nation if Congress were to pass a law actually protecting access to IVF treatment across our country?

Ms. HEARD. Thank you, Senator, for asking. It would mean everything. It would make me and my husband feel very much supported by this great State that we live in, great country that we live in. There are so many like myself that are experiencing infertility, and IVF is the only way that we can expand our family. So, if we can get something passed that protects our access to that, it would absolutely mean a lot.

Senator COONS. Thank you. Thank you to all our witnesses today. Thank you, Mr. Chairman for indulgence.

Chair DURBIN. Thank you, Senator Coons. Senator Cruz.

Senator CRUZ. Thank you, Mr. Chairman. We are witnessing today an act of political misdirection by the Democrats on this Committee. I'm going to start with three propositions that are indisputably true and should be unassailable.

Proposition number one. The question of abortion is a question that is hotly contested in this country. Reasonable people of good conscience and good morals can disagree on the question, and they do. In every State in the union, there are sharp, passionate, emotional, personal disagreements on this issue that people rightly care very deeply about.

That's precisely why the U.S. Supreme Court in *Dobbs* said an issue like this that divides the American people should be decided by the American people. It should not be nine unelected judges decreeing the rules for everyone to obey, but rather the voters should make those determinations.

My Democrat colleagues are fond of beating their breast and saying we must defend democracy except when the voters vote for

things they dislike. As long as the voters cooperate and vote for a left-wing Democrat agenda, they like democracy in that instance. If they ever vote for anything to the contrary, few things horrify my Democrat colleagues more than actual democracy.

What is the State of law in America right now? Each State determines what the rules are that shall govern abortion, and the rules that they adopt reflect the values and mores of those citizens. We would expect the people of Texas to adopt different rules than the people of California. That is perfectly okay, and that is the beauty of our Federalist system that welcomes diversity.

But here's the second proposition that is equally unassailable. The position of today's elected Democrats in Congress on abortion is wildly out of step with the American people. It is a radical proposition. Every Democrat in the Senate, every single one, has voted for legislation that would strike down every single common-sense restriction on abortion adopted by every State in America.

The position of the Democrats is they would strike down every law, they would legalize abortion up until the very moment of birth. They would legalize partial birth abortion. They would strike down every law providing for parental notification or parental consent. If your daughter gets a tattoo or a piercing, a mom or dad has a right to know about that, but the Democrats would strike down a law that entitles the parents to know before an abortion is given to their daughter.

The position of the Democrats is not a mainstream position. Indeed, national polling shows roughly 9 percent of Americans agree with that position. Ninety-one percent of Americans disagree with the position of every single elected Democrat in this body. Understand, I'm not ascribing that view to them. They have voted for legislation that would strike down those common-sense restrictions.

And that leads to the third proposition that is indisputable. IVF is fully protected in law. It should be fully protected in law, and it'll remain 100 percent fully protected in law. Every Democrat knows that. Out of 100 Senators, 100 Senators in this body support IVF treatments. I strongly support IVF treatments.

In fact, the State of Texas IVF treatments are protected in law. And in fact, since 1987, Texas has mandated IVF coverage for many group health insurance plans. The Democrats know this. It's a lot of focus on the Alabama Supreme Court decision. The Alabama Supreme Court decision was not a decision striking down IVF.

In fact, it was a case brought by parents seeking IVF against a clinic that had negligently cared for the embryos. It was a decision in defense of preserving IVF, but a whole lot of partisan elected officials and a whole lot of partisans in the media immediately seized on that decision to say, aha, IVF will be struck down. Well, I will say the State of Alabama acted promptly, bright red. Ruby red Alabama acted promptly to say, no, IVF is protected.

Right now today, roughly 2 percent of live births are brought into the world through IVF. IVF is a wonderful gift that lets parents who want to welcome a son or daughter, a child to love, lets them welcome that child into the world. But understand why we're having a hearing on IVF, not because there's any threat to IVF, but because the Democrats cannot defend their position on abortion.

They have not convened a hearing on whether the country should adopt the Democrat position and allow partial birth abortion in all 50 States. That is their position, but it's wildly unpopular.

So, for any mom or dad at home looking to have a child through IVF, understand IVF is 100 percent protected in law. It should be, it'll be, I strongly support it. And so does every other Member of this body.

Chair DURBIN. Senator Klobuchar.

Senator KLOBUCHAR. Thank you very much, Chairman. I think I'm going to ask some experts questions here. Ms. Rivera, in June, the Supreme Court shredded nearly five decades of precedent protecting June of 22, protecting a woman's right to make her own healthcare decisions. What has happened? Governors race to the State capitals in certain States to pass laws that completely restricted a woman's right to make her own decisions, leaving it to politicians.

Now, 21 States we have seen bans, partial bans, you name it. Can you talk about the chaos and cruelty the *Dobbs* decision has unleashed?

Ms. RIVERA. Thank you, Senator. We are experiencing an American dystopia with abortion bans preventing people from getting access to care as early as they need it where they live. And so, for those who can, they have to travel hundreds of mines, and there are many people who can't. So, they're not getting access.

Women's and pregnant people's obstetric crises are not getting the standard of care because doctors fear getting arrested and going to jail like in Texas for a hundred years. So, this is the kind of landscape, and the backdrop of this is the U.S.s' internal mortality rate that exceeds that of other industrialized nations. And criminalization contributes to that disparity, contributes to poor maternal and infant health outcomes.

Senator KLOBUCHAR. Thank you for bringing up some of these other problems that have been spawned by this. I would say one of them is the fact that we're starting to see less people going into OB–GYN. Dr. Dennard as of last year, both the number of OB–GYN medical students applying to residencies in States with abortion bans dropped by over 10 percent. Dr. Dennard, as both a practicing OB–GYN and a woman who sought abortion care in a State with strict abortion laws, how do you think these restrictions harm both patients and providers?

Dr. DENNARD. Thank you for that question. I love Texas. My family's there. I love practicing medicine, but it is becoming so difficult to do so in my State. There are, as you said, residents who are choosing to move, medical students who are choosing not to match to programs in my State, and it's causing incredible health crisis for pregnant people.

I'd like to also comment on what Dr. Wubbenhorst had said previously. She mentioned how dangerous abortion is. Abortion is not dangerous. Abortion is safe, and abortion is essential healthcare. What is really dangerous is pregnancy, and especially pregnancy without access to abortion care. Medical situations are complicated. There is an art to practicing medicine. This is not a black or white issue. It's not a yes or no answer. We need to be able to take care of women in each and individual situation.

Senator KLOBUCHAR. Okay. Ms. Rivera, on Tuesday, the Supreme Court will hear oral arguments in the Texas medication abortion case. As you know, this is about mifepristone. We know that this drug is safe. American Medical Association has stated that, "There is no evidence that people are harmed by having access to this safe and effective medication." It's been on the market for within two decades. In 2023, it accounted for 63 percent of all abortions in the U.S. It's been approved in dozens and dozens of countries. How would a decision whereby justices on the Supreme Court second guess scientists and experts at the FDA impact women throughout the United States, and really, how has the Texas decision already impacted them?

Ms. RIVERA. Thank you, Senator. Well, luckily the Supreme Court has maintained the status quo——

Senator KLOBUCHAR. Yes.

Ms. RIVERA [continuing]. Until the case is heard or decided. It would have a devastating impact on access to care, quality of care, and reproductive health outcomes if medication abortion is scaled back, which is what this case could result in even in States where abortion is accessible and legal. So, this basically would have national impact on abortion care as well as the reproductive health status of pregnant people.

Senator KLOBUCHAR. Just a last question to respond to some of what Senator Cruz has said. We'd be here for quite a while if you were to respond to all of it. But could you respond to the fact that, in fact, the Alabama Supreme Court did cite the *Dobbs* decision and that cases like this in other areas have been unleashed since that decision came out from the U.S. Supreme Court?

Ms. RIVERA. Absolutely. So, while the *Dobbs* decision, its holding, did not rely on fetal personhood, but it basically opened the door and invited States to define embryos, fetuses, and fertilize eggs as persons if they so choose. And so Alabama cited to the *Dobbs* decision in making and redefining child to include a frozen embryo.

And so, I think this is the tip of the iceberg. There are 11 States with broad fetal personhood laws that have yet to be interpreted, and so I think this is the tip of the iceberg. And the legislation that Alabama adopted, as I said, it could be temporary, and it's very narrow, and it may not survive the next challenge when somebody takes it up to the State Supreme Court again.

Senator KLOBUCHAR. Thank you. And I think it's one of the reasons so many of us are devoted to codified *Roe v. Wade* into law which, of course, does allow for restrictions as the case had in the third trimester as long as the women's health and life is protected. So that, again, something in response to something Senator Cruz said.

But it's very, very important that we do this for the Nation and not have a patchwork of laws across our country for IVF, for mifepristone, or any of the issues we've discussed here today. And that's my last question. Just one answer. Would you agree?

Ms. RIVERA. Absolutely. And there's been a lot of mischaracterization today about the Women's Health Protection Act.

Senator KLOBUCHAR. Thank you.

Chair DURBIN. Thank you, Senator Klobuchar. Senator Blumenthal.

Senator BLUMENTHAL. Thanks, Mr. Chairman. When I first introduced the Women's Health Protection Act, now about 12 years ago, we never thought we would be here. We never thought that *Roe v. Wade* would be overturned. We never thought that IVF would be under threat. We never thought that speeches would be made like Senator Cruz telling us that everything's okay with IVF. No reason to worry because the State of Texas protects IVF.

Well, here we are, *Dobbs* has overturned *Roe v. Wade*, and for reasons that you've just described so forcefully, *Dobbs* has opened the door to a panoply of evils. It has unleashed from that Pandora's box, a collection of threats to women's reproductive rights.

I would like you to comment on why those kinds of State laws that Senator Cruz referred to, whether it's Texas or elsewhere, fertility treatment protection laws, and the Alabama statute that you mentioned are really inadequate to protect those rights. Building on the question that Senator Klobuchar just asked you.

Ms. RIVERA. Thank you, Senator Blumenthal. I think we have to step back and look at the bigger picture here. The overarching goal here is to establish fetal personhood under the 14th Amendment of the Constitution. I think that is the real danger. And all of these laws that recognize legal rights for embryos, and fetuses, and fertilized eggs in State law are paving the path to that.

And all of these services are in danger because if you believe a fertilized egg is legally a person with all the same rights as everybody here in this room, then it endangers IVF contraception and any medical care that would "endanger" that fertilized egg, embryo, or fetus, including people who are begging to have their humanity, their healthcare needs met, and saving their bodily organs and lives in emergency rooms because their health is deteriorating.

The other case being considered by the Supreme Court is the EMTALA challenge, which the Federal EMTALA statute is meant to prevent people's health from deteriorating. But what Idaho is arguing that their State law should override EMTALA until somebody's health has deteriorated to be staring death in the face before they can get access to healthcare.

Senator BLUMENTHAL. And the Women's Health Protection Act would provide a guarantee of rights against those State laws, personhood laws, restrictions on clinics, and whatever other kinds of inadequate conditions are placed on the exercise of these reproductive health rights. Would it not?

Ms. RIVERA. Yes. And I also want to correct some mischaracterizations about the Women's Health Protection Act. What the Women's Health Protection Act would do is it would establish a national floor for access, because what had been happening for over years and years are layers upon layers upon layers of restrictions to shut down abortion clinics and abortion health providers. So the Women's Health Protection Act would restore that access.

Senator BLUMENTHAL. And there's nothing about the Women's Health Protection Act that requires anybody to be in favor of abortion or seek an abortion. Correct?

Ms. RIVERA. Absolutely not.

Senator BLUMENTHAL. And there's nothing in it that requires someone to engage in IVF?

Ms. RIVERA. Absolutely not. The point is that individuals should be able to make their own reproductive healthcare decisions.

Senator BLUMENTHAL. Dr. Dennard, you said I think that what's dangerous is not pregnancy, but the lack of access to abortion where a woman chooses to have it. And I guess the way I'd put it is what's really dangerous is lack of access to healthcare, because abortion is a form of healthcare. And I think that when we recognize that reproductive rights are women's rights, are human rights, are healthcare rights, we have a frame to protect these rights from the kinds of deceptive and misleading attacks on them. Would you agree?

Dr. DENNARD. Absolutely. I would agree with what you're saying.

Senator BLUMENTAL. Thank you.

Dr. DENNARD. I've been pregnant six times and I have three children. That is because the road to becoming a parent is not always straightforward. Every person's journey to becoming a parent is different. There are lots of twists and turns. I've had abortions, I've had miscarriages, and I have three healthy children. And in order to have those three healthy children, I needed access to, as you describe, basic medical care. And that's what my patients need. That's what I need to be able to provide them good care.

Senator BLUMENTHAL. Thank you. Thanks, Mr. Chairman.

Chair DURBIN. Senator Hirono.

Senator HIRONO. Thank you, Mr. Chairman. One of the reasons that I was very much awakened to politics as a way to support social changes was on the issue of abortion. I was in college when the State legislature in Hawaii took up the issue of abortion rights. And in fact, the State of Hawaii was the first State to decriminalize abortion before *Roe v. Wade*.

This is an issue that is very fundamental. What could be more fundamental than a person's right to control her own body and to make decisions relating to her body? What could be more invasive than to force us to have babies? I can't think of a similar thing that we do basically to men that is as invasive as a bunch of politicians saying to a male person, you have to do this. I can't think of an instance. And yet, something as invasive and fundamental as a woman's right to control her own body is under assault.

So here comes *Dobbs*. I never thought I'd live to see the day when we have a Supreme Court majority that just summarily decides that something that I had taken as a constitutional right for almost 50 years, a constitutional right, where they just say, well, it's no longer a constitutional right. What kind of Supreme Court is that if the ultimate arbiters of what is constitutional or not constitutional decides that this right, that I had for almost 50 years no longer exists, and you leave it to the politicians in each State to make that decision.

I have no words to express what an assault this is on women in our country to force us to have babies. And now even for the women who want to have babies, IVF is under assault. So I say, if you don't support abortion, don't get one, but leave the rest of us alone.

There are good-hearted people, fair-minded people on both sides of the abortion issue. I acknowledge that. And that is why it should never be a decision that is left up to a bunch of politicians. It's a decision that is so personal and so fundamental that it should be left to the person, individual, and her doctor if she so chooses.

So, the ripple effects of *Dobbs* never ending, and we know that already people are making decisions as to what States they're going to live in, because if they live in one of the many States that that criminalize abortion, they have to travel out of State to get the kind of reproductive healthcare that they need. And not all women, or not all families have that capability.

So once again, like the, so-called right to abortion. If you were a poor person that lived in a State that did not provide funding or Medicaid abortions, you're pretty much out of luck. Hawaii was one of the few States that provided, that paid for Medicaid abortions because that is a constitutional right if that right to be exercised depending on your economic situation.

So, we now have the circumstance where after *Dobbs* individuals have to travel out of State to get their abortion care and other reproductive care that they need. And don't tell me that IVF is legal everywhere. So why did Alabama have to pass a law that so-called legalizes IVF in that State? And even that is not protective enough, because if I were a clinic providing IVF care, I would definitely not want to take the chance that that Alabama law is going to protect me.

Just as in Texas, their law protects the—if the life of a woman is endangered, she can get an abortion. Oh, really? I don't think that's the case because what doctors or providers are going to take the chance that maybe they did not determine that correctly, and that they have to wait till the woman is practically on deaths door in order to deem the protection of her life to be one that would enable her to get an abortion.

So, you know, the *Dobbs* decision has so much negative effects. Mifepristone. Oh yes, we have a Supreme Court that is about to determine whether or not a medication that more than half of people resort to legally in order to have an abortion. That could very well be banned because we have a Supreme Court that seems perfectly willing to just eliminate what was deemed a 50-year constitutional right.

So I came down to who's going to make the decision on whether or not a woman has a right to make reproductive decisions, bodily autonomy. Is it the woman, or should it be a bunch of us, or State legislators? It is so clear to me who should have that decision-making. And all of these bills, all of these efforts, and all of these ways that—and really to say that this is an issue that good-hearted and right-minded people have very—you know, they come to different conclusions. And I say that's right, and that is why we should have bodily autonomy.

If you don't support abortion, don't get one. Leave the rest of us alone. Thank you, Mr. Chairman.

Chair DURBIN. Thanks, Senator Hirono. Senator Booker.

Senator BOOKER. Thank you, Mr. Chairman. Ms. Rivera, *Dobbs* has really created this patchwork of laws all across the country that make it very difficult for people to access what is really impor-

tant in terms of their healthcare. But on IVF in particular, it's created real challenges on sort of this patchwork on affecting women depending on where they live. Can you discuss that for a minute for me and let me know more specifically what's that doing to the profession as a whole?

Ms. RIVERA. Thank you, Senator. I think, you know, the Alabama situation is the tip of the iceberg, and we'll have to see how the rest of it plays out. There are these 11 States with very broad fetal personhood laws. They haven't yet been fully enforced.

So, we'll have to see what challenges are brought, what those State Supreme Courts decide, but that's the point. Senator Hirono has a point, right? What's happening is that it's been kind of left to the States to decide—women's fundamental freedoms are being left to be decided State by State.

Senator BOOKER. Let me just drill in for this for a second, because many people don't realize that this insecurity or uncertainty is affecting women's access to reproductive care.

Ms. RIVERA. Yes.

Senator BOOKER. And so, let's be very specific. Are there, yes or no, doctors, OB–GYNs leaving certain States to go to other states, leaving these holes in the kind of care that individuals can get, that women can get in their communities?

Ms. RIVERA. Yes. One of the impacts in the post-*Dobbs* environment is that OB–GYNs that are leaving States in areas that are already extremely underserved. So, there are increasing OB–GYN deserts that's happening.

Senator BOOKER. And are those in wealthy communities? What are those communities look like that these deserts exist?

Ms. RIVERA. Is that disproportionate impact is in communities of color, let's be very clear. In rural areas, in communities of color who already have trouble accessing appropriate reproductive healthcare. So and this, all of this, we are going to have to watch the maternal mortality rate very carefully and who it's going to be impacting, because I think it's going to be increasing over time. It already is increasing. And for the first time in 2021, Latinas had high maternal mortality rates than White women.

Senator BOOKER. And so let's just, I mean, jump into the outrage of this. The United States of America has one of the highest maternal mortality rates writ large of other industrial nations. Correct?

Ms. RIVERA. That is correct.

Senator BOOKER. And that's for the whole country. But when you start looking at it by race, you see for African American women that there is almost a four times higher maternal mortality rate. And what you're saying right now that these laws that are creating this patchwork are further exacerbating the access to maternal healthcare of African American women and low-income women.

Ms. RIVERA. That is correct, and I'll say two more things. One is that there's a big overlap in the worst maternal mortality and infant mortality rates with abortion ban States. And second, that criminalization of pregnancy contributes to these poor health outcomes because it deters people from accessing care.

Senator BOOKER. And so, Black women who are most at risk in dying for a childbirth, Black women who are most at risk for having low birth weight babies, Black women who are most likely to

have fetal deaths in giving birth are now being put in a situation where their lives are greater at risk, where their babies are at greater risk, where their long-term healthcare is at greater risk because of all of these laws that are being passed that are restricting access to not just maternal care, but even to OB–GYNs in the first place.

Ms. RIVERA. Let me put it this way. Black women in this country are the ones most likely to be staring death in the face during pregnancy. And so, it's so important and critical for them to be able and be in the driver's seat, to be making their own reproductive healthcare decisions.

Senator BOOKER. And this is the last point. The outrage is that a lot of these laws, the women that are both most being scrutinized over miscarriages, the women that are being more scrutinized over the idea that their lives are threatened because of their pregnancy, you see disproportionately, is it true or not, that these are African American women and low-income women.

Ms. RIVERA. So, on the criminalization of pregnancy Black women are certainly overrepresented in the number of people who are being charged with crimes. But the biggest impact—we actually have more poor White women who are being charged and arrested for supposed harm to fetuses. So, this is also a situation of poverty, right, of who is poor and who is a person of color.

Senator BOOKER. So, people of color, low-income women, poor women——

Ms. RIVERA. Yes.

Senator BOOKER [continuing]. Are facing the brunt of these laws that are often ending up putting their lives, their health, and their well-being, greater at risk, and also putting them at greater risk for low-birth-weight babies, fetal deaths, as well as maternal mortality?

Ms. RIVERA. That is correct, and also being criminalized and put in prison.

Senator BOOKER. Thank you, Mr. Chairman.

Chair DURBIN. Thank you, Senator Booker. Senator Padilla.

Senator PADILLA. Thank you, Mr. Chair. I do have at least one a question I'd like to get to, but first thing I want to do is associate myself with Senator Booker's comments, line of questioning on the equity, racial and otherwise element of this important conversation.

And second, Mr. Chairman, I can't help but feel the need to respond to some of the comments I heard earlier from Republican Members of this Committee. So let me clarify that first of all, Democrats are not trying to deflect here. We're not trying to mislead here. We're trying to stand up for what's right, and what stood as a right for half a century in the United States of America. And we're not afraid of democracy. You want to hear who's afraid of democracy? Those who were more than just disappointed by the outcomes of elections in a number of States.

Folks, this question has been on the ballot since the *Dobbs* decision. Questions put before voters whether or not to make access to reproductive healthcare more restricted or to strengthen access. And State after State, the public has sided with more access, not just in the State of California, which is considered, oh, it's a deep

blue State. I'm talking States like Virginia and Michigan, very purple States by some people's measure, but also States like Missouri, Ohio, Kentucky.

So we're not afraid of democracy, but we do believe that there are some issues that rise to the level that warrant national Federal protections. It would be wrong to suggest that there shouldn't be any for the whole country and just let each State do what they want.

Now, I do believe that some of our colleagues who would like to leave a question of things like marriage equality to the States, and we shouldn't have Federal protections. We should, and we do. I'm sure there's some of my colleagues who would rather return the question of interracial marriage to the States, and we shouldn't have Federal protections. We should, and we do. So, I'm sure there's some of my colleagues who think there shouldn't be Federal protections for our fundamental right to vote out. We should, and we kind of do. That's some unfinished business, but that may be a topic for a hearing on another day.

And the question of Alabama, the way we have portrayed the decision by the Alabama Supreme Court relative to IVF is actually right on point. It's why former President Trump has tried so quickly to distance himself from that decision. And when people call—Republicans called on the Alabama legislature to respond to it.

And my colleague on this Committee says, well, you are wrong, you're wrong, you're wrong, but it should be fixed and it will be fixed. You can't have it both ways. It was right. Or, it's wrong. Clearly, the Alabama Supreme Court got it wrong, and the Alabama legislature was put in the position of having to rectify.

Now, to today's hearing. Since the decision by the Supreme Court to overturn *Roe v. Wade*, thousands of women have been forced to travel outside of their home State, sometimes hundreds of miles to access the reproductive healthcare that they need.

California's among several States, that has seen a significant rise in out of State women seeking essential care. And it's more critical now than ever that all women are able to freely travel to access the reproductive healthcare that they need.

It's equally important to ensure that States like California also are supported with the adequate resources to provide women with that quality care regardless of where they come from.

Ms. Rivera, we keep turning to you for your tremendous perspective and expertise here. How has the influx of out-of-state women seeking care impacted healthcare systems in States like California where abortion remains legal?

Ms. RIVERA. Thank you for your question, Senator. So, States like California, a number of States have really stepped up and expanded access to abortion care because of the anticipation that more people will need it, which is great.

On the other hand, it strained those systems in the State so people inside those States have longer waiting periods, for example because it's harder to get an appointment because of the influx of people from other States. So, on one hand, it is great that States like California are able to serve people coming from out of State, and at the same time, it really is taxing the health system in in your State.

Senator PADILLA. Okay. Thank you very much. Thank you, Mr. Chair.

Chair DURBIN. Thanks, Senator Padilla. Senator Welch.

Senator WELCH. Thank you, Mr. Chairman. I want to thank the witnesses. Just to comment about this decision by the Supreme Court in *Dobbs*, which I think was profoundly cynical based on "originalism" and that's in the mind of the Supreme Court Justices who wanted to overturn what had been settled doctrine.

And the second thing, so disturbing about this, and I'm sorry, Senator Cruz isn't here, the idea that the privacy rights that were enshrined in *Roe v. Wade*, that value that we placed constitutionally uncertain realms of decisionmaking that belonged to the individual person is challenged, and then is turned over to a political process.

Senator Hirono said it best, you make your own decision. You respect the decision another person makes because that's her, right? That's all upside down now, and it's unleashed this whirlwind where States are having bans from the moment of conception where a personhood of—where IVF is threatened, where every right that we've had is thrown into turmoil.

And it's all on the basis of the Supreme Court rejecting the notion that there are certain spheres where it is the individual who has the freedom to make the decision that is best for her and not impose her decision on others and will reap in the whirlwind.

And I just want to express to you, Ms. Heard, thank you so much for coming in. I can't believe what you went through, and you and your husband, in the effort to create a family. And my apologies to you that your court has done to you what it did.

I do want to ask a question, just on a practical level, about what's the implication on the cost to a family who wants to have IVF. Ms. Rivera, could you talk about that? What's the implication here about an already expensive procedure? What's it going to cost a family, like the Heard family, if they want to do this?

Ms. RIVERA. I am not an expert on this, Senator Welch, but I can tell you that anything that makes it harder for an already emotionally and physically taxing process where people have out-of-pocket costs, depending on insurance coverage, for example. And timing is everything from what I understand with IVF, and anything that makes it more difficult just creates enormous barriers.

Senator WELCH. Okay. And, Doctor, I want to give you a chance to respond to some of the questions that Senator Cruz was asking about late-term abortion. And my understanding is that late-term abortions are very rare, and it's almost always, really, probably always where there's a medical emergency and the life of the woman is imperiled.

And if we as U.S. Senate try to figure out what should be done in that moment, in circumstances that we know nothing about, that's going to jeopardize, in my view, very much the life of the mother. Now, can you speak about the agony of the decision that has to be made and what the considerations are?

Dr. DENNARD. Of course, and thank you for that question. Like I've said before, medicine is not black and white. It's not straightforward, and abortion access and the ability for an individual to receive an abortion is basic healthcare and medical care.

I invite you, Senator Welch, or Senator Cruz, if he wants to come back, to follow me around in the hospital and really see what it's like to take care of patients, and to see what it could potentially be like to try to have an exception for a patient who's critically ill, what that really looks like, because I haven't seen it work yet. I've seen patients on mechanical ventilation, patients who have active cancer, patients who are extremely ill, none of them have received abortions, they've remained pregnant.

So, the whole idea of—I don't even know what a late-term abortion is, to be quite honest. The vast majority of abortions occur in the first trimester, but that's not really the point. The point is that it needs to be a decision for an individual after shared decision-making and good counseling by a provider so that they can make the best decision for themselves.

Senator WELCH. Thank you very much. I yield back.

Chair DURBIN. I want to thank the panel. I have two things I'd like to raise, and you've been very patient to this point. But going back to Senator Cruz's statements, I listened to him, and then I read some information given to me by my staff. What are the reasons for really late-term abortions? Well, there are three, and the information I'm reading from comes from the Center for Disease Control.

"Why Women need access to abortion; latent pregnancy, maternal health, endangerment, diagnosis of severe fetal abnormality which didn't show up or develop until late in the pregnancy, restrictive State laws that made it difficult for a woman to get an abortion early in her pregnancy."

And we're talking about 1 percent of all abortions. I do politics for a living. So, if you want to make your case, you make it in the extreme. "The day before she gave birth." Should she get an abortion then because she didn't like the gender of the baby that's going to be born? That was one of the examples that was used by one of the Senators here. And you think to yourself, does that really happen? Could it happen? Well, it might, in the extreme case, in the exceptional case.

What they're really getting to is they don't trust the woman to make the decision. Implicit in that statement is the notion they're going to get it wrong, or they're going to do something stupid and this innocent baby that might've been born is not going to be born. It hardly ever happens, and the reasons are set out by the CDC in extreme cases.

And I trust women a lot more than I trust the politicians of Alabama or even Illinois to make that same decision for that woman. I think that's the bottom line is as far as the late-term is concerned.

And the other thing, you look at the bills that many of my Republican colleagues have on the subject of abortion, and many of them have exceptions for IVF. They say so when they come to the Committee hearing. We're not arguing about IVF. We have difference of opinion on abortion.

Here's the fundamental problem I see. If you believe that life begins at the moment of conception, if that is your premise for your policy and your law, how are you going to explain IVF? Because at the end of the day, there are going to be embryos that are not im-

planted and something has to happen to them. And if they're treated as humans, persons, whatever you characterize them as they worried about in Alabama, you're drawn to one conclusion.

If you think that life begins at the moment of conception, you have to do something to protect that embryo. But I have to tell you, I don't believe that. I don't believe that is the premise that we should start off on because it takes us to a place that is impossible to live with. As far as I'm concerned with the extraordinary circumstances that face many people.

I hope that there will be some people as a result of this hearing who will think a little bit more on the subject. I will certainly think a little bit more. We had an excellent turnout by the Committee because the issue is not only topical, but it's real, and it's human, and we all know somebody like Ms. Heard, whose life has been positively impacted by IVF. Thank you so much for bringing your experience to it, and thanks to all the witnesses.

The hearing will remain open for 1 week for submission of additional materials for the record. And with that, the hearing is adjourned.

[Whereupon, at 5:01 p.m., the hearing was adjourned.]

[Additional material submitted for the record follows.]

**Senate Judiciary Committee Hearing:**
The Continued Assault on Reproductive Freedoms in a Post-Dobbs America
March 20, 2024

**Testimony of Dr. Austin Dennard**

Chairman Durbin, Ranking Member Graham, and Members of the Senate Judiciary Committee, thank you for having me here today.

My name is Austin Dennard. I'm a mother, Texan and practicing obgyn. I'm here today to describe what life has been like in Texas since the federal right to abortion was taken away by the Supreme Court and my home state began criminalizing and banning abortion care.

Nothing brings me more joy than being a mother to my three young children. But a close second is being an obstetrician/gynecologist. I get to be present for so many incredible moments. There's nothing quite like the moment a baby is born and a family is created; to this day it still takes my breath away.

But intertwined in these celebrations are also moments of complete heartbreak: pregnancy loss, a devastating diagnosis, infertility. Since SB8 was enacted and the Dobbs decision came down in 2022, those tough moments have become even more tragic. In Texas, where my husband and I both practice medicine, we live in fear, as physicians and patients.

I can speak to both of those perspectives because I am a Texan and obgyn who needed an abortion but couldn't get one in my home state.

In the summer of 2022, SB8 had come into effect in Texas. After careful consideration and many prayers, my husband and I were delighted to find out that we were pregnant again. Between our two toddlers and our growing surgical practices, we were feeling really busy but also very blessed.

But at 11 weeks of pregnancy, I had a routine ultrasound that would change the course of my family's life forever. The brain and skull had not formed. A condition known as anencephaly. The most severe neural tube diagnosis. One-hundred-percent fatal.

I will never forget looking up at the ultrasound screen in complete disbelief and utter devastation. This was not going to be a little brother or sister for my children. I needed an abortion but would need to flee my state to get one. Texas; my state. Where my family has lived for 6 generations. Where I practice medicine and am raising my family.

My mind began to spin: *Where would I go? Who would take care of me? Who will take care of my children? What about my patients? What if this is the last time I ever get to be pregnant?*

Because of Texas's new laws, we were afraid to use credit cards or to tell people why we were traveling to the East Coast so suddenly. We were terrified that my husband could be arrested for "aiding and abetting" my abortion – just for traveling with me. Under Texas's new laws, the penalties are severe: up to 100 years in prison, huge fines and loss of medical license. We were absolutely humiliated.

We flew to the East Coast for a 10-minute procedure. Standard medical care. Healthcare.

Through it all, I felt so broken and abandoned by my home state, and at the same time I had never seen my own luck and privilege with more clarity. What did other people do in this situation without the medical connections and the means to cover extensive costs and lost wages? Why should anyone in the United States have to be lucky or privileged to access essential medical care?

As heartbreaking and traumatizing as that was for me, it is even more disturbing to be a working obgyn in Texas today, trying to abide by these paralyzing and punitive laws while still providing timely, compassionate and ethical care to our patients.

Conversations in the office are different now. Couples arrive for their pregnancy confirmation visits more filled with worry than with joy. They know how much is at stake now. *What if it is an ectopic pregnancy? What if I start bleeding? What if I become really sick?*

I have the same answer for all of them: I will do everything in my power to keep you safe.

But the truth is, the ramifications of a fatal fetal diagnosis or medically complicated pregnancy feel enormous in this new environment. We all collectively hold our breath as we pass pregnancy milestones, awaiting genetic screening results, anatomy scans, and those fragile weeks of peri viability.

Because my patients know that lawmakers have stripped away their rights. Their rights to make decisions about our own health, their own body and their own family. So long as they remain on Texas soil, their pregnancies belong to the state. Until their babies are safely swaddled in their arms, we have no say. Exceptions are said to exist in the laws but in reality, they are only a fiction.

These bans have stolen so much from all of us. I have spent the greater part of my adult life dedicated to studying medicine and becoming the best doctor I know how to be – yet somehow lawmakers have taken control of my body and my practice as if they know better.

I have never wanted to be a public person, but I can't be silent anymore. The silence is too painful. These cruel laws and the harm they cause my patients and my profession, must change. Texas women deserve better. Americans deserve better. My 4 year old daughter deserves better.

Mornings in our household start quite early these days. And for me, there is no sweeter way to wake up than to the sounds of our little ones. Their sweet voices can be heard through our bedroom wall. It is not long before I hear their giggles migrating to the nursery where I usually find the toddlers cuddled in the crib with their baby brother.

I think about how blessed we are; my three healthy children are here because of the excellent medical care I received. But I also think about how fragile it all is, how easily things could have ended differently – all because of the dangerous and cruel obstacles my state has inflicted on us and others like us who just want to build a family.

Thank you.

Thank you Chairman Durbin, Ranking Member Graham, and Members of the Senate Judiciary Committee. Thank you for the opportunity to testify before you today.

My name is Jamie Heard and I am from Birmingham, Alabama. I'm here to share how the Alabama Supreme Court's decision to declare personhood for frozen embryos has affected me and my family.

In 2012, I was diagnosed with Polycystic Ovary Syndrome, the most common cause of female infertility. I can remember my body feeling heavy as I listened to the doctor explain the challenges I would face in getting pregnant. Untimely news that not only changed the planned trajectory for my hopes of building a family of my own, but news that found me on the wrong side of time as we dealt with the loss of both my mother and my husband's father to cancer, and subsequently, the death of my only sibling. Our family's sorrow became the cornerstone of our inspiration to build and expand our family.

As my husband and I began the journey to grow our family, we were met with obstacles as the doctor had previously prepared me for. We discussed options for having kids, but at the time it seemed very far-fetched because we couldn't afford the out-of-pocket costs of the medical treatment the doctor said we needed. But then, to our great surprise and luck, my employer expanded its health insurance to include fertility treatments, including In Vitro Fertilization (IVF). My heart was filled with so much joy and hope to finally have a chance to grow our family. This coverage was the answer to our prayers and the only way we would have access to the necessary medical care to treat my infertility.

We continued to encounter many obstacles and heartaches as we went through fertility treatments, from failed attempts at conception to the devastating loss of an ectopic pregnancy. After taking a pause on further treatments for a while due to the emotional and physical distress, we ultimately made the decision to begin the journey again. We met with our doctor who explained that after trying other medical treatments that did not work, our best chance would be with IVF. We began with months of intensive tests and procedures. And while the journey through infertility treatments was not an easy one, we were finally blessed with our beautiful son through IVF.

After taking our son on his first Disney trip, a truly magical experience, we felt so inspired and ready to grow our family. We decided to start the IVF journey again to have our 2nd child. We began that process on February 14, 2024, when we met with our fertility doctor to put a plan together to begin that process, which again involves multiple tests and procedures.

Just a few days later, we saw in the news the Alabama Supreme Court's ruling classifying frozen embryos as children. We later saw a statement from our clinic that they made the decision to pause new IVF treatments due to the legal risk to their clinic and their embryologists. Our hearts broke hearing the news of our clinic pausing treatments. My heart breaks as I hear and read comments such as our health conditions are nature's way of telling us we shouldn't have kids.

I've never been actively involved in politics or advocacy before. I'm truly an ordinary individual living an ordinary life. Even to appear before you today, with the support of my husband and very dear friend, has brought its own separate challenges. Although I'm typically not on the front lines advocating for any particular cause or issue, I knew I needed to fight not only for my rights as a woman but fight for my future family and all those individuals who are too deep in emotional and physical trauma of infertility. Now my husband and I are filled with so much uncertainty about how we move forward with expanding our family without the risk of being prosecuted. All these questions, all these decisions, regarding my body and my family, being decided by those that aren't here with me to fight the anguish of infertility.

IVF is hope for those of us struggling to conceive. IVF is medically necessary care due to my and many other people's circumstances. Access to medical treatments, without restrictions, is a basic human right. It is enough of a traumatic experience dealing with infertility and going through fertility treatments, to now have a basic human right being politicized, to further expand that trauma. I'm asking you to truly put families first, which begins with having the fundamental right to build a family and the access to the needed resources to do so. You play a vital role in fostering compassion, understanding, and support, for those in your communities, your neighbors, who are confronting the hardships of infertility.

Daily, I look and just stare at my son, still in awe that I've been afforded the opportunity to be a mom to such a beautiful miracle. A dream that for a while I didn't think would come true. But it did, through IVF. I ask the committee to think about the hope that IVF means for patients like me. Protect that hope, do not restrict it, but instead nurture that hope.

Thank you again for letting me share my story.

Jamie Heard
Birmingham, Alabama

**Testimony of Lourdes A. Rivera**
**President, Pregnancy Justice**
**before the United States Senate Judiciary Committee**
**March 20, 2024**

Thank you for the opportunity to submit this testimony to the Senate Judiciary Committee and for convening today's hearing, "The Continued Assault on Reproductive Freedoms in a Post-Dobbs America." Pregnancy Justice is a non-partisan legal advocacy organization that for over 20 years has defended and advocated for the rights of pregnant people facing criminalization and other rights violations.

This testimony will first explain "pregnancy criminalization" and "fetal personhood," and then discuss the path to Alabama's in vitro fertilization ("IVF") decision. Pregnancy criminalization occurs when law enforcement charges pregnant people[1] for actions that would not be crimes, except for the fact of the pregnancy or the pregnancy outcome.[2] This includes being charged with murder for experiencing a stillbirth or self-managing an abortion,[3] or for having a miscarriage and not knowing what to do with the fetal remains,[4] as if there were an instruction manual for such things. Pregnant people are charged for actions during pregnancy that allegedly posed a risk to the fetus—conduct that is typically legal for every other member of society.

Pregnancy Justice has documented over 1,800 cases of pregnancy criminalization in the years 1973 to 2022, from *Roe* to *Dobbs*.[5] The majority of those cases—1,400 of them—occurred in the last 15 years: as fetal personhood has gained traction in state law, the rate of pregnancy criminalization has accelerated.[6] Unsurprisingly, those targeted are overwhelmingly poor or disproportionately people of color.[7]

Bestowing legal personhood status on fertilized eggs, embryos, and fetuses is what underlies these prosecutions, and it's the same premise that underlies abortion bans, and that threatens IVF and birth control.[8] Attempts to define fetuses as legal persons have been rejected by voters in nearly every state in which it has been put on the ballot,[9] including in Mississippi.[10] Yet, state legislatures in at least 11 states passed broad fetal personhood laws before *Dobbs*.[11] These laws could potentially be read to extend full rights to fertilized eggs. Constitutional protections provided by *Roe v. Wade*, however, meant that fetal personhood laws could not always be fully enforced.

*Roe v. Wade* forcefully rejected the idea of fetal personhood, asserting that "the word 'person,' as used in the Fourteenth Amendment, does not include the unborn"[12] and that "the unborn have never been recognized in the law as persons in the whole sense."[13] The Supreme Court instead affirmed the personhood of the pregnant person, focusing on the pregnant person as the only rights-holder: "This right of privacy, whether it be founded in the Fourteenth Amendment's concept of personal liberty and restrictions upon state action, as we feel it is, or, as the District Court determined, in the Ninth Amendment's reservation of rights to the people, is broad enough to encompass a woman's decision whether or not to terminate her pregnancy."[14] Thus, the Court

ultimately concluded that "we do not agree that, by adopting one theory of life, [states] may override the rights of the pregnant woman that are at stake."[15]

Even with *Roe* in place, though, states have sought to enshrine fetal personhood. Ten years ago, for example, the Alabama Supreme Court held that embryos and fetuses are the same as "children" under the state's criminal chemical endangerment law,[16] and that pregnant people can be charged as "child abusers" from the moment of fertilization if they use substances while pregnant.[17] With over 600 women being charged under the state's chemical endangerment law since 2006, Alabama leads every state in the nation on pregnancy criminalization.[18] While horrifying, it is hardly surprising that the Alabama Supreme Court decided to extend its reasoning to frozen embryos. Alabama—along with Oklahoma and South Carolina, whose Supreme Courts have also designated fetuses as children under their state criminal laws[19]—accounts for two-thirds of arrests of pregnant people nationally, regardless of whether they have a live, healthy birth or experience a pregnancy loss.[20]

When conduct during pregnancy or pregnancy outcomes are punished, pregnant people and their families suffer irreparable harm. This includes dire health consequences, incarceration, and families torn apart.[21] Our nation is facing a maternal and infant health crisis, and pregnant and postpartum people—but especially Black women—face increased risks of death and severe complications, including due to mental health conditions.[22] The three states with the highest prevalence of pregnancy criminalization also have some of the highest rates of maternal mortality in the nation.[23] Alabama ranks fourth[24] and has some of the worst infant health outcomes.[25] In fact, Alabama's own maternal mortality review committee has called for the elimination of the state's chemical endangerment law—which, despite being passed to prevent harm to children exposed to the toxic environments of home-grown methamphetamine labs, has been used to prosecute pregnant women who use prescribed and illicit substances[26]—because it makes it harder for pregnant women to seek treatment for substance use disorder, thus leading to worse maternal mortality outcomes.[27]

Research shows that the criminalization of pregnancy is contributing to the maternal health crisis because if people fear being reported to the police for seeking care, they will not get essential prenatal care and other supports.[28] Over 15 major medical and public health associations in the nation, including the American Medical Association, the American College of Obstetricians and Gynecologists, and the American Academy of Pediatrics, oppose criminalizing pregnancy because it interferes with the patient-provider relationship and deters access to needed health care.[29]

The antiabortion movement's push to endow fertilized eggs, embryos, and fetuses with full rights has also led to the passage of fetal homicide laws in over 35 states.[30] Homicide is a leading cause of death during pregnancy and the postpartum period, and most murders of pregnant people are linked to intimate partner violence (with 70% of perpetrators using guns to kill their pregnant partner).[31] But fetal homicide laws do absolutely nothing to deter the homicide of pregnant or postpartum people. In fact, state abortion bans are making it harder for people to escape intimate partner violence. The National Domestic Violence Hotline reported seeing a 100% increase in calls since *Dobbs*;[32] pregnancy criminalization and the exodus of obstetrician-gynecologists from states with abortion bans means that pregnant people have less contact with someone who can

provide help.[33] There are multiple ways to intervene without resorting to granting separate legal rights to an embryo or fetus, which makes pregnant people even more vulnerable to homicide. If lawmakers are concerned about making pregnant women safer, they should ensure the bodily autonomy and reproductive decision-making of pregnant women.

Let us be very clear: the struggle for fetal personhood today is not about when life begins, or whether Americans see life in the womb as having value, or protecting babies and children. The idea of personhood that the antiabortion movement advances today is about controlling and punishing women, pregnant people, and communities that are already marginalized. When antiabortion lawmakers endow fertilized eggs with personhood rights, they seek to ban abortion and IVF and threaten contraception. As legal personhood advances, more pregnant people can face criminal charges for any conceivable risk to their pregnancies, or even to a fertilized egg before implantation.[34] This is not hyperbole. Our clients are living this reality right now.

Indeed, Alabama may have passed legislation theoretically protecting IVF,[35] but IVF is still vulnerable in the state. The legislation states that "no action, suit, or criminal prosecution for the damage to or death of an embryo shall be brought or maintained against any individual or entity when providing or receiving services related to in vitro fertilization," but it does not address or refute the idea that an embryo is a person.[36] It is also unclear if the legislation will survive legal challenges; a state constitutional amendment passed in 2018 reads, "[t]his state acknowledges, declares, and affirms that it is the public policy of this state to recognize and support the sanctity of unborn life and the rights of unborn children, including the right to life,"[37] and the Alabama Supreme Court relied, at least in part, on that constitutional amendment in its decision finding that embryos are people.[38] The IVF legislation is also exclusively centered around immunity for providers and patients, but it does not address when patients cease being patients, such that they may face liability for destroying embryos years after their IVF treatments have ended.[39]

Additionally, even if IVF in Alabama is fully protected, IVF patients and providers in other states are still at risk. Laws defining life beginning at conception and/or endowing fertilized eggs, embryos, and fetuses with full rights vary greatly state to state, and several laws make no mention of IVF and define "life" in such ways that could endanger the procedure.[40] And the federal Life at Conception Act, if ever adopted, would risk creating the conditions now seen in Alabama on a national scale—banning abortion, threatening the right to IVF, endangering access to birth control, and expanding the government's ability to police pregnant people and criminalize pregnancy and pregnancy outcomes.[41]

In the face of these attacks, and the crisis we are facing, we must remember that women and pregnant people are and must be treated as fully autonomous, rights-bearing persons who are entitled to health care and bodily integrity, and who must be allowed to make their own decisions.

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[1] Throughout this testimony, Pregnancy Justice uses the terms "pregnant people" or "pregnant person" more frequently than "pregnant women." This is because in the face of "fetal personhood" it is important to exert the personhood of the people who are pregnant. This is also in recognition that not everyone who becomes pregnant identifies as a woman. At the same time, sexism based on the gender binary is a clear throughline in pregnancy criminalization cases, and the patriarchal desire to impose traditional gender roles on women must be acknowledged. In recognition of all of these complexities, we use the terms "pregnant person/people" and "pregnant woman/women."

[2] AMNESTY INTERNATIONAL, CRIMINALIZING PREGNANCY: POLICING PREGNANT WOMEN WHO USE DRUGS IN THE USA 5 (2017) (defining pregnancy criminalization as "[t]he process of attaching punishments or penalties to women for actions that are interpreted as harmful to their own pregnancies. This includes laws that punish actions during pregnancy that would not otherwise be made criminal or punishable. It also refers to other laws not specific to pregnancy but which are either applied in a discriminatory way against pregnant women and/or have a disproportionate impact on pregnant women which can in practice work as de facto criminalization").
[3] PURVAJA S. KAVATTUR ET AL., THE RISE OF PREGNANCY CRIMINALIZATION: A PREGNANCY JUSTICE REPORT 31–34 (2023).
[4] *See, e.g.*, Claretta Bellamy, *Black woman charged after miscarrying in bathroom shares feelings about arrest*, NBC NEWS (Jan. 26, 2024, 4:49 PM), https://www.nbcnews.com/news/nbcblk/brittany-watts-miscarriage-bathroom-charged-rcna135861.
[5] Lynn M. Paltrow & Jeanne Flavin, *Arrests of and Forced Interventions on Pregnant Women in the United States, 1973-2005: Implications for Women's Legal Status and Public Health*, 38 J. HEALTH POL., POL'Y & L. 299 (2013); PURVAJA S. KAVATTUR ET AL., THE RISE OF PREGNANCY CRIMINALIZATION: A PREGNANCY JUSTICE REPORT (2023).
[6] KAVATTUR ET AL. at 4.
[7] *Id.*
[8] *Id.* at 2.
[9] *See, e.g.*, Laura Bassett, *Colorado and North Dakota Voters Reject Fetal Personhood Measures*, HUFFPOST (Nov. 4, 2014, 10:14 PM), https://www.huffpost.com/entry/personhood-colorado_n_6104120; Dahlia Ward McManus, *Voters to Personhood: Stick a Fork In it. You're Done.*, ACLU (Aug. 30, 2012), https://www.aclu.org/news/reproductive-freedom/voters-personhood-stick-fork-it-youre-done (detailing failed efforts to establish fetal personhood in Oklahoma, Ohio, Oregon, Mississippi, Montana, Nevada, Arkansas, Florida, California, Alabama, Georgia, Iowa, South Carolina, Washington, and Wisconsin).
[10] Frank James, *Mississippi Voters Reject Personhood Amendment By Wide Margin*, NPR (Nov. 8, 2011, 11:28 PM), https://www.npr.org/sections/itsallpolitics/2011/11/08/142159280/mississippi-voters-reject-personhood-amendment#:~:text=The%20Mississippi%20%22personhood%22%20amendment%20on,41%20percent%20voting%20%22yes.%22.
[11] PREGNANCY JUSTICE, WHEN FETUSES GAIN PERSONHOOD: UNDERSTANDING THE IMPACT ON IVF, CONTRACEPTION, MEDICAL TREATMENT, CRIMINAL LAW, CHILD SUPPORT, AND BEYOND 3 (2022).
[12] *Roe v. Wade*, 410 U.S. 113, 158 (1973), *overruled by Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022).
[13] *Id.* at 161.
[14] *Id.* at 153.
[15] *Id.* at 162.
[16] ALA. CODE § 26-15-3.2.
[17] *Ex parte Ankrom*, 152 So. 3d 397 (Ala. 2013).
[18] KAVATTUR ET AL. at 4, 20.
[19] *State v. Green*, 474 P.3d 886 (Okla. 2020); *Whitner v. State*, 492 S.E.2d 777 (S.C. 1997).
[20] KAVATTUR ET AL. at 4.
[21] *See, e.g.*, Rebecca Stone, *Pregnant women and substance use: fear, stigma, and barriers to care*, HEALTH JUST., 2015 Feb 12;3:2. doi: 10.1186/s40352-015-0015-5. PMCID: PMC5151516; Meghan Boone & Benjamin J. McMichael, *State-Created Fetal Harm*, 109 GEO. L.J. 475 (2021).
[22] 2023 MARCH OF DIMES REPORT CARD FOR UNITED STATES (2023), https://www.marchofdimes.org/peristats/reports/united-states/report-card; Katie Kindelan, *Maternal and infant care in 'crisis' in US, new report finds*, ABC NEWS (Nov. 16, 2023, 7:06 AM), https://abcnews.go.com/GMA/Wellness/us-earns-grade-preterm-birth-maternal-infant-care/story?id=104909605 ("This year's report shows the state of infant and maternal health in the United States remains at crisis-level, with grave disparities that continue to widen the health equity gap.").
[23] CTRS. FOR DISEASE CONTROL & PREVENTION, MATERNAL DEATHS AND MORTALITY RATES: EACH STATE, THE DISTRICT OF COLUMBIA, UNITED STATES, 2018-2021, https://www.cdc.gov/nchs/maternal-mortality/MMR-2018-2021-State-Data.pdf.
[24] *Id.*
[25] 2023 MARCH OF DIMES REPORT CARD FOR ALABAMA (2023), https://www.peridev.marchofdimes.org/peristats/reports/alabama/report-card (giving Alabama a F because of its high rate of preterm birth and infant mortality).

[26] Nina Martin & Amy Yurkanin, *Special report: Alabama leads nation in turning pregnant women into felons*, PROPUBLICA & AL.COM (Sept. 23, 2015, 9:00 AM), https://www.al.com/news/2015/09/when_the_womb_is_a_crime_scene.html#incart_special-report.
[27] ALA. DEP'T OF PUB. HEALTH BUREAU OF FAM. HEALTH SERVS., ALABAMA MATERNAL MORTALITY REVIEW REPORT FOR 2018 – 2019 (2023), https://www.alabamapublichealth.gov/perinatal/assets/2018-2019_annual_mmr.pdf (recommending that Alabama "[]eliminate the chemical endangerment law so that women will seek care when pregnant and promote voluntary treatment").
[28] *See, e.g.*, Rebecca Stone, *Pregnant women and substance use: fear, stigma, and barriers to care*, HEALTH JUST., 2015 Feb 12;3:2. doi: 10.1186/s40352-015-0015-5. PMCID: PMC5151516; Meghan Boone & Benjamin J. McMichael, *State-Created Fetal Harm*, 109 GEO. L.J. 475 (2021).
[29] PREGNANCY JUSTICE, MEDICAL AND PUBLIC HEALTH GROUP STATEMENTS OPPOSING PROSECUTION AND PUNISHMENT OF PREGNANT PEOPLE (updated June 2023).
[30] PREGNANCY JUSTICE, WHO DO FETAL HOMICIDE LAWS PROTECT? AN ANALYSIS FOR A POST-ROE AMERICA 2 (Aug. 16, 2022).
[31] Heather Grey, *Homicide is Top Cause of Death During Pregnancy*, HEALTHLINE (Oct. 27, 2022), https://www.healthline.com/health-news/homicide-is-top-cause-of-death-during-pregnancy.
[32] Amna Nawaz & Shoshana Dubnow, *The link between a lack of reproductive rights and domestic violence*, PBS (Jul. 14, 2023, 6:45 PM), https://www.pbs.org/newshour/show/the-link-between-a-lack-of-reproductive-rights-and-domestic-violence.
[33] Maryn McKenna, *States with Abortion Bans Are Losing a Generation of Ob-Gyns*, WIRED (Jun. 20, 2023, 6:00 AM), https://www.wired.com/story/states-with-abortion-bans-are-losing-a-generation-of-ob-gyns/.
[34] PREGNANCY JUSTICE, WHEN FETUSES GAIN PERSONHOOD: UNDERSTANDING THE IMPACT ON IVF, CONTRACEPTION, MEDICAL TREATMENT, CRIMINAL LAW, CHILD SUPPORT, AND BEYOND (2022).
[35] S.B. 159, 2024 Leg., Reg. Sess. (Ala. 2024).
[36] *Id.*
[37] ALA. CONST. art. I, § 36.06.
[38] *LePage v. Ctr. for Reprod. Med., P.C.*, No. SC-2022-0515, 2024 WL 656591, at *8 (Ala. Feb. 16, 2024) ("Here, the text of the Wrongful Death of a Minor Act is sweeping and unqualified. It applies to all children, born and unborn, without limitation. It is not the role of this Court to craft a new limitation based on our own view of what is or is not wise public policy. That is especially true where, as here, the People of this State have adopted a Constitutional amendment directly aimed at stopping courts from excluding 'unborn life' from legal protection.").
[39] Jan Hoffman, *Alabama's I.V.F. Protection Law Will Reopen Clinics But Curb Patient Rights*, N.Y TIMES (Mar. 26, 2024), https://www.nytimes.com/2024/03/06/health/ivf-law-alabama.html.
[40] For example, Oklahoma's wrongful death statute, OKLA. STAT. ANN. Tit. 12, § 1053, includes "the death of an unborn person as defined in Section 1-730 of Title 63 of the Oklahoma Statutes." OKLA. STAT. ANN. Tit. 63, § 1-730 defines "unborn child" or "unborn person" as "the unborn offspring of human beings from the moment of conception, through pregnancy, and until live birth including the human conceptus, zygote, morula, blastocyst, embryo and fetus," which means a wrongful death suit could theoretically be brought for the destruction of an embryo through the normal course of IVF. The South Dakota criminal code defines "unborn child" as "an individual organism of the species homo sapiens from fertilization until live birth," S.D. CODIFIED LAWS § 22-1-2, and South Dakota's homicide statute encompasses the death of an unborn child, S.D. CODIFIED LAWS § 22-16-4, which could theoretically reach the destruction of embryos. South Dakota's wrongful death statute, S.D. CODIFIED LAWS § 21-5-1, has also been construed by some South Dakota courts to include fetuses, *see, e.g.*, *Wiersma v. Maple Leaf Farms*, 543 N.W.2d 787 (S.D. 1996), and is unclear about whether it could be construed to include embryos. Missouri's code generally states that "[t]he life of each human being begins at conception" and that "the laws of this state shall be interpreted and construed to acknowledge on behalf of the unborn child at every stage of development, all the rights, privileges, and immunities available to other persons, citizens, and residents of this state." MO. REV. STAT. § 1.205. The Missouri code does not have obvious exemptions or protections for IVF.
[41] Life at Conception Act, H.R. 421, 118th Cong. (2023).

United States Senate Committee on the Judiciary

Testimony of

# O. Carter Snead

Charles E. Rice Professor of Law
Concurrent Professor of Political Science
Director, de Nicola Center for Ethics and Culture
University of Notre Dame

March 20, 2024

Good afternoon, Chairman Durbin and Senator Graham, and thank you for inviting me to testify before you today.

When the Supreme Court decided in *Dobbs* that the Constitution does not preclude the people from governing themselves on the fraught question of abortion, it brought us into alignment with most nations around the world who have always addressed the issue through the political branches (most of whom restrict purely elective abortion between 10 and 14 weeks of pregnancy).

After nearly fifty years of being deprived of the authority to meaningfully govern ourselves in this domain, the current political and legal landscape is widely varied, complicated, and a work in progress. But our system of federalism allows for divergent approaches to vexed questions. Some states have enacted strict limits on abortion whereas others have dramatically increased access. Voters have supported abortion rights in every state referendum since *Dobbs*, going so far in Montana as to reject a proposed law protecting newborns who survive abortions. A similar proposal was rejected by this body.

I would like to respectfully make three suggestions for good governance in this difficult area.

First, it is important to be clear about the complexity of the issue. It is not simply a variation of the health care debate, or even reducible to the important values of equality or bodily autonomy of women facing serious burdens on their health and future. Rather, the issue challenges us to consider how these goods stand in relation to the life of the unborn child – a whole, living, distinct member of the human species who, if all goes well, will move herself along the trajectory of development from embryo to fetus to newborn, provided she has the necessary support and sustenance

in her mother's womb – the first place of belonging for every human being. She is not a trespassing stranger; she is the biological child of this particular mother.

Our public debate is impoverished when those who support abortion rights fail to acknowledge, much less respond to this reality. On the other hand, our discourse suffers when pro-life elected officials fail to acknowledge and seek to alleviate the sometimes crushing burdens of unwanted pregnancy and parenthood. To govern ourselves wisely, justly, and humanely, we must begin by articulating the problem before us in its full complexity, without question begging.

Second, we must fairly and accurately characterize the legal landscape. Here too, we have fallen short. A recent Alabama case has been widely misdescribed as a theocratic power grab heralding the demise of IVF. In fact, the victorious plaintiffs there were IVF patients suing a clinic for the negligent destruction of their frozen embryos, using a statute that already allowed such claims for the death of embryos in the womb. In response, the conservative legislature and governor moved immediately to grant blanket civil and criminal immunity to IVF clinics for such misconduct.

Popular accounts of women in Texas being denied life-saving medical care are similarly lacking. Texas abortion law allows exceptions to protect a mother's life or prevent her substantial bodily impairment. But many of these cases involved women seeking abortions because their *unborn child* was the one to receive a heartbreaking diagnosis of disability or terminal illness. Texas does not authorize abortions because of an unborn baby's disability or poor prognosis.

Regarding risks to mothers, Texas just passed a bipartisan law stating that previable premature rupture of membranes and ectopic pregnancies fall under the health exception. The same goes for miscarriage management. The Texas Supreme Court just clarified that serious health risks need not be imminent to justify abortion. And the "reasonable medical judgment" standard for clinicians invoking such exceptions has been in place without issue since the passage of Texas' 20-week abortion ban in 2013. Since then, there have been 238 abortions performed at 20 weeks or later with zero prosecutions. This week the Texas Medical Board will meet to develop clinical guidelines in this area.

Finally, I would invite the members to reimagine the framing of the human context in which the question of abortion arises. Instead of a zero-sum conflict among strangers over the permissible use of lethal force, think of it instead as a crisis facing a mother and her child. Then ask how we can work together across our differences to come to their aid not just during pregnancy, but throughout life's journey.

**Testimony of Dr. Monique Chireau Wubbenhorst, M.D., M.P.H., FACOG, FAHA**

**Hearing before the**

**Senate Committee on the Judiciary**

**"The Continued Assault on Reproductive Freedoms in a Post-Dobbs America"**

**Wednesday, March 20, 2024**

**Dirksen Senate Office Building, Room G50**

**2:30 p.m.**

Chair Durbin, Ranking Member Graham, and members of the Committee:

Thank you for the opportunity to testify at this hearing. It is an honor to be here. My name is Dr. Monique Wubbenhorst, and I am a practicing board-certified obstetrician-gynecologist with more than 30 years' experience in patient care, teaching, research, health policy and global health. In my clinical career, I have focused on providing obstetric and gynecological care for underserved and disadvantaged populations in both domestic and international settings. For example, I have cared for women in such places as rural North Carolina, inner city Boston, Native American reservations, as well as women in India, Nepal, the Philippines, Kazakhstan, Ghana, Cameroon, South Sudan and most recently Kenya. I have chaired the Women and Special Populations Committee for the American Heart Association and worked as a senior consultant to the United States Veterans Administration, and was on the faculty of Duke University School of Medicine. Subsequently I was recruited by the United States Agency for International Development to a senior executive position focusing on global health programs and policy, prior to assuming my current role at the de Nicola Center for Ethics and Culture at the University of Notre Dame. I have authored over twenty peer-reviewed publications and been a member of review boards for several peer-reviewed journals, including *The British Journal of Obstetrics and Gynecology, Public Health, The Journal of Medical Ethics, PLOS 1, Journal of General Internal Medicine, Issues in Law and Medicine, Journal of Medical Ethics, and The North Carolina Medical Journal*. My research interests include the epidemiology and management of adverse pregnancy outcomes; adverse pregnancy outcomes and long-term cardiovascular health; the molecular biology of adverse pregnancy outcomes;

reproductive health; health services research; racial-ethnic disparities in women's health; women veteran's health; global health; and ethics in reproductive health. I currently practice OB/GYN in Indiana.

Following the Dobbs decision, which returned decision-making regarding abortion to the people of the United States and their elected representatives, there have been many changes and many opportunities to mitigate abortion's harms to women, their children and their communities. Abortion not only poses risks to the mother, it is always lethal to an unborn child. As the number of children who are aborted has decreased, the number of births in states such as Texas and Mississippi has increased, reversing a longstanding decline in fertility in the United States. Our current fertility rate is 1.7, well below replacement (which is 2.1). Future economic growth and national stability depend on healthy population growth by a country's citizenry.

The above-mentioned changes have also resulted in vigorous debate on various topics related to abortion and the humanity of the embryo, the unborn child. For example, there has been significant focus on abortion of disabled fetuses. In particular, there has been a great deal of discussion regarding such fetal anomalies as Trisomy 18 and anencephaly.

**The unborn child is a human being.** At the heart of this debate is whether the unborn child is a human being. Science clearly demonstrates that the unborn child is human. First, at conception, a human female gamete (the egg) and a human male gamete (the sperm), each with 23 chromosomes, combines to form a unique, new human being, a zygote with 46 chromosomes whose DNA is different from that of the parents. The zygote, and then the embryo and fetus, are human because they have unique human DNA and have been conceived by 2 human parents. The zygote is a separate, unique human being, not a part of the mother's body. All mothers are female with two XX sex chromosomes, but approximately half of their children are male, with an X and a Y chromosome. Mothers and babies often have different blood types. An unborn child's DNA is different, in every cell of their body, from that of the mother. The unborn child is therefore not a part of the mother's body, in the way that her heart or her pancreas are; he or she is a unique human being, in a unique relationship with his or her mother. There is scientific consensus that the zygote, embryo and fetus are human. For example:

1. Langman, Jan. *Medical Embryology*. 3rd edition. Baltimore: Williams and Wilkins, 1975, p. 3:

"The development of a human being begins with fertilization, a process by which two highly specialized cells, the spermatozoon from the male and the oocyte from the female, unite to give rise to a new organism, the zygote."

2. Thibodeau, G.A., and Anthony, C.P., *Structure and Function of the Body*, 8th edition, St. Louis: Times Mirror/Mosby College Publishers, St. Louis, 1988. pages 409-419:

"The science of the development of the individual before birth is called embryology. It is the story of miracles, describing the means by which a single microscopic cell is transformed into a complex human being. Genetically the zygote is complete. It represents a new single celled individual."

3. Ronan R. O'Rahilly, Fabiola Muller, *Human Embryology & Teratology*, , (New York: Wiley-Liss, 1996), 5-55:

"Fertilization is an important landmark because, under ordinary circumstances, a new, genetically distinct human organism is thereby formed... Fertilization is the procession of events that begins when a spermatozoon makes contact with a secondary oocyte or its investments... The zygote ... is a unicellular embryo..."

4. *The Developing Human: Clinically Oriented Embryology*, 6th ed. Keith L. Moore, Ph.D. & T.V.N. Persaud, Md., (Philadelphia: W.B. Saunders Company, 1998), 2-18:

"[The Zygote] results from the union of an oocyte and a sperm. A zygote is the beginning of a new human being. Human development begins at fertilization, the process during which a male gamete or sperm ... unites with a female gamete or oocyte ... to form a single cell called a zygote. This highly specialized, totipotent cell marks the beginning of each of us as a unique individual."

5. Keith L. Moore, *Before We Are Born: Essentials of Embryology*, 7th edition. Philadelphia, PA: Saunders, 2008, p. 2:

"[The zygote], formed by the union of an oocyte and a sperm, is the beginning of a new human being."

At the same Senate Judiciary Committee hearing mentioned above, scientific experts provided the following testimony regarding the humanity of the human zygote, embryo and fetus:

Dr. Alfred Bongiovanni, Professor of Pediatrics and Obstetrics, University of Pennsylvania School of Medicine, concluded:
"I am no more prepared to say that these early stages represent an incomplete human being than I would be to say that the child prior to the dramatic effects of puberty ... is not a human being....I have learned from my earliest medical education that human life begins at the time of conception."

Gordon, Hymie, M.D., F.R.C.P., Chairman of Medical Genetics, Mayo Clinic, Rochester:
"By all criteria of modern molecular biology, life is present from the moment of conception...Science has a very simple conception of man; as soon as he has been conceived, a man is a man."

C. Christopher Hook, M.D. Oncologist, Mayo Clinic, Director of Ethics Education, Mayo Graduate School of Medicine:
"When fertilization is complete, a unique genetic human entity exists."

Dr. McCarthy de Mere, medical doctor and law professor, University of Tennessee, testified:
"The exact moment of the beginning of personhood and of the human body is at the moment of conception."

The official Senate report from the 1981 Senate Judiciary Committee reached this conclusion: "Physicians, biologists, and other scientists agree that conception marks the beginning of the life of a human being - a being that is alive and is a member of the human species. There is overwhelming agreement on this point in countless medical, biological, and scientific writings."

It seems self-evident that an unborn child is human. As noted in the *Dobbs* decision, "When parents see the embryo on ultrasound, they recognize that this is their son or daughter"[1]. The unborn child is human, not a part of a woman's body; "...the zygote does not itself serve a functional role in the biological economy of either parent; it is a separate organism...its growth and development is...determined from within. It contains within itself the "genetic programming"...to

direct its own biological progress. It possesses the active capacity for self-development toward maturity using the information it carries"[4].

The unborn child is also not any other type of life. Human embryos and fetuses are demonstrably members of the human family. "A human embryo is not something different from a human being, like a rock, or a potato, or a rhinoceros. A human embryo is a whole living member of the species *Homo sapiens* in the earliest stages of his or her natural development...He or she is not an individual of some other or intermediate kind of species. Rather, the human zygote, embryo, or fetus is a human being at a certain stage of development..."[5].

From the above evidence, "...there can be little question concerning exactly what the early embryo is. The early embryo is a human being at the earliest stage of his or her development. Not "potential" human being or a "pre" human being, or a mass of cells, or mere tissue, but an individual member of the species Homo sapiens"[6].

**Human beings have rights at all stages of life.** It is clear, then, that the human zygote, embryo and fetus are human from conception to birth. It is also clear that "when someone destroys a human embryo, it is a human being that is killed. This is true of any embryo, from the end of fertilization on: every embryo is a human being; therefore, ending an embryo's life is ending a human being's life"[7]. Not only this, but embryos and fetuses, unborn human beings, are the smallest, weakest, most defenseless and consequently most vulnerable members of the human family. Embryos and fetuses are human, "human beings as such as persons worthy of fundamental moral respect, and subjects of fundamental human rights"[8].

One of those rights is the right to life. No human being can exercise any of his or her other rights if they are never born. Neither can a human being exercise any right that disadvantages the inalienable rights of another human being. Yet disabled unborn children, as well as those who are "unwanted", are subject to abortion, even though they are human and deserving of special protection.

The so-called right to abortion has been supported by the assertion that "abortion is safer than childbirth". We can trace this to papers by Grimes (2006 and 2012) which were published in leading OB/GYN journals, and which reiterated earlier, similarly inaccurate claims. Studies making the claim that abortion is safer than childbirth contain statistical and methodological errors, they do

not acknowledge that all pregnancy outcomes are not equivalent, do not address incorrect denominators, data limitations and faulty comparisons; and omit a breakdown of maternal mortality by gestational age at the time of the abortion. Further, they do not take into account the biology of fetal and uterine development and adaptation or the epidemiology of spontaneous abortion, induced abortion and term delivery.

When induced abortion mortality is compared to spontaneous abortion- and childbirth-related mortality in the proper context of gestational age and the biology of pregnancy, abortion does not appear to be safer than childbirth or spontaneous abortion. At higher gestational ages, comparatively, the risk for death from abortion appears to be greater than that from childbirth. Indeed, the risk for mortality – not morbidity, i.e. complications and injuries – from abortion increases exponentially by 38% for each week of increasing gestational age. Bartlett et al (Bartlett L, Berg C, Shulman M, Zane S, Green C, Whitehead S, Atrash H. Risk Factors for Legal Induced Abortion–Related Mortality in the United States. *Obstet Gynecol* 2004,103:729 –37) found that the risk for mortality from abortion increased exponentially by 38% with each week of gestation. This is not true for pregnancy.

The increased risk for mortality with increasing gestational age is worse for black women. These authors also found that "The second most significant risk factor for death [from abortion, after gestational age] overall was race. Women of black and other races were 2.4 times as likely as white women to die of complications of abortion . . . At all gestational ages, women of black and other races had higher case mortality rates than white women."

**Abortion is associated with harms to women.** Abortion not only poses risks to the mother, it is always lethal to an unborn child, and approximately half of those unborn children are female. Most abortions are elective. Because elective abortions are not performed out of medical necessity, the bar for safety should be very high. There is evidence that the safety of both surgical and medical abortion is overstated.

First trimester medication abortion carries substantial risks to the mother. A study by Niimaki et al used data from Finland's health service administrative database, which included all women in Finland undergoing abortion from 2000 to 2006 (42,619 women) and collected follow up data for 42 days post abortion (Niinimäki M, Pouta A, MD, Bloigu A, Gissler M, Hemminki E, Suhonen S, Heikinheimo O. Immediate Complications After Medical Compared With Surgical Termination of

Pregnancy. *Obstet Gynecol* 2009;114:795–804). This study design captured all outcomes for all women undergoing abortion in an entire country over a longer period of time than most studies of abortion complications. As a result, it is free of methodological problems and bias that plague other studies of abortion, including those conducted in the United States.

An example of the sort of methodological problems inherent in most studies of abortion can be seen in the study by Upadhyay et al. (Ushma D. Upadhyay, Sheila Desai, Vera Zlidar, Tracy A. Weitz, Daniel Grossman, Patricia Anderson, Diana Taylor. Incidence of emergency department visits and complications after abortion. Obstet Gynecol 2015;125:175–83). This study has many limitations, similar to other retrospective administrative database research studies. These include potential confounding associated with inaccurate coding; the absence of clinical data, especially on gestational age at the time of abortion and method of abortion; and the likelihood that women with complications did not engage with the medical system. As with many studies of this type, no charts were reviewed. There was very limited follow up. The authors acknowledge some of these issues and note as well that, for example, second trimester abortion complications in their study were lower than in other studies, suggesting that their population may not be representative, or that cases were incompletely ascertained.

In the study by Niimaki et al researchers found that 20% of women underwent medical abortion, and 5.6% underwent surgical abortion, stating that "The overall incidence of adverse events was fourfold higher in the medical compared with the surgical abortion cohort. The risk of hemorrhage with medical abortion was 15.6%, and 2.1% with surgical abortion. The risk of incomplete abortion with medical abortion was 6.7%, and 1.6% with surgical abortion. The risk of emergency surgery with medical abortion was 5.9% with medical abortion, and 1.8% with surgical abortion". In this study, women undergoing medical abortion had 8 times the risk for hemorrhage from medical abortions compared to those undergoing surgical abortion. They had 5 times the risk for a curettage to remove retained placenta or fetal parts and 4.2 times the risk for an adverse event compared to those undergoing surgical abortion. Other studies have confirmed the increased risk of hemorrhage with medical abortion.

First trimester surgical abortion carries immediate risks of hemorrhage, infection, continuing pregnancy, death, perforation of the uterus, damage to organs including hysterectomy. These complications are described in the National Abortion Federation 2020 Clinical Policy Guidelines for

Abortion Care. All of these findings have significant implications given the increased use of medical abortion.

Rates of complications associated with second trimester abortion are higher than for first trimester abortion. For example, Turok et al (Turok D, Gurtcheff SE, Esplina MS, Shahb M, Simonsena SE, Trausch-Van Horn J, Silvera RM. Second trimester termination of pregnancy: a review by site and procedure type. Contraception 77 (2008), pp. 155–161) studied differences in complications between second trimester abortions performed in 475 women, in hospitals vs. free-standing clinics. The authors found that major complications (defined as death, uterine perforation, hysterectomy, transfusion, clotting disorders, deep venous thrombosis, pulmonary embolus, stroke or heart attack, need for exploratory surgery, and prolonged hospitalization) occurred in 11% of women undergoing hospital D&E, 10% of women undergoing hospital induction of abortion, and 1% of women undergoing abortion in clinics (though there were no deaths in study participants).

Other complications included: need for readmission (24% in the hospital D&E group, 1% in the clinic D&E group, and 16% in the hospital induction group); need for curettage after abortion for retained placenta and/or fetal parts (0% in the hospital D&E group, 1% in the clinic D&E group, and 28% in the hospital induction group); infection of the fetal membranes after initiation of the procedure (1% in the hospital D&E group, 0% in the clinic D&E group, and 6% in the hospital induction group); and uterine infection (1% in the hospital D&E group, 4% in the clinic D&E group, and 5% in the hospital induction group). Of note, those women undergoing abortion or pregnancy termination in-hospital had more medical problems, were further along in pregnancy (higher gestational ages) and were more likely to be undergoing non-abortive pregnancy termination for fetal death in utero than those seen in the clinic. The authors also note that complications may have been underreported due to loss to follow-up.

Edlow et al. (Edlow AG, Hour MY, Maurer R, Benson C, Delli-Bovi L, Goldberg A. Uterine evacuation for second-trimester fetal death and maternal morbidity. *Obstet Gynecol* 2011;117:307–16) noted that "[higher] gestational age was significantly associated with maternal morbidity", with women undergoing abortion at > 20 weeks' being 2 ½ times more likely to suffer a complication than women undergoing abortion at < 20 weeks' gestation.

Lederle et al. (Lederle L, Steinauer JE, Montgomery A, Aksel S, Drey E, Kerns JL. Obesity as a Risk Factor for Complication After Second-Trimester Abortion by Dilation and Evacuation. Obstetrics

and Gynecology 2015 September; 126(3): 585–592) found a 30% increased risk for complications with each additional week of gestation.

There are many claims related to abortion that on closer scrutiny, are not supported by data. For example, it is stated that increasing contraception and sex education will decrease the abortion rate. Yet England, France and the United States have extremely high contraceptive prevalence, yet also have high rates of abortion. Induced abortion also does not decrease maternal mortality. Countries with highly restrictive laws at present or in the past (such as Chile, Malta and Ireland) have or have had extremely low rates of maternal mortality. In addition, African American women have the highest rates of abortion, and also the highest maternal mortality. Both cannot be true if abortion decreases maternal mortality.

"Reproductive rights" are not human rights, because they "disappear" the fetus, who is human. Human rights are not conferred by the state; if the state conferred them, then the state could take them away. Rather, such inalienable rights are inherent to being human. The so-called right to abortion does not exist because it requires the violent destruction of a human being, thereby violating their rights.

The unborn child is never the subject of such discussions of rights. So-called "reproductive justice" is in fact reproductive *injustice*, because it destroys black and brown babies, who are 100% of the future of their ethnic groups. The same eugenic mindset that led to the sterilization of African American, Native American and Hispanic women continues in the disproportionate rates of abortion in black women, and rising rate of abortion in Hispanic women. Racial-ethnic disparities in abortion receive enormous attention. But when it comes to racial-ethnic disparities in abortion, which are putting tremendous pressure on the African American population, and are the prevalent cause of the decline in African American births, there is silence from leaders, activists and the scientific community.

The issue of the humanity of the unborn child is also a topic of debate related to *in vitro* fertilization (IVF). In 2022, three infertile couples filed a wrongful death suit in Alabama because their frozen embryos were destroyed by a patient at the adjoining hospital who gained unauthorized access to the embryos. The families could have filed a property suit, but specifically chose to file for the wrongful death of their unborn children. On February 16th, 2024, the Alabama Supreme Court issued an opinion allowing the couples to seek compensation for the wrongful death of their

embryos under Alabama's Wrongful Death of a Minor Act. This ruling set up a national discussion about in vitro fertilization (IVF). Unfortunately, much of the reporting on the subject incorrectly equates embryo protection with prohibitions on IVF.

The ruling correctly assigns value to the embryo. The ruling does not prohibit IVF. It speaks only to whether embryos should be destroyed. Louisiana, for example, has both allowed IVF and provided protection for embryos as people, not property, since 1986. Embryos are unique human beings who deserve to be respected and treated ethically. This court ruling allows for embryos to be treated with the highest level of respect and care. The plaintiffs in this case were couples who used IVF for their families. These families chose to seek justice for their destroyed embryos by suing for wrongful death of their unborn children. They knew there was something special about their embryos. This has been understood and recognized, for example in the heroic efforts by first responders to save embryos on the upper floors of a hospital flooded by Hurricane Katrina. These men and women would not have risked their lives if they were not trying to save lives.

Recognizing the biological fact that embryos are distinct human organisms with their own DNA creates an incentive to avoid the creation of excess embryos. This is an important point. As noted by Harvard Health Plan (Embryo donation: One possible path after IVF - Harvard Health):

> "If you became a parent through IVF and have remaining embryos, you are not alone. Estimates vary on the number of cryopreserved embryos in the United States, but it's likely to be in the hundreds of thousands. You may be among the many people or couples who plan to use their embryos, or among those whose family feels complete. And you may be starting to figure out what to do with your embryos, or you may be putting the decision on hold, paying for annual embryo storage and feeling no urgency to make a decision, since embryos can remain safely frozen for many years. **Having "extras" in deep freeze may offer comfort, kind of a psychological insurance policy after years of disappointment and loss.** Sooner or later, though, most people find themselves at a decision point, considering these options:
>
> **You can discard your remaining embryos**. This may feel harder than you anticipated but absolutely doable. You see these embryos as part of the IVF process that enabled you to have your cherished child or children. The word "discard" sounds harsh, but you are not prepared to parent another child and do not see donating them to others as an option.
>
> You can decide to have an additional child. A larger family wasn't what you'd planned on or hoped for, but you see extra embryos as part of IVF, and a new child as meant to be. You look at the family you have and decide it is worth undergoing at least one more embryo transfer before making a final decision to discard. You can decide to donate your embryos to science. Unfortunately, if you begin to explore this, you'll discover there is no easy route for it. Perhaps you will choose to explore other possible pathways, or decide to focus on one of the other options.

> **You can decide to donate your embryos to science.** Unfortunately, if you begin to explore this, you'll discover there is no easy route for it. Perhaps you will choose to explore other possible pathways, or decide to focus on one of the other options.
> **You can donate your embryos to another person or couple**. For some, this feels natural: you have been given the gift of children and you want to pay it forward to others longing for pregnancy and parenthood. However, for many the decision to donate does not feel easy or natural. Rather, it poses a huge dilemma: you want to honor the embryos and offer them a chance at life, but you have unsettled feelings when you think of your genetic offspring being raised by another family.
> **Not to decide is to decide**. In listing options, it is important to acknowledge that some of your fellow IVF parents are deciding not to decide. They are among the many who have "abandoned" their embryos (the term clinics use for families that avoid contact). **They stop paying their storage fees; they fail to respond to outreach calls and letters** [emphasis added]".

What happens to embryos whose parents abandon them? Is it not true that "donating embryos to science" constitutes human experimentation? Is preimplantation genetic testing, in fact, eugenics in its purest form? All of these questions show the moral and ethical dilemmas associated with IVF.

Some of these questions are summed up in the consent form for IVF. One such form states the following:

> "The option of preimplantation genetic testing...was discussed...We did discuss that sperm injection may be associated with an increased risk of sex chromosome abnormalities with most recent studies relating risk to intrinsic sperm issues. Risk of mosaic embryo was also discussed with special consideration of these embryos and genetic consult before possible transfer. Recommend transfer of all euploid embryos [those with normal chromosomes] before possible transfer of mosaic embryo due to increased risk of miscarriage or failed cycle with mosaic embryo transfer.
>
> We reviewed our desire to limit the number of embryos transferred to minimize the risk of multiple gestation. The potential complications arising from multiple gestation were reviewed including: low birth weight, prematurity, pulmonary, gastrointestinal and visual complications. The greatly increased risk of cerebral palsy was reviewed. Reviewed the possible risk of an IVF cycle including: ovarian hyperstimulation syndrome (OHSS), multiple gestation and complications from oocyte retrieval. However, we also discussed the overall strategy of IVF is to obtain many eggs for insemination...a percentage of the eggs will not be mature...approximately twenty percent of eggs will not fertilize, and approximately half of the fertilized eggs will stop developing prior to transfer or freeze....only a portion of the developing embryos are likely to be graded of high quality and have a reasonable likelihood of implantation...".

This consent form documents some of the risks associated with IVF, and also how the "highest quality embryos" are selected.

Louisiana and Germany have established ethics and safety standards for IVF that prevent embryo destruction. In Louisiana, per the most recently available CDC data (2021), there were approximately 1500 embryo transfers and over 700 live births in Louisiana. And, according to one fertility doctor, there are around 1,000 babies born through IVF in Louisiana each year. For comparison, the same CDC data reported only 966 embryo transfers and 437 live births in the state of Alabama. It is not IVF that is at issue, but rather whether embryos should be destroyed. People can be in favor of IVF without agreeing with the destruction of embryos.

Embryo destruction can be addressed by reducing the creation of excess embryos. For example, since 1990, Germany has had in law "The Embryo Protection Act." The Act regulates for what purpose and in what way embryos may be handled:

- In procedures, the number of fertilized ovum cells that mature into embryos in the laboratories may not exceed that of those that are transferred to the woman during a treatment attempt.
- No more than three embryos may be stored per treatment attempt.
- Sex selection is prohibited.
- Embryonic research is prohibited.

The IVF industry is highly profitable. Costs for an individual cycle range from $15,000 to more than $30,000, and the industry has been described as "the Wild West" (UVA Law Professor Examines the 'Wild West' of the Fertility Industry | UVA Today (virginia.edu); Fertility Industry Is a Wild West - NYTimes.com). IVF is associated with risks, including low birthweight, preterm birth, hypertension in pregnancy, placental complications, postpartum hemorrhage, increased rates of cesarean delivery, and ovarian hyperstimulation syndrome, as well as autism spectrum disorders (https://www.news-medical.net/news/20231121/Association-between-infertility-and-autism-spectrum-disorder-risk-among-children.aspx).

Anyone who knows, or has a family member, or who has cared for parents undergoing IVF can testify to the enormous mental, emotional and financial costs and burdens of this intervention. Prospective parents are willing to undergo these costs and associated risks because they want to build their families. But are all aspects of the IVF process compassionate and just, especially to the children who are created, and to the women who undergo the risks? These are the questions that we must grapple with.

Another issue related to the dignity of the unborn is how we view, and treat, the fetus with anomalies. For example, Trisomy 18 is a chromosomal abnormality associated with fetal and newborn birth defects. However, in Japan, where intensive intervention is often provided for infants with Trisomy 13 and Trisomy 18, one-year survival rates approach 56% in some centers. In the United States, Nelson et al. noted that although one-year survival for infants with Trisomy 13 or 18 has been stated to be less than 10%, forty-one percent of hospital records for children with Trisomy 13 and 32% of records for children with Trisomy 18 were for children older than one year. In more than 10% of discharges, children were older than eight years. This suggests that the prognosis for this anomaly is not as grim as has been stated, and that life-affirming physicians will continue to push the boundaries for conditions that have formerly been described as lethal, to the benefit of these children and their parents who are often pushed to undergo abortion.

Another fetal anomaly, anencephaly, is a congenital neural tube defect that is estimated to occur in approximately 2/10,000 pregnancies, with very wide variation across countries. Spina bifida and anencephaly are the most common neural tube defects. Per CDC, anencephaly "is characterized by a total (holo) or partial (mero) absence of the brain with absence of the cranial vault (calvarium) and covering skin"[62]. Anencephaly is a NTD that results from a failure of the anterior (rostral) portion of the embryonic neural tube (anterior neuropore) to close properly" at around 25-27 days post-conception. While the brain begins to develop normally, because it is not covered by meninges and bone, exposure to amniotic fluid causes it to disintegrate. As a result, the skull, cerebellar and cerebral structures do not develop. Children with anencephaly lack portions of the skull (acrania), scalp and brain. Specifically, the cerebral cortex and cerebellum are almost absent. Anencephaly is part of a spectrum of brain and neural tube fetal anomalies that includes spina bifida.

**Diagnosis.** Anencephaly is diagnosed either using maternal serum alpha-fetoprotein (a prenatal blood test), or by ultrasound. The diagnosis is established using ultrasound in more than 95% of cases. However, some infants diagnosed with anencephaly are found after birth to have other, less lethal diagnoses. Per CDC as referenced above, anencephaly can be "confused with craniorachischisis, acrania or amniotic band syndrome. For this reason, a prenatal diagnosis of anencephaly should always be confirmed postnatally. When this is not possible (e.g. termination of pregnancy or unexamined fetal death), the program should have criteria in place to determine whether to accept or not accept a case based solely on prenatal data"[63].

But prenatal diagnosis is by definition presumptive. That is, until postmortem examination of the aborted fetus has been carried out, the prenatal diagnosis cannot be confirmed. Confirmation of a diagnosis of fetal abnormality is mandatory to identify false-positive cases and to attempt to reduce or eliminate their occurrence. Situations where an erroneous prenatal diagnosis results in abortion of a normal child are devastating to parents[64].As a quality measure, pathologists have studied whether the fragmentation of the fetal body caused by D&E hinders confirmatory postmortem examination. Struksnaes et al (2016) carried out a study correlating fetal ultrasound and autopsy findings in 1029 aborted fetuses. They noted a 1.3% false-positive rate and emphasized that "fetal autopsy remains a quality control of ultrasound findings resulting in TOP [termination of pregnancy]". What this study seemed to show, however, was that 1 out of 100 diagnoses of fetal abnormalities in aborted fetuses was incorrect, and that a normal fetus had been aborted[65]. This has been noted in the media as well (These Prenatal Tests Are Usually Wrong When Warning of Rare Disorders - The New York Times (nytimes.com)).

Boecking et al (2017) studied 448 fetuses aborted by D&E. They found that for 89 pregnancies, a decision was made to abort the unborn child due to ultrasound diagnosis of central nervous system (CNS) abnormalities. In 86% of these, postmortem correlation was prevented by fragmentation of brain tissue and spinal cord structures, including "all 110 intracerebral abnormalities", which would include anencephaly[66].

Several risk factors are known to be associated with anencephaly. These include obesity in the mother and elevated blood sugar (for example in diabetes), which increase the risk threefold. Exposure to antiseizure medications, high temperatures (for example saunas, or fever) and opioids increases the risk of neural tube defects. Per CDC, "The birth prevalence of NTDs (proportion of babies in the population born with an NTD) has decreased by 35% in the United States, since folic acid fortification was required in 1998...Mandatory folic acid fortification of cereal grain products has helped about 1,300 U.S. babies to be born without an NTD each year"[67]. Folic acid supplementation in prenatal vitamins as a public health measure, especially around the time of conception, could likely reduce rates of neural tube defects even further.

Several studies have reported on maternal risks and outcomes for women with an unborn child affected by anencephaly. Stumpf et al (The Medical Task Force on Anencephaly) state, with no citations or data presented, that "Labor and delivery are commonly associated with an unstable

fetal lie, dysfunctional labor (poor dilatation or dystocia [labor abnormalities], and postpartum hemorrhage"[68].

Ekmekci and Gencdal (2019) reported on 87 women who had children with anencephaly. They noted that the average age at which anencephaly was diagnosed was 18 weeks. 28 out of 87 patients chose to not abort their fetuses. 32% of births were stillbirths and 68% were live births. All died within the first week of life. 68% of patients gave birth vaginally. Of those who underwent cesarean delivery, 7 of 9 did so because of previous uterine surgery. Notably, 64% of patients underwent induction of labor, the reason for this was not given. 6 patients developed polyhydramnios. 2 patients had shoulder dystocia and one had postpartum hemorrhage. The authors also state that "shoulder dystocia is an expected complication" but the reference they provide does not support this statement[69].

However, because this was a descriptive study with no comparison group, other risk factors for shoulder dystocia and hemorrhage were not identified (including parity, maternal body mass index, maternal diabetes, fetal weight, gestational age, etc.). For these reasons, these results may not be generalizable to the population of pregnant women with an unborn child with anencephaly and do not appear to inform the literature on maternal complications with anencephaly.

Another study by Obeidi et al (2010) stated that "Common maternal complications reported include polyhydramnios, dysfunctional labor and postpartum hemorrhage"[70]. However, the citation given for this statement is listed as "Anonymous, 1990" ", and no reference with this title is provided in the literature cited.

The American College of Obstetrician-Gynecologists (ACOG) Practice Bulletin #187 on neural tube defects states that "Polyhydramnios can occur as a result of impaired fetal swallowing especially with anencephaly and higher-level spinal lesions and those lesions associated with aneuploidy, leading to uterine overdistention and increased risk of preterm contractions, umbilical cord prolapse, and placental abruption. Breech presentation is common at term with anencephaly and spina bifida"[71]. However, no studies are cited to support this statement. Polyhydramnios is a known and manageable complication of pregnancy, occurring with gestational diabetes and other clinical entities.

Jaquier *et al* performed a web-based survey of parents who had had children with anencephaly. She found that polyhydramnios (an excess accumulation of amniotic fluid) occurred in 27% of 211 pregnancies. Premature delivery was more common in the group with polyhydramnios. One mother had hypertension and one had hemorrhage. Cesarean delivery occurred in 26% of pregnancies. The authors note that "Many mothers asked for cesarean section with the aim of avoiding stillbirth"...Spontaneous vaginal delivery did not feel different to mothers who had previously delivered a healthy baby, contrary to the belief that delivery may be prolonged due to the small head". They concluded that "Contrary to common belief, only a small number of anencephalic fetuses died *in utero*. More than half of the babies were born at term, 10% even after term". This was a survey study and therefore also descriptive. The authors concluded that "Continuation of pregnancy after a diagnosis of anencephaly is medically safe and should be considered as an option"[72].

There appears to be a paucity of data, within the limits of this literature review, to indicate that complications such as hemorrhage, shoulder dystocia and dysfunctional labor are greatly increased in pregnancies where the unborn child has anencephaly. Polyhydramnios appears to be a common and treatable complication in pregnancies with an unborn child who has anencephaly, as it is in other clinical situations.

Information on the natural history of infants with anencephaly is important to accurately inform parents of their child's diagnosis. Most children with anencephaly die within the first month of life or less, but many survive longer especially when given medical care. Studies have documented prolonged survival for children with anencephaly.

In 1983 Baird et al published survival data from British Columbia for children born with anencephaly. They found that in contrast to the standard assumption that most of these newborns die within 24 hours, 42.5% "can be expected to survive longer than 24 hours...and of these, 35 percent will still be alive on the third day and 5 percent...on the seventh day...". In their series, one newborn lived for 2 weeks. They emphasized that "it is important to verify the diagnosis of anencephaly" since some survivors had been misdiagnosed, having instead less severe syndromes. These survival rates are of interest because the field of neonatology was in an early stage in 1983[73].

A 1993 study case report by McAbee et al noted two infants who survived for 7 and 10 months, respectively, without intensive medical support[74]. Dickman et al in 2016 presented a case report of prolonged unassisted survival in an infant with anencephaly who lived for 28 months[75].

In a review by Machado *et al* (2006) of 130 anencephalic children, 90% delivered vaginally and 10% delivered by cesarean delivery. 83% were born preterm. 38% of births were stillbirths. For the live births, postnatal length of survival was 1 minute to 48 hours. 67% of infants died within the first hour of life and 94% of infants died within 24 hours[76].

Jaquier et al (2006) found that of the 153 liveborn infants in their survey, 28% within 1 hour, 67% died within 24 hours, 25% within 2-5 days, 3% within 6-9 days, and 4% within 10-28 days. "The longest survivals were 10 days (four), 18 days (one) and 28 days (one)"[77].

Tolczyk and DeWitt (2022) cited studies reporting 100% mortality within the first weeks of life, with others reporting 100% mortality within the first year of life. The latter group often needed assistance to breathe with a ventilator. Their case report focused on an infant with anencephaly who survived at least 9 months with intensive medical intervention[78].

Additional media reports indicate survival for children with anencephaly of 3 years[79]; 3 years and 8 months[80] and one year and 8 months[81].

One of the most intriguing studies of a child with anencephaly, a boy, was entitled "Instincts and emotions in an anencephalic monster" and was carried out in 1949 and cited by Sekulic et al. This infant lived for 85 days. The diagnosis of anencephaly was confirmed by autopsy. This child's survival was remarkable in an era when neonatal care was rudimentary, antibiotics were not widely available, and understanding of newborn and infant physiology was limited[82]. We should not dismiss all of these cases as exceptional. They point to the possibility that with improved care, many more infants with anencephaly could survive.

But any such advances at current are impeded by perceptions about these children. They are described as grotesque, misshapen. In a culture that prizes beauty and "the perfect child", these children do not fit. Described as "monsters" as noted above, and uniformly assigned a bleak prognosis, they have not benefited from the same intensive research efforts and clinical care that are associated with improved outcomes in other children with severe and life-limiting disabilities.

The perception of children with anencephaly as subhuman or not-human likely hinders any efforts in this direction and results in parents being pushed to abort them. In fact, at present there is little information on survival of anencephalic infants, because so many are aborted.

Is the unborn child with anencephaly human? This critical question has been debated due to attempts to utilize newborns with anencephaly as a source of organs for transplant (see below). Like other unborn children and neonates, the child with anencephaly has human parents and human DNA. He or she came into existence after the fusion of two human gametes, the sperm and the egg. He or she is fully human, developing toward the adult form. The developmental accident that caused him or her to not develop a normal cerebellum and cerebrum does not make him or her a monster or subhuman, since we are human based on our being part of the human family, not because we lack certain characteristics. The only difference between children with anencephaly and those without is their disability. Berger notes in this regard that newborns with anencephaly are "living human beings"[83]. It has been pejoratively stated that children with anencephaly are "born dying". In fact, we are all born dying; from the time of our birth, we are on a journey that inexorably, and for everyone, moves toward and ends in death. Of course, the speed with which this process occurs varies, but again, the humanity of an individual or group of individuals does not depend on whether death is imminent. This argument, that the rights and dignity of human beings does not matter because they were going to die anyway, was used by the Nazis, and others as they attempted to justify horrific experiments on and abuse of their victims.

The dehumanization of children with anencephaly is widespread in the medical literature. But the child with anencephaly is clearly human and worthy of protection.

A 1990 article by Stumpf et al in the *New England Journal of Medicine* acknowledged that for the unborn child with anencephaly, some neurologic function is preserved. The authors go on to say that

"Many neurologic functions are retained in live-born infants with anencephaly, even though extensive areas of the brain stem may be malformed. Some brain stem functions may appear to be absent when they are not. Special sense organs and facial muscles are frequently malformed, impeding input and output from the central nervous system; this may compromise the ability to measure intact reflexes of the central nervous system that depend on this input and output. Many behaviors of newborns have been ascribed to cerebral hemispheric activity; however, the presence

of these behaviors in infants with anencephaly indicates their brain-stem origins. These behaviors include responses to noxious stimuli, (avoidance, withdrawal, or crying), feeding reflexes (rooting, sucking, or swallowing), respiratory reflexes (breathing, coughing or hiccups), and many interactions involving eye movements and facial expressions that are seen in newborns with intact cerebral hemispheres"[84].

These authors go on to infer that infants with anencephaly cannot suffer, but as we have seen, more recent evidence does not support this conclusion.

Mothers also describe feeling their children with anencephaly move and kick while in the womb. This is borne out by research, suggesting that the central nervous system is functioning to some extent. A case report in 2005 by Andonotopo *et al*. compared *in utero* behavior for a normal fetus with that of a fetus with anencephaly using 4D ultrasound. The authors found that while the movement patterns for the child with anencephaly were different from those of the normal fetus, and appeared more limited, "a functional movement of [the] CNS was observed". They concluded that "movements patterns are abnormal and can exist in spite of a serious reduction in the quantity and change in in the fetal CNS"[85].

Further evidence that the newborn with anencephaly has neurologic function is provided by other studies. Berger cites a study by D.A. Shewman which indicated that newborns with anencephaly "are functionally closer to normal newborns than they are to adults in chronic vegetative states"[86].

The newborn with anencephaly can perceive and respond to the environment and to his or her mother. Sekulic *et al* cite studies of infants with anencephaly whose behavior was studied postnatally. In one case, an infant lived for 85 days after birth. Postmortem examination (the child died from a brain abscess) proved that he did not have anatomical brain structures above the level of the thalamus. It was noted that if the child was

"...handled roughly, he cried weakly, and when the investigator coddled him, he showed contentment and settled down in the arms of the investigator. He would sleep after feeding and awaken when hungry. He expressed his hunger by crying. In response to painful stimuli, he withdrew his limbs...Sweet tastes of sugar elicit positive facial expressions of liking, whereas bitter or salty tastes elicit negative facial expressions of disgust in anencephalic newborns. If the skin of the anencephalic newborn is exposed to stinging, pressure or punching, they cry painfully. Based

on neurological examination of anencephalic newborns it is concluded that responses to noxious stimuli such as avoidance, withdrawal, or painful crying are of a brain stem origin in the human species. They also express sleep/wake cycles. When novel acoustic stimuli were presented, the anencephalic infant showed an orienting response, and cardiac slowing...

What implications do the abovementioned behavior of newborns with anencephaly have on the process of the fetus starting to have pain? Pain contains sensory and affective components. The sensory component is clearly visible in avoidance reactions and withdrawal to noxious stimuli. Crying in response to rough handling shows affective components in interactions with the mother or with medical staff. Showing contentment and settling down as a response to treatment with care or kindness also shows affective components in interaction with other people. Such interaction is necessary for bonding between the mother and the newborn, and the further emotional relationship between mother and infant, and represents one step in the emotional development of the infant. If the general definition of perception is taken into account, stating that it includes the organization, identification, and interpretation of sensory information...anencephaly demonstrates that the basic, most general, appropriate interaction with the environment can be achieved with a functional brain stem"[87].

It is clear from this very precise scientific and clinical perspective that despite his or her handicaps, the child with anencephaly is not only human, but demonstrates behaviors similar to unaffected infants, including interacting with his or her mother.

What are the outcomes of pregnancies after diagnosis of anencephaly? Most pregnancies where the unborn child has been diagnosed with anencephaly are aborted.

A systematic review by Mansfield et al of termination rates following diagnosis of fetal anomalies showed that the vast majority of unborn children with anencephaly are aborted[88].

Table 1—Systematic literature review based on 20 studies of trisomy 21, spina bifida, anencephaly and sex chromosome anomalies

| | Study number[a] | Year of study | Total numbers terminating | Country | Total percentage terminating | Confidence intervals |
|---|---|---|---|---|---|---|

| | | | | | | |
|---|---|---|---|---|---|---|
| Anencephaly | 7 | 1991 | 163/208 | UK | 78% | 75%–81% |
| | 7 | 1991 | 15/16 | Belgium | 94% | 88%–100% |
| | 7 | 1991 | 4/5 | Denmark | 80% | 62%–98% |
| | 7 | 1991 | 9/16 | Holland | 56% | 44%–68% |
| | 7 | 1991 | 82/87 | France | 94% | 92%–97% |
| | 7 | 1991 | 15/15 | Italy | 100% | — |
| | 15 | 1995 | 18/18 | US | 100% | — |
| | | | **306/365** | | **84%** | **82%–86%** |

This study also found that abortion rates increased from 0% in the 1980s to 88 % in the 1990s.

Table 2—Termination rates (95 per cent CI) following prenatal diagnosis by year of publication

| | Down syndrome | Spina bifida | Anencephaly | Turner syndrome | Klinefelter syndrome |
|---|---|---|---|---|---|
| 1980s (study numbers: 2, 4, 5, 6, 9, 11, 12, 14, 16, 17, 19)[a] | | | | | |
| Numbers diagnosed and terminated | 87/91 | 9/9 | 0/0 | 55/76 | 91/156 |
| Termination rates (95 per cent CI) | 96% (92–100%) | 100% | 0% | 72% (62–82%) | 58% (50–66%) |
| 1990s (study numbers: 1, 3, 7, 8, 10, 13, 15, 18, 20)[a] | | | | | |
| Numbers diagnosed and terminated | 4549/4944 | 139/208 | 306/365 | 71/100 | 0/0 |
| Termination rates (95 per cent CI) | 92% (91–93%) | 67% (61–73%) | 84% (80–88%) | 71% (62–80%) | 0% |

Limb and Holmes (1993) studies outcomes for pregnancies where the child was affected by anencephaly before and after the widespread use of abortion after diagnosis. These investigators were careful to document the race of patients in their study by tracking as far back as the four grandparents of each infant. 74 infants with anencephaly were diagnosed from 1972-1990, with 47% being diagnosed prenatally in 1972-1974 and 90% being diagnosed in 1979-1981. From 1972-1974, "before the advent of routine prenatal diagnosis in the second trimester, 47% of the affected infants were liveborn and 53% were stillborn. By the early 1980s more than half of the pregnancies with affected infants were terminated electively. By 1990 all of the affected infants were detected prenatally, and 100% of the pregnancies were terminated". The authors also note that "The fact that there have been no live born infants with anencephaly in recent years is relevant to the **proposed use of affected infants as organ donors**"[89]. This is an entirely eugenic sentiment. It is also noteworthy that the 100% of abortions performed in this study (and comparable rates of abortion contemporaneously) typically occur in the late second trimester, with accompanying painful death of the fetus and elevated risk to the mother of not only complications and injury, but death.

How have attitudes toward fetal and newborn children with anencephaly affected their care? Because these children are not seen as human, there has been a push to use them as sources of organs for transplantation, apparently starting in the late 1980s. An article in the *New England Journal of Medicine* in 1989 "speculated that, with increased awareness across the country of the feasibility of transplantation surgery in newborns, the list of waiting recipients will grow…However, this increased awareness will also intensify the already critical shortage of small organs. Therefore, some other mechanism for increasing the donor pool of solid organs for infants must be sought. Possible options include…**a change in the current law to allow the procurement of organs from anencephalic infants as a separate category of donors to whom the current standards for total brain death would not apply**"[90]. In other words, these authors were proposing the removal of organs from living children with anencephaly.

This was apparently already being done. In another article in the *New England Journal of Medicine* (The Medical Task Force on Anencephaly, 1990), the authors reiterated that "Infants with anencephaly are potential sources of organs for transplantation". They state, without providing any scientific data whatsoever, that "infants with anencephaly presumably cannot suffer. Anesthetic agents…are not necessary to minimize or prevent suffering". They proposed four general approaches to obtaining these children's organs. In one approach, "The infant is immediately placed on maximal life-support systems at birth. The organs are removed as soon as technically possible, without regard to the presence or absence of various brain-stem functions (whether or not brain death has occurred)", that is, while they are still alive. They cite a 1987 study by Holzgreve *et al* in which kidneys were removed from 3 infants while they were still living, perhaps (as the authors suggest), without anesthesia[91].

Evidence has been presented above to show that these children can feel pain. One must therefore wonder what it was like for them to be cut open and to have their organs removed, possibly without anesthesia, while their hearts were still beating and they were still alive. Did they cry? After their kidneys were removed, were they left to die from shock and exsanguination? What were the final moments of their lives like?

Contemporaneous with the above report, this question was addressed by the American Medical Association's Council on Ethical and Judicial Affairs. The AMA's website describes the debate on this subject under the title " Anencephalic Newborns as Organ Donors":

In June 1988, 2 resolutions concerning organ donation were brought before the AMA House of Delegates and referred to the Council on Ethical and Judicial Affairs (CEJA) for investigation. One requested the AMA to reexamine the criteria used to select organ donors. The other sought ethical guidelines to address the use of prenatal diagnoses and organ "harvesting"; both concerned the transplantation of organs from anencephalic infants, some of whom were now able to survive for up to several days. The implicit question in the resolutions was this: Is it ethical to declare organ donor status for anencephalic newborns on the basis of prenatal diagnosis and, with parental consent, to procure the organs before the infant died of its neurologic devastation? In December 1988, CEJA reported its recommendation to the House of Delegates. The answer was, "No."

Here are CEJA's words: "[CEJA] supports the voluntary donation of organs in appropriate circumstances. However, the Council does not view the use of organs of anencephalic newborns prior to a determination of death, i.e., the complete and irreversible cessation of all brain function, as appropriate for transplantation purposes." The 1989 edition of the Code contained no separate entry on anencephalic neonates as organ donors. The first separate opinion on anencephalic neonates as donors appeared in the 1992 edition, giving public voice to the view expressed in the 1988 report. The new opinion stated that the newborns could be kept on ventilators and provided other treatment to sustain 'organ perfusion and viability until such time as a determination of death can be made in accordance with accepted medical standards and relevant law.' The opinion went on to emphasize that retrieval of organs was "ethically permissible only after such a determination of death is made."

Articles similar to the one above by Peabody appeared in journals, pushing for the use of children with anencephaly as organ donors, and for modification of the laws regarding transplantation. Then,

"By 1994, things had changed. In June 1994, "after more than a year of deliberation," the Council issued a lengthy report, a version of which was subsequently published in JAMA [the Journal of the American Medical Association]. The extensively researched and documented report grounded its conclusions on 3 facts or assumptions: anencephalic newborns faced certain death, usually within 3 days; they lacked any degree of consciousness; and parents of such newborns often requested that their children's organs be donated. The Council reached the conclusion that, with prior

consent of the newborn's parents, it was ethically acceptable to transplant the organs of anencephalic neonates without waiting for them to die naturally.

In each case, justification for permitting retrieval of organs from anencephalic newborns before they had been declared dead seemed to outweigh the arguments against doing so. The Council's recommendation was accepted by the House of Delegates and replaced the former opinion on organ donation by anencephalic neonates in the 1994 edition of the Code. After defining anencephaly, the new opinion stated: It is ethically permissible to consider the anencephalic as a potential organ donor, although still alive under the current definition of death only if: (1) the diagnosis...is certain and confirmed by two physicians who are not part of the organ transplant team; (2) the parents of the infant desire to have the infant serve as an organ donor and indicate such in writing; and (3) there is compliance with the Council's Guidelines for the Transplantation of Organs...the opinion drew special attention to the fact that its new opinion marked a noteworthy exception to its guidelines on donation of organs necessary for life because these infants have "never experienced and will never experience consciousness."

Reaction to the report and opinion was immediate, widespread, and highly critical. During the year following the opinion's release, the AMA and CEJA received protests from individual parents and physicians, advocacy groups...and medical specialty societies. And the Council became aware that its new opinion on anencephalic newborns as organ donors was incompatible with the policy of the United Network for Organ Sharing (UNOS), the organization established by the US Congress in 1984 to administer the nation's Organ Procurement and Transplantation Network. UNOS policy stipulates that organ procurement must occur after declaration of death by medical and legal standards.

The Council on Ethical and Judicial Affairs considered the clear message it had received from members of the profession and the public. Society was not about to tolerate alteration of principles derived from the closely held value it placed on the sanctity of life, no matter how damaged that life might be. If the owner of that life, himself or herself, vehemently refused treatment to sustain it, that was one thing, but others who had never known the will of the person in question should not end its life. In its December 1995 report entitled, "The Use of Anencephalic Neonates as Organ Donors—Reconsidered," the Council rescinded its 1994 opinion, pointing to concerns about accurate diagnosis of anencephaly and incomplete understanding of the possible level of consciousness in

these newborns. The report urged the scientific community to continue to investigate the consciousness of neonates and provide knowledge to guide future policy making on this topic. Promising to continue assessing relevant information, the Council recommended—and the House of Delegates approved—reinstating the 1992 opinion. Nearly a decade later, the 1992 opinion remains in the Code[92].

The 1994 conclusion reached by the CEJA was horrifying, and properly condemned as inhumane. But the committee opinion makes a key point. Once vulnerable members of society, such as children with anencephaly, indeed any anomaly, are dehumanized and their rights abridged – including through license given to abort them – it is only a matter of time before further erosion of their dignity and worth occurs. These articles demonstrate the grave danger of a eugenic approach to these children, which categorizes them as less than human. Those who deem them less than human can justify aborting them using the brutal second-trimester D&E procedure. For those who are not aborted, the same reasoning can be used to justify any use that can be made of them, including cutting their organs out while they are still living. In most countries, this would be impermissible even for animals being slaughtered for food.

What are the mental health outcomes in women whose fetus has been diagnosed with an anomaly, including anencephaly, following abortion or carrying to term? Multiple studies indicate that women who undergo abortion for fetal anomalies experience significant negative mental health outcomes. Calhoun et al (1997) noted that a disproportionate number of adverse mental health outcomes occurred following abortion for fetal abnormalities, citing a study by Zolese et al (1992). The authors of that study stated that "Those requiring therapeutic abortion on medical grounds because of foetal abnormalities or serious medical complications are consistently found to be associated with poorer psychological outcome..."[93].

In a review of published research, Sullivan and Faoite (2017) noted that "Data from the studies examined indicate that many women, having aborted due to serious anomaly, suffer from PTSD [post-traumatic stress disorder], a mental health problem"[94]. According to the American Psychiatric Association "PTSD is a psychiatric disorder that may occur in people who have experienced or witnessed a traumatic event, series of events or set of circumstances. An individual may experience this as emotionally or physically harmful or life-threatening and may affect mental, physical, social, and/or spiritual well-being... People with PTSD have intense, disturbing thoughts

and feelings related to their experience that last long after the traumatic event has ended. They may relive the event through flashbacks or nightmares; they may feel sadness, fear or anger; and they may feel detached or estranged from other people. People with PTSD may avoid situations or people that remind them of the traumatic event, and they may have strong negative reactions to something as ordinary as a loud noise or an accidental touch"[95].

Sullivan and Faoite continue by saying that "The disorder is shown in multiple studies to continue for months and even years in some women". While the percentage of women with PTSD appears to diminish over time, "...the number of women still dealing with PTSD a year or more after termination of pregnancy remained surprisingly high". The authors reported that "Kersting et al (2009) found that 45% of subjects were demonstrating signs of PTSD 14 days after the abortion. Korenromp et al (2009 and 2007) found that 44% and 46% of women, respectively, were suffering form PTSD four months after pregnancy termination. Davies et al (2005) found that 67% of participants screened positive for PTSD at six weeks, which fell to 50% at six months".

The mental health effects of pregnancy termination often lasted more than a year. For example, these authors state that "Kersting et al (2009) found that 30.9% of women were still experiencing post-traumatic stress 14 months after pregnancy termination. Korenromp et al (2009) reported that at 16 months after termination 20.5% of patients still showed pathological levels of PTSD". Davies et al (2005) reported that 41% screened positive for PTSD at 12 months post abortion". Similar findings were noted in these studies for depression. "Davies et al (2005) documented a slow increase in depression following pregnancy termination", with 30% of subjects screening positive for depression at 6 weeks, 39% at six months, and 32% at 12 months. Sullivan and Faoite concluded that "These articles repeatedly conclude that abortion for reason of potentially fatal anomalies can have a lasting and negative psychological impact".

Interestingly, they note that "experiences highlighted in the research suggest that induced termination did play a role in the psychological issues these mothers faced. Gammeltoft et al (2008) found: 'Even though their obstetrician had advised abortion, most felt that the ultimate decision to terminate the pregnancy had been their own, made in consultation with their relatives. The harshness of their loss seemed to be magnified by the fact it was 'chosen' by themselves'".

Hunsfeld *et al* (1993) of women who were carrying babies that had been diagnosed with severe or lethal anomalies who were surveyed shortly after their diagnosis and again after giving birth. While

a high percentage of these mothers (45%) were diagnosed with "severe mental imbalance" shortly after their ultrasound diagnosis, by 3 months this number had declined to 22%. The percent of women with sleeping disorders (69%) declined dramatically at the 3 month mark to 5%. The percentage of women with eating disorders declined from 56% to 14%[96].

Research has specifically examined the question of whether outcomes are better for women who undergo termination of pregnancy for an unborn child with anomalies vs. carrying to term. Rates of mental health problems for women who underwent induced abortion for a fetus with anomalies are higher than those for women carrying an affected child to term. Cope et al (2015) studied the impact of abortion vs carrying a pregnancy to term when the unborn child was affected by anencephaly[97]. The authors also explored the fact that the psychological impact of pregnancy loss on men is understudied, noting that "Descriptive studies of men have reported that men struggle with grief, anger and helplessness following the loss and often feel forgotten by health care providers and society...the few published studies indicate that men also experience grief, depression and post-traumatic stress..." In this study, women who underwent abortion had much higher scores on a standard measure of perinatal grief than women who continued with their pregnancies (52% vs. 33%, respectively). Women who underwent abortion also had higher rates of depression than those who continued their pregnancies (48% vs. 27%). The authors note that "A significant number of women and men reported symptoms of grief, post-traumatic stress and depression within the pathogenic range...psychiatric distress tended to decrease over time. However, it is important to note that there was tremendous individual variability...there were participants whose pregnancies ended over 10 years ago still scoring within the pathogenic range".

Of note, "Pregnancy continuation was also associated with less psychiatric distress in women. As a group, women who continued reported significantly less despair, avoidance and depression than women who terminated. And "items related to guilt were significantly associated with termination in women. The active choice involved in termination does appear to increase the likelihood that guilt will be experienced, even in the case of lethal fetal anomalies...Termination at a later gestational age was associated with greater psychiatric distress in both men and women, although this was only statistically significant in men. Cope *et al* concluded that "There appears to be a psychological benefit to continue the pregnancy following prenatal diagnosis of a lethal fetal defect"[98].

Can compassionate palliative care for newborns with anencephaly improve outcomes for parents? Malloy et al stated "As Hoeldtke and Calhoun note, while the explosive growth of prenatal diagnostic technologies in particular has resulted in earlier diagnoses of life-limiting and life-threatening diagnoses, 'the ability to accurately diagnose a fetal condition often outstrips the ability to prevent or treat that condition. This is especially true for some specific fetal congenital defects' and would include anencephaly. "Infants carrying these diagnoses who are born alive may die in the neonatal period or experience long stays in intensive care units. Parents of these fetuses face significant emotional, logistical, and social challenges related to the outcome of their pregnancy. Recently, options for perinatal hospice have become more prevalent and established for those whose pregnancies are complicated by such diagnoses. A subset of perinatal or prenatal palliative care, perinatal hospice care, is an extension of established adult and oncologic palliative care models, which originated in the 1960s. Perinatal hospice care provides comprehensive prenatal, perinatal, and postnatal medical care and support to infants with life-threatening and life-limiting diagnoses, and their families, in order to improve their quality of life. Perinatal hospice is family centered and addresses the emotional, social, spiritual, and other needs of families within their cultural contexts. This nascent field is rapidly developing, with more than 200 perinatal hospice programs in the United States"[99].

Between 40-85% of women will typically choose perinatal hospice or palliative care for a fatal fetal anomaly, if given the option[100-104].

Malloy et al further noted that "Perinatal palliative care services can also help care for those parents who choose to terminate their pregnancy. Such families often experience significant loss and grief, without adequate support, which could be provided by a palliative care team...In a five-year study of families choosing perinatal hospice for their newborns, 49% of cases were infants affected by Trisomy 18 or 21, or by anencephaly. Families in this study expressed a wide variety of needs and preferences related to their fetus' diagnosis, which were or could be addressed by perinatal palliative services. These included participating in a perinatal hospice program which could help them develop a birth plan, provide counseling, address concerns regarding resuscitation, and bring support in navigating social issues such as how to tell friends and family about their diagnosis. The authors also noted that 'many families experience spiritual distress, highlighting the need for a spiritual counselor' as part of the team"[105].

Similar to the goals of adult and oncologic hospice, the goals of perinatal hospice can be simply stated - to provide healing without cure for the patient. Palliative perinatal care, however, does not consist of comfort measures only, and may include cesarean delivery and newborn intensive care. For example, in Japan, where intensive intervention is often provided for infants with Trisomy 13 and Trisomy 18, one-year survival rates approach 56% in some centers[106,107]. In the United States, Nelson et al. noted that although one-year survival for infants with Trisomy 13 or 18 has been stated to be less than 10%, forty-one percent of hospital records for children with Trisomy 13 and 32% of records for children with Trisomy 18 were for children older than one year[108].

A common theme in research on perinatal hospice is parents' positive experience of the process, even when their child's life was brief[109,110]. For example, "Guon et al. reported that many parents noted that their family was 'strengthened and enriched since the birth - and often the death - of a child with a chromosomal abnormality". They also found that while "many parents experience intense grief reactions regardless of the choice they make," in multiple studies, those who received support through perinatal palliative care described positive experiences[111]. Another common theme was parents' "unanimous and strong need to acknowledge the personhood of their baby, and his/her role in the family," and their desire for "people to legitimize the baby's life and not to pretend the infant does not exist[112,113]. Perinatal palliative care has helped parents with this process in the prenatal period by using the baby's name to reinforce the child's identity[114-116].

Increasingly efforts are being made to facilitate parents' desires to give birth to their child affected by anencephaly as a viable alternative to abortion. A case report by B. Chapman (2013) described parents giving birth in a perinatal palliative care pathway. The parents were aware of the diagnosis prenatally. According to the author, "Hope's journey illustrates how integration of the multidisciplinary hospital team and community care can assist and support the family when planning a way forward, tailored to the family's personal, physical, emotional and spiritual needs. After her mother's full term pregnancy and vaginal birth after caesarean section (VBAC), Hope was discharged home seven hours after her birth as her parents wished for palliative care. She lived 14 hours, a life filled with love, dying in her family home as her parents wished. This case illustrates how perinatal palliative care pathways can support and assist professionals working in maternity units when parents decide to continue a pregnancy with a baby with a terminal condition. It also provides a framework to facilitate the parents to have the option of taking their baby home to die with appropriate support in place...This case study illustrates how the parents can be kept at the

centre of care providing space for them to make informed choices with the support of integrated care from both the hospital and community"[117].

Jaquier et al (2006) surveyed parents whose unborn children were diagnosed prenatally with anencephaly. The survey collected information on 211 pregnancies and noted that "Contrary to common belief, only a small number of anencephalic fetuses died *in utero*. More than half of the babies were born at term, 10% even after term...Judging from these data, and collected via this homepage [Anencephaly info] and compared with the notion of Limb and Holmes, it seems that a larger proportion of mothers carrying an anencephalic fetus are opting to continue the pregnancy rather than elective termination. From the perspective of these mothers/parents, it is important to experience as normal a bonding as possible between mother/parent and baby and to see and touch the baby, stillborn or liveborn. It is impressive to hear from these parents who contacted homepage that none have regretted their earlier decision to continue the pregnancy...On the other hand, a considerable number of mothers who contacted the homepage following an elective pregnancy termination, mentioned their regret at not having seen their baby"[118].

My clinical experience is in agreement with this. In caring for a newborn with anencephaly, a cap is usually placed on the baby's head and he or she is swaddled. The parents' first impression is often that the baby "didn't look as abnormal as they thought it would". They may receive their child cautiously, then happily, even though they know that he or she might not live for very long. In my experience, holding their baby was an important part of parents' honoring his or her life.

Thill notes that "A dichotomy exists in the practice of medicine" due to differential treatment of two equally human fetuses:

> "...one fetus is accorded patient status and humanity, to whom beneficence and nonmaleficence are owed, while for the other fetus, this status is withheld. This cognitive dissonance disturbs and causes significant tension within the practice of medicine in view of objective medical evidence as well as in light of the fundamental mission of medical professionals as healers. There is an ethical obligation to prevent unnecessary pain and suffering, as well as an obligation for beneficence and nonmaleficence, which must be judiciously applied to both the pregnant woman and the fetus, while safety and health concerns are carefully balanced"[119].

An article by R. Wayne Willis published in 1990 summarizes many key points regarding the humanity and human dignity of the child with anencephaly. In an article published in 1990, he provides a hypothetical debate on this topic, responding to critiques that the child with

anencephaly is not human, again in the context of organ donation. But the arguments apply to abortion of the child with anencephaly as well.

"You employ the word "use" when you speak of the anencephalic newborn. I'm sorry, but I don't believe human beings are meant to be used [or aborted]. Things are to be used. Objects are to be used. People are to be loved. One of the fundamental principles of civilized societies is that people are not to be used solely as means to an end. You are proposing that this anencephalic newborn be *used*. You see this baby as having no rights...I think most moral people believe that is wrong. You showed your true colors, revealing your utter disregard for the rights or the inherent worth of this handicapped baby, by referring to the baby as "an anencephalic". You make the baby an "it", a thing. She is not an anencephalic *newborn* or an anencephalic *baby* or an anencephalic *infant*. We depersonalize patients when we refer to them as a diagnosis, as a "heart" or a "head" or a "Down's," or "an anencephalic". Sir, are anencephalic babies persons or things? They can suck. They can cry. They can swallow. They can withdraw from painful stimuli. They can distinguish their own mother from other persons. Are they persons or things?...there are several documented cases of newborns who were originally diagnosed with anencephaly, a flawed diagnosis that later proved out to the microcephaly or hydranencephaly. Making the diagnosis of anencephaly cannot be done without an occasional error...One famous physician put it this way: "The level of civilization attained by any society will be determined by the attention it has paid to the welfare of its infants and children"[120].

In 2019 a physician wrote an article for the series "On being a doctor" in the 4 June 2019 issue of *Annals of Internal Medicine* called "The Myth of Choice". In it, he or she decries the withholding of abortion from a mother whose unborn child had anencephaly:

"A woman meets a man, starts a relationship, wants a family. She comes to your hospital so pregnant that her belly is huge. She hasn't come before because she has no car. Her man works long days, paid cash for his labor. Turns out the baby has no brain, no skull. Only a stem. This condition has no survivors. None.

You are in OB triage, crammed on a stool between the woman's stretcher and the wall. When you move, the stool squeals. Her hand rubs her belly. You find an interpreter, you sit beside her, you tell her congratulations and you are so sorry all in the same breath. The interpreter is a stranger on a screen, mounted to a pole on wheels. You try to angle the screen so the interpreter sees your face. He is aghast at what you ask him to repeat. The cadence of your words is carefully measured, but your beautiful cadence is mangled by his hesitation.

You wait for the patient to break the silence. The baby's heartbeat trots through the monitors while you softly hold her gaze. Her eyes plead with you. End it. You talk to the obstetricians, because eventually it will end. But nobody will do it. Not in this state. Not in this hospital. And so, the mother goes home, pregnant and grieving.

She returns a few days later. She's having a miscarriage. Her labor is managed just like that, like labor. The baby is born with no skull, eyes like gumballs too big for their sockets. Alive, briefly. It hurts to look. Grotesque is all you can think, but you cannot say it. Thinking it calms you inside so you can calm everyone else. That is your job. To lead, to calm. Because everyone is upset. Some of the nurses need you to fix it, to save this baby with the magic of medicine. You remind them that he

is very premature, that he has no brain, that he cannot survive. This is not an ambiguous diagnosis. You encourage the mother to hold her child, but she does not want this bond. She cannot see the deformed creature she birthed, because once seen it cannot be unseen.

It doesn't last long, these precious but vulnerable moments. Gently, the baby dies. He is warm, whole, and not alone. There are no doughnuts at the nurses' station that night as this young mother is wheeled to a room in the back corner of labor and delivery, away from the other mothers and their pink, crying babies. She will walk out of the hospital with breasts swollen and weeping for her dead child. Her hips loose and large will force her pants to tug. She will struggle with her gait for weeks, punctuating loss in the waddle of each step, until, gradually, she retires her maternity pants and her steps become firm, upright, and forward.

You've done this before, cared for women whose wishes were warped by politics. You've commanded millions of health care dollars on behalf of infants born with fatal diagnoses. You've seen these infants cut, lanced, and battered in the name of intensive care. Do everything. Because who does not want to save her child? Sometimes all we can control is our grief. The middle-of-the-night pangs for a world where motherhood means potty training and muddy cleats. Sometimes the idea of choice is just a lie. And sometimes all you can provide is compassion. Dignity in grief is the gift. You've enabled false hopes, not for cures but for time to bond, hope, and heal. It is the parents you are healing. The hopes false. All these children died in the end[121].

While the author does convey that “It doesn't last long, these precious but vulnerable moments. Gently, the baby dies. He is warm, whole, and not alone” – and the baby would be none of these if he had been aborted – the physician paradoxically also expresses disgust at the appearance of the newborn, seeing him as “grotesque”, a “deformed creature” who like other newborns with “fatal diagnoses” seems to not be really human, who needs to be aborted rather than having healthcare dollars wasted on them, since “All these children died in the end”. This leads the physician to the conclusion that “hope’s false”.

Responses to this article were quite informative. One physician stated eloquently that

“The anonymous author laments that at his/her institution pregnancy termination and withholding of care for babies with very serious defects is not often possible. The author then concludes with statements concerning providing compassion and dignity in grief. What are compassion and dignity? Who defines these terms and determines how they are applied? The Oxford English Dictionary defines compassion as: “sympathetic pity and concern for the sufferings or misfortunes of others.” The same dictionary defines dignity as: “the state or quality of being worthy of honour or respect.” The author is concerned about the parents, the health care team and society (costs). The position taken clearly places the interests of the unborn and newborn child subservient to others. Traditionally, the patient’s interests are paramount. Disturbing changes in medical ethics have devalued the humanity of patients when they are seriously disabled and ill. There is a growing trend towards paternalism and unilaterally applying the concepts of societal over individual interests.

The author uses language that is contradictory such as "baby" and "infant" followed by objectifying, grotesque, and dehumanizing descriptions followed by the paternalistic cry of "end it." Is the unborn or severely disabled child human or not? Is such a child worthy of dignity and care? The author's revulsion betrays the true subject of "compassion" and "dignity." It is not the child but the suffering author who represents each of us in this story.

Does this approach capture the fullness and true meaning of dignity and compassion? In the Judeo-Christian tradition, compassion can be described as: "Quality of showing kindness or favor, of being gracious, or of having pity or mercy" and human dignity is grounded in the imago Dei. Therefore, human dignity is: "The unalterable, inherent value due every person by virtue of being a human being." Utilitarian ethics are foreign to these concepts and ministries that flow from them.

The author fails to identify the cultural and religious beliefs and values of the parents and in turn the child. Actions desired by the author as compassionate may be abhorrent to others. The family's view of human dignity may extend fully to their anencephalic child. They may view abortion as murder. External pressure by providers, hospitals and insurers adds to their agony...Tragedy and suffering do not demand a utilitarian response but one of grace, mercy, kindness, and love towards all those affected".

At the heart of the debate are two opposing worldviews: utilitarian and Judeo-Christian. History attests that the utilitarian worldview takes us down the same dark road as the Baby Bollinger Case and the Aktion T4 program. We must teach current and future generations of physicians to critically think these issues through and understand the true meaning of compassion and dignity lest we repeat the same horrors"[122].

In another response to this nihilistic depiction, Dr. Elvira Parravicini, a neonatologist, and Frances McCarthy, a clinical coordinator, from Columbia University Medical Center, wrote a beautiful paraphrase, filled with hope. They note that "This is the real story of a real family who delivered in 2015 at Morgan Stanley Children's Hospital / Columbia University Medical Center in New York, NY under the care of the Neonatal Comfort Care Program", commenting that "In the US there are more than 200 services of Perinatal Palliative Care".

A woman, pregnant with a baby with anencephaly comes to your hospital. Long-term survival is not an option. Her eyes plead with you. Help me. You take her hand, look her in the eye and offer to walk with her through this journey that she does not wish to be on. You explain to her that while her child's life may be brief, it is precious and that she is not alone. The mother's love for her baby does not die with the diagnosis or with the death of her child. Choice is the not the issue. Grief is. The truth of medicine is this: patients die. The issue here is about valuing the relationships that we, as providers, have with our patients. It requires us to be with them in the discomfort of delivering a terminal diagnosis.

Can we then, walk with them during such sad and difficult times in their lives?

When born, the baby is gently placed on her mother skin to skin. She dies quietly, peacefully in the arms of her mother, never knowing hunger, pain, or sadness. Her mother will grieve her in some way

for the rest of her life. She has loved and lost, but she has also gained. She was able to bond, to love and to hope and she will heal. She is changed but not defeated.

She is not the first and she will not be the last to face the death of a child. Hope for a cure eludes us daily but hope for healing is different. Healing is not just about disease; it is about the spirit, the resilience that rests in all of us. This baby's life, while brief, was filled with love and dignity and without pain. This baby made her a mother. This baby changed her. All of us die in the end. It is the nature of everything that lives. Death is the final act but it does not tell the whole story. In medicine, we cannot be there only for the living; we must be there for the dying as well[123].

The rights of a mother with an anencephalic fetus, or one with Down syndrome, or even an unexpected or "unwanted" pregnancy are not in opposition and should not be seen as competing, nor should we pit them against one another. Rather, their rights are intertwined. Both the mother and her child have inherent human dignity. Both deserve not only compassion and justice, but love, because love seeks the best and highest for another. They also deserve the best of care, which does not include abortion because abortion is not health care. Abortion violates the bodily integrity and the rights of the mother, exposes her to injury and death, and kills the unborn child, with no evidence of benefit. The value of a child's life has nothing to do with how long it is, or how he or she was conceived.

To conclude, the Dobbs decision, as noted, returned legislative decisions about abortion to the people of the United States and their elected representatives and also resulted in vigorous, even fractious, debate. Debate is positive. A similar debate should ensue on IVF, if only to address pressing questions, such as the commodification of reproduction, and the fate of the estimated one million frozen embryos in the United States. Values, especially as they relate to human dignity, as well as compassion, justice, and scientific and clinical data, should inform this process.

Thank you.

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Questions for the Record from Senator Charles Grassley
U.S. Senate Committee on the Judiciary
"The Continued Assault on Reproductive Freedoms in a Post-*Dobbs* America"
March 20, 2024

Questions for Professor O. Carter Snead:

(1) Alabama enacted a law granting civil and criminal protections for in vitro fertilization (IVF) facilities and workers in response to an Alabama Supreme Court ruling, which held embryos are human beings and those who fail to protect or destroy embryos can be held liable for wrongful death.

Based on your research and experience, what remedies might remain for those who have had their embryos damaged or destroyed as a result of IVF clinic negligence in Alabama?

ANSWER: I am not an expert in Alabama law, but it certainly seems that the blanket civil and criminal immunity extended to IVF clinics by the new legislation is very broad indeed. Perhaps there might be some contractual grounds for recovery, depending entirely on the agreements signed by the patients and the clinics. But the short answer is that I am not aware of any avenue for legal redress.

(2) Medical facilities of all sorts have security measures limiting who can access certain areas. For example, a hospital's nursery has tight security measures to ensure the safety and security of the newborn infants in the hospital's care. Similarly, operating rooms in medical facilities have safeguards to ensure patient safety and security during procedures.

Is there a minimum level of security IVF facilities should have to ensure the safety of embryos? If so, what security factors ought to be considered?

ANSWER: I am not an expert in such security measures, but it would certainly seem to me that IVF facilities should have very strong and reliable security measures sufficient to prevent the damage to or destruction of embryos, the violation of patient privacy, among other possible harms.

(3) How do IVF safeguards and regulations in the United States compare to various countries in Europe?

ANSWER: The United States is unique in lacking meaningful regulation of the IVF industry. The United Kingdom has a regulatory agency – the HFEA – dedicated to providing oversight, issuing licenses, and the like. Germany has an "Embryo Protection Act" that provides standards that touch and concern IVF. The U.S. is unusual in this regard.

(4) Based on your experience, does the IVF industry need better regulation to protect women, would-be mothers, and the embryos created? If so, what types of measures ought be considered by the Federal Government or by the states?

ANSWER: There is a pressing need for better regulation of IVF and assisted reproduction in the United States to provide for the health and well being of women, would-be-mothers, and embryonic human beings conceived by IVF – both those that are transferred to initiate a clinical pregnancy, as well as those that are not (many of which languish in cryostorage for years). I believe that the recommendations of the President's Council on Bioethics (attached) almost exactly twenty years ago are still very much needed. In particular, I would draw the committee's attention to the recommendations under Roman Numeral I ("Federal Studies, Data Collection, Reporting and Monitoring Regarding The Uses and Effects of These Technologies"). There, the Council recommended unanimously (despite members' disagreements on abortion and the moral status of embryonic human life) that the federal government should sponsor longitudinal studies on the health effects of IVF and related techniques on women and children conceived with their aid. The Council further recommended strengthening of the mostly toothless Fertility Clinic Success Rate and Certification Act of 1992. I would also recommend a study to make a reliable assessment of the number of human embryos in cryostorage in the United States, and what their custodians have designated for their future disposition. (One such study was published by RAND in 2003- https://www.rand.org/pubs/research_briefs/RB9038.html).

To this I would add, following on the recommendations in Chapter 4 of my book *What It Means to be Human: The Case for the Body in Public Bioethics* (Harvard University Press 2020)(attached), that any legal regulation should strive to protect the welfare of every human being involved in this process – genetic parents, gestational parents, rearing parents, and most of all, children (at every stage of their biological development). None should be left outside the law's concern. It is worth studying those jurisdictions (domestic and international) that have sought to achieve this comprehensive goal.

Rather than recapitulate the recommendations of the Council or the arguments in Chapter 4 my book, I am attaching both for the Committee's benefit and for inclusion in the record.

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# 4

# Assisted Reproduction

> [Reproductive technologies] are means to achieve or avoid the reproductive experiences that are central to personal conceptions of meaning and identity.
>
> —PROF. JOHN A. ROBERTSON, *Children of Choice*, 4 (1994)

> Reproductive medicine is helping prospective parents to realize their own dreams for a disease free legacy.
>
> —DR. GERALD SCHATTEN, TESTIMONY BEFORE THE PRESIDENT'S COUNCIL ON BIOETHICS (DECEMBER 13, 2002)

In 1969, British researchers Robert G. Edwards and Patrick G. Steptoe achieved a feat that changed the world forever. As described in the *Nature* article entitled "Early Stages of Fertilization *in vitro* of Human Oocytes Matured *in vitro*," their research team conceived a living human embryo by combining ova and sperm in a glass dish (literally "in vitro").[1] Steptoe and Edwards were thus able to hold and observe the human organism at the earliest stage of development outside the body. In natural re-

production, the embryo emerges from sperm-egg fusion in the fallopian tube but is not detectable by modern techniques of pregnancy testing until days later. Steptoe and Edwards were able to bring out into the light what had long been shrouded in mystery.

Of course, there were major transformations in human procreation before and after Edwards and Steptoe developed *in vitro* fertilization (IVF). Nine years earlier the FDA's approval of an oral contraceptive pill—Enovid 10 (known colloquially as "The Pill")—had created the possibility of reliably severing sexual intercourse from pregnancy.[2] Four years after the publication of their article in *Nature,* the Supreme Court's decision in *Roe v. Wade* recognized a constitutional right to abortion—the freedom to break the necessary connection between pregnancy and birth.[3] But IVF was altogether different. IVF promised not only a possible avenue for infertile people to conceive biologically-related children, it fractured almost entirely the previously integrated component parts of human reproduction—fertilization, gestation, and raising children. For the first time, it was possible to create a human being whose genetic parents (providers of egg and sperm), gestational mother, and rearing parents were five different people, not including the practitioner and staff who prepared and cultured the gametes and performed the fertilization itself.

In 1978, Edwards and Steptoe's research moved from bench to bedside with the birth in England of Louise Brown, the first "test tube baby," as she was described in the press.[4] And, three years later, in 1981, Elizabeth Jordan Carr became the first such baby born in America.[5] Along with the relief promised to the

infertile through this revolution in medicine, IVF presented new and radical challenges to seemingly stable conceptions—the nature and meaning of human procreation; the identity, worth, and definitional boundaries of human persons; the substance and contours of parenthood and obligations to children; the fitting ends and means of biomedical science; what it means to be a "patient"; conceptions of health and wholeness; and norms against commodification of the body and its parts.

To date, more than one million babies conceived by IVF have been born in the United States.[6] According to the Centers for Disease Control in 2016 (the last year for which such numbers are available), 76,897 infants were born in the United States following IVF, representing 1.9 percent of all babies born that year (3,941,109).[7] From 2007 to 2016, the number of assisted reproductive technology (ART) cycles performed in America had increased 39 percent.[8] To be sure, these children represent the fulfilments of the hopes and dreams of a vast array of loving parents, and relief from the suffering caused by infertility.

But, as with all paradigm shifts in humankind's enhanced power over nature, there is another side to this reproductive revolution. In the United States alone there are reports of one million human embryos frozen in cryostorage.[9] Their existence stokes a constant and growing demand for their use and destruction in biomedical research (for example, for the derivation and the study of human embryonic stem cells), even though surveys have shown that the vast majority of these embryos have not been designated for donation to researchers.[10]

There is a growing market for gametes, including nationwide advertising campaigns soliciting highly intelligent, athletic,

and accomplished female college students to sell their ova, sometimes for tens of thousands of dollars in compensation. One for-profit enterprise, California Conceptions, procures sperm and ova and creates "batches" of embryos which it then sells to patients for implantation (to initiate a pregnancy) at a fraction of the cost of conventional IVF, including a money-back guarantee.[11] The firm typically conceives multiple embryos from a single donor of ova and sells the embryonic siblings to different clients. Prospective patients can browse the catalogue of gamete donors in the hopes of having a baby with preferred traits. An earlier iteration of this business model was the "Repository for Germinal Choice," a sperm bank that purported to make available the sperm of Nobel Prize winners and, when that proved to be too difficult, other "Renaissance Men" of great achievement and quality.[12] Only three Nobel Laureates, including avowed eugenicist William Shockley, actually donated sperm, but no ova were fertilized with their seed. Most of the sperm donors, it turned out, were perfectly ordinary people. It closed its doors in 1999.

Embryo screening for sex selection has become a common feature of IVF practice; 73 percent of clinics in the United States offer this testing.[13] There are patients who use genetic screening to identify and initiate pregnancies with embryos who are immunocompatible to an older sibling who needs an umbilical cord blood stem cell transplant (harvested upon birth of the newborn). Babies born from this process are sometimes called "savior siblings." The *Guardian* has reported that an American biotech company named "Genomic Prediction" goes beyond testing for single-gene mutations or chromosomal abnormalities

to aggregating data to develop "polygenic risk scores" that indicate an increased probability of having a child with a variety of health difficulties, but also tests embryos for probable "low IQ."[14] According to the *Guardian,* "the company projects that once high-quality genetic and academic achievement data from a million individuals becomes available, expected to be within five to ten years, it will be able to predict IQ to within about 10 points."[15]

As will be developed further below, all of the foregoing is perfectly legal and essentially unregulated beyond the usual laws governing the practice of medicine, the use of human tissues, cells, and tissue and cell-based products, and the general civil and criminal laws of the separate states.

It is this second domain of public bioethics—assisted reproduction—to which this inquiry now turns.

Whereas the public questions of abortion involve the termination of pregnancy, the avoidance of parenthood, and the ending of nascent human life, the domain of inquiry of this chapter—assisted reproduction—concerns the initiation of pregnancy, the pursuit of parenthood, and the creation of new human life. Both contexts are also distinguished by understandably profound and overwhelming emotional counterpoints—on the one hand, dread and panic at the prospect of the burdens and disruptions of unwanted pregnancy and parenthood, and on the other, desperate sadness and longing for a child of one's own flesh. But normatively, anthropologically, and legally speaking, these vital conflicts of American public bioethics are deeply linked to one another. Unlike American abortion law, which is shaped by nearly fifty years of jurisprudence, the realm of as-

sisted reproduction is notable for the *absence* of law governing it. Even though this is the case, assisted reproduction is squarely rooted in the anthropology of expressive individualism.

United States law defines ART as "all treatments or procedures which include the handling of human oocytes or embryos" for the purpose of establishing a pregnancy.[16] This includes *in vitro* fertilization and its variants, egg or embryo cryopreservation and donation, and gestational surrogacy. It does not include artificial insemination (injection of sperm into the uterus) by a donor or from a woman's partner. For the sake of brevity, our discussion will not engage in depth with the important questions of determining legal parentage (which varies from state to state), insurance coverage, the patchwork landscape of state laws governing surrogacy, and the novel and projected techniques of ART that are on the more distant horizon, such as deriving sperm and egg from stem cells or aborted fetuses, artificial wombs, creation of live born animal-human hybrids or chimeras, genetic engineering of children (for example, by cloning or gene "editing"), or gestating babies in machines or nonhuman animal surrogates. These important questions will be reserved for a future analysis, which will depend, of course, on the more fundamental anthropological analysis to be set forth in the pages that follow. The discussion here focuses primarily on IVF and the closely-related techniques in current use.

## IVF: A PRIMER

As conventionally practiced, IVF involves five steps: (i) collection and preparation of gametes; (ii) fertilization; (iii) screening

and transfer of the resulting embryos to the gestational mother's uterus and disposition of non-transferred embryos, if any; (iv) pregnancy; and (v) birth. Each stage involves distinct interventions and possible adjunct techniques and entails various risks to mother and child-to-be.

Sperm is most often obtained directly from the prospective father; less frequently it is procured from a donor. Obtaining ova is significantly more difficult, painful, and costly. The ova provider is most often also the prospective gestational and rearing mother. The process usually involves the chemical stimulation of her ovaries to produce many more mature ova than the single egg released during a typical menstrual cycle. This is called "superovulation." One possible complication from this procedure is "Ovarian Hyperstimulation Syndrome," which involves severe enlargement of the ovaries and fluid imbalances that in extreme circumstances cause serious health risks, including death. Such severe cases of the disorder are rare, with a clinical incidence of 0.5–5 percent.[17]

The clinician tests the patient's blood and monitors the ova maturation. Once mature, the ova are harvested, most often by ultrasound-guided transvaginal aspiration. Using ultrasound to visualize the procedure, the clinician inserts a needle into the wall of the vagina and withdraws the ova from the ovarian follicles. Complications from this procedure are rare but can include accidental perforation of nearby organs and the typical risks associated with outpatient surgery.

Once the ova are removed they are placed in a culture medium. Sperm are modified—seminal fluid is removed and replaced with a synthetic medium. Sometimes sperm are sorted for motility.

Conception is attempted *in vitro* by combining the gametes in a dish, in hopes that a sperm fuses with the egg, from which arises a new, genetically distinct living human organism, the embryo. The traditional method of attempting fertilization is simply to collocate ova and sperm and wait for fertilization to occur as it might in the fallopian tube. There are other methods, including Gamete Intrafallopian Transfer (GIFT), in which the gametes are inserted into the patient's fallopian tube in hopes that fertilization will occur.[18] But an increasingly common fertilization technique is called Intracytoplasmic Sperm Injection (ICSI), which involves the direct injection of one sperm into the ovum.[19] ICSI was discovered by accident (when Belgian researchers mistakenly injected a sperm into an ovum) but was later developed as a method of fertilization for men suffering from male factor infertility. Its rate of use has increased dramatically even for cases not involving this condition. From 2007 to 2016, the total percentage of cycles involving ICSI increased from 72 percent to 81 percent.[20] Among cycles *without* male factor infertility, ICSI use increased from 15.4 percent in 1996 to 66.9 percent in 2012.[21] The reason for this increase is not clear. According to the CDC, the "use of ICSI did not improve reproductive outcomes, regardless of whether male factor infertility was present."[22] While instances of fertilization may have improved, the rate of live births has not. "For cycles without male factor infertility, ICSI use was associated with decreased rates of implantation, pregnancy, live birth, and multiple live births compared with conventional IVF."[23] Some have speculated that the inefficacy of ICSI may be connected to the circumvention of the usual competition among sperm to penetrate

the egg, allowing "unfit" sperm that would not have survived this natural process to fertilize the egg.

If fertilization is successful, the embryos are placed in a culture medium and evaluated for qualities that are associated with enhanced likelihood of implantation (though according to clinicians this is an inexact "science").

Some embryos are evaluated using preimplantation genetic diagnosis (PGD) to test for a variety of conditions, not all of which relate to the physical health of the resulting child. A 2018 study found that among all ART clinics in the United States, 92 percent offer PGD.[24] In this process, the early embryo is "biopsied," and cells are removed for analysis. Clinicians can perform the biopsy on the polar bodies just after fertilization, on embryos three days following conception at the six-to-eight cell stage of development ("cleavage stage" or "blastomere" biopsy), or on day five or six at the blastocyst stage of development ("blastocyst" biopsy), when the embryo is comprised of approximately one hundred twenty cells.[25] PGD is almost always combined with ICSI to make embryo biopsy a cleaner and easier process. Two-cell biopsy has been associated with a decline in successful implantation compared with single-cell biopsy. Some have raised concerns about the long-term health effects on children born following embryo biopsy—which, in the case of blastomere biopsy, can involve removal of a significant percentage of the embryo's cells prior to implantation. The biopsied cells are evaluated for specific genetic or chromosomal conditions. Those embryos that meet the predetermined criteria are transferred to the patient or surrogate's uterus or

are frozen for future reproductive purposes. Those embryos that fall short of the criteria are discarded and destroyed.

PGD is commonly used to screen embryos for chromosomal abnormalities associated with implantation failure and various disorders, including Down Syndrome. It is also used to detect single-gene disorders such as cystic fibrosis, Tay Sachs, and sickle cell disorder. (At present, more than 1,000 single gene disorders have been identified.) PGD can also be used to test for a heightened risk for some single-gene late onset diseases and conditions such as certain forms of ovarian and breast cancer, Huntington Disease, and Alzheimer's Disease.[26] PGD can even be used to identify embryos that are immunocompatible with a sick older sibling. Such embryos are transferred to a woman's uterus to initiate a pregnancy, and once such children are born, stem cells are harvested from their umbilical cord blood and transplanted to the elder sibling. This procedure has been used to treat children with Fanconi anemia.[27]

But PGD is also used for nonmedical purposes. Chromosomal analysis in PGD can be used to determine the sex of the embryo. As of 2018, 73 percent of American IVF clinics offered PGD for sex selection.[28] Of these clinics, 94 percent offered sex selection for "family balancing" (for example, choosing the sex of one's offspring in light of current family composition), and 81 percent offered it regardless of the patient's rationale.[29] Moreover, 84 percent of clinics offered PGD for family balancing and 75 percent offered it for purely elective sex selection for patients not suffering from infertility, who could conceive and bear children without assistance.[30] Jeffrey Steinberg, a clinician in

California, advertised screening not just for sex selection, but to choose skin, eye, and hair color. After public outrage, he discontinued screening for skin color, but continues to offer it to choose eye color, a test with a reported success rate of 60 percent.[31]

Once the screening and evaluation is complete, the selected embryo or embryos are transferred to the woman's uterus in order to initiate a pregnancy.[32] Less often, the embryo is transferred to the patient's fallopian tube in a process called Zygote Intrafallopian Transfer (ZIFT).

The number of embryos transferred depends on a variety of factors, including the patient's age. Overall for cycles involving newly-conceived (not frozen) nondonor embryos, 40 percent involved single embryo transfer, 49 percent two embryo transfer, 9 percent three embryo transfer, 2 percent four embryo transfer, and 1 percent five or more embryo transfer.[33]

According to the CDC, the average number of embryos transferred per patient has decreased dramatically over the past several years. The percentage of elective single-embryo transfers has simultaneously increased; from 2007 to 2016 the rate tripled from 12 percent to 40 percent of all cycles.[34] During this time period, the percentage has jumped from 5 percent to 43 percent for women under the age of 35, and from 3 percent to 25 percent for women 35–37 years old. At the same time, the percentage of transfers of three embryos has dropped from 26 percent to 9 percent.[35] As will be seen in the passages that follow, the number of embryos transferred has a significant impact on the health and well-being of mothers and children, and is thus crucial to any reflection on the regulation of assisted reproductive technology.

Embryos not transferred or discarded due to failed screening are cryopreserved in freezers. Studies suggest that the vast majority of these embryos are designated for use in future reproductive cycles. Very few (as a percentage) are discarded, donated to other patients, or to researchers. Most remain in cryostorage indefinitely. It has been estimated that one million human embryos are stored in freezers in the United States.[36]

There have been several high-profile court cases involving custody disputes over frozen embryos, usually featuring the ex-spouses who conceived them. Most often, one ex-spouse seeks to implant the embryos and bring them to term (either herself or by donation to another fertility patient), whereas the other wants the embryos destroyed in order to prevent the birth of children with whom he or she would have a biological relationship.

In IVF, embryos are most commonly transferred to the recipient's uterus to initiate a clinical pregnancy, marked by implantation of the embryo in the uterine lining.

Pregnancies are monitored closely, and women frequently receive treatments, including progesterone, to maintain the health of the child-to-be. In 2016, 27 percent of IVF cycles (and 44 percent of embryo transfers) resulted in a clinical pregnancy.[37] A significant percentage were multi-fetal pregnancies (21 percent). Among the cycles involving newly-conceived non-donor embryos, 20 percent of the pregnancies involved twins, and 1.1 percent triplets or more; 73 percent of the pregnancies were singleton.[38]

Multiple gestation pregnancies, attributable in large part to the practice of multiple embryo transfer described above, pose greater health risks to women. As reported by the President's

Council on Bioethics in its 2004 report *Reproduction and Responsibility: The Regulation of New Biotechnologies*, potential complications associated with multiple gestation pregnancies include high blood pressure, anemia, preeclampsia, uterine rupture, placenta previa, or abruption. Multiple gestation pregnancies are also more likely to aggravate preexisting health conditions than a singleton pregnancy.[39]

According to the CDC's most recent analysis, 22 percent of IVF cycles (and 36 percent of embryo transfers) involving newly-conceived nondonor embryos resulted in a live born child.[40] Of the all pregnancies initiated via IVF, 81 percent resulted in live births. Of these births, 19.4 percent involved multiple newborns (18.8 percent twins) and 81 percent singleton babies.[41] By way of comparison, the *overall* birth rate of twins in the U.S. during the same period was 3 percent (one third of which is attributed to fertility treatments).[42] Seventy-seven percent of higher order multiple births in the U.S. are attributed to ART.[43] However, statistics compiled by the CDC indicate that there is a downward trend in these numbers due to improvements in IVF and the increased incidence of single-embryo transfer. "From 2007 through 2016, the percentage of multiple-infant live births decreased from 35 percent to 20 percent for women younger than age 35, from 30 percent to 21 percent for women aged 35–37, from 24 percent to 18 percent for women aged 38–40, and from 15 percent to 13 percent for women aged 41–42."[44]

IVF is associated with preterm births (defined as birth before thirty-seven weeks of pregnancy) and low birthweight (5.5 pounds or less). A recent study found that IVF increases the risk

of preterm birth by 80 percent. The study set the rate of preterm birth from natural pregnancy at 5.5 percent.[45] According to the CDC, in 2016 the percentage of cycles resulting in preterm births for single infants from singleton pregnancies was 11.1 percent (16.7 percent for single babies born after multiple gestation pregnancies). For twins and higher order multiple newborns, the rates of preterm birth and low birthweight increase dramatically. The CDC reports that for twins, 57.6 percent of cycles resulted in preterm birth and 54.4 percent of cycles involved low birthweight. For triplets or more, the percentages of preterm birth and low birthweight jump, respectively, to 97.2 percent and 87.8 percent.[46]

Preterm birth and low birthweight are associated with a host of adverse health outcomes for children. According to the CDC, such children are "at a greater risk of death in the first year of life, as well as other poor health outcomes, including visual and hearing problems, intellectual and learning disabilities, and behavioral and emotional problems throughout life."[47]

There has been some concern raised that the use of IVF increases the incidence of birth defects among children conceived with its aid. The CDC recently conducted a study of four million infants and found that "singleton infants conceived using ART were 40 percent more likely to have a nonchromosomal birth defect (such as cleft lip and/or palate or a congenital heart defect) compared with all other singleton births."[48] But the authors of the study caution that more investigation is required, as the researchers did not control for "some factors related to infertility" that might account for the increased rate of birth defects.[49]

Despite the enhanced risks, the rate of birth defects overall is relatively low. A 2012 study in the *New England Journal of Medicine* found that the rate of birth defects for children conceived by ART was 8.3 percent versus 5.8 percent for those conceived naturally.[50]

The CDC likewise reports that "overall, children conceived using ART were about two times more likely to be diagnosed with ASD [autism spectrum disorder] compared to children conceived without ART." The reason for this higher rate appears to be linked to increased rate of adverse ART pregnancy and delivery outcomes that seem to correlate with an ASD diagnosis, including being born a twin or higher order multiple, preterm birth, and low birthweight. The CDC has called for more study of the issue.[51]

The use of ICSI, which appears to be increasing every year, including among male patients without male-factor infertility, has been associated with possible adverse outcomes. A diagnosis of ASD is more common for children conceived using ICSI than conventional IVF. The CDC reports, "Findings from some but not all studies suggest that ICSI is associated with an increased risk of chromosomal abnormalities, autism, intellectual disabilities, and birth defects compared with conventional IVF."[52] However, the report cautioned that these risks "may also be due to the effects of subfertility."[53] For example, if a man who suffers from a particular form of male factor infertility (associated with low sperm count and a particular Y-chromosome deletion) is able to successfully fertilize an ovum via ICSI, he risks passing this chromosomal abnormality on to the child, who, if male, will likewise be infertile.

## SURROGACY

While the issue of surrogacy is vast and complex, and largely beyond the scope of this chapter, a few brief comments are in order. The CDC reports that the overall use of gestational surrogates is rare (around 3 percent), but the incidence has more than doubled over the past decade and a half.[54] Between 1999 and 2013, the agency reports that ART cycles involving gestational surrogates resulted in 13,380 deliveries and the birth of 18,400 babies.[55] Intended parents who use gestational carriers are generally older than those who do not. The majority of gestational carriers are younger than 35.[56] ART cycles involving gestational carriers had higher rates of success than cycles where the intended mother carried the baby, measured by pregnancies and live births. However, due to the transfer of a greater number of embryos per cycle (two or more), gestational carrier cycles had higher rates of multiple births and preterm delivery.[57]

## LEGAL LANDSCAPE

Assisted reproductive techniques are subject to the federal laws regulating the safety and efficacy of drugs, devices, and biological products, and preventing the spread of communicable disease. The physicians who work in ART must be licensed and certified to practice medicine, and are, like all doctors, subject to the incentives and deterrents of medical malpractice law and the more general civil and criminal laws of the jurisdictions where they reside. But as such, the legal landscape of ART is famously and controversially sparse. The absence of specific and

meaningful regulation of ART in the United States is quite surprising, especially to foreign observers, given that it is the only medical intervention that ostensibly results in the creation and birth of a new human being. Moreover, ART is singular in the world of medicine because it frequently does not aim at curing the patient's underlying pathology, but rather at circumventing it. IVF does not cure infertility, it works around it. Be that as it may, there is simply not much law dedicated to regulating ART *qua* ART in the United States.

The only federal statute specifically dedicated to ART, the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), is a weak consumer protection law.[58] It does two things. First, it creates a model program for the certification of embryo laboratories that clinicians are free to adopt voluntarily if they wish. There is no evidence that this has had any perceptible effect; in its analysis the President's Council on Bioethics reported that not a single embryo laboratory in America had adopted the model framework offered by the statute.[59]

The second function of the FCSRCA is to mandate that all clinics in the United States practicing ART report annually to the CDC certain data relevant to success rates. CDC contracts with the Society for Assisted Reproductive Technology (SART)—an ART professional organization comprised of most clinics in the nation—to validate the information provided. SART conducts an audit of a small sample of clinics each year to confirm data reported. The CDC analyzes the data and issues publicly available reports that include some (though not all) of the information gathered. It reports success rates (reported both per "cycle," defined as a process that starts "when a woman

begins taking fertility drugs or having her ovaries monitored for follicle production," and per embryo transfer), type of ART performed, and patient diagnoses of infertility.

The CDC does not, however, report information of crucial relevance to prospective patients. It includes no information on the types or rate of adverse health outcomes to mother or child (beyond noting the percentage of term, normal weight, and singleton births). It does not include any information regarding the costs of procedures. It does not include information on the number of human embryos created, frozen, or destroyed.

Some clinicians reported to the President's Council on Bioethics that "success rate" as a reporting metric is highly manipulable by unscrupulous clinics.[60] For example, the numbers could be artificially inflated by accepting only the most promising patients, by terminating and reclassifying unsuccessful cycles rather than reporting them, and by other similar tactics.

Most worrisome to critics of the CDC surveillance regime established by FCSRCA is that there are no serious penalties for noncompliance other than the publication of the offending clinic's name in the report itself. Beyond the listing of these names on the CDC's website, the FCSRCA has no enforcement mechanism.

There is an additional federal law that has an incidental effect on ART research. In 1996, Congress, via an appropriations "rider" (a spending restriction appended to the annual federal statute that appropriates funding to government agencies), prohibited federal funding for "the creation of a human embryo or embryos for research purposes" as well as for research "in which a human embryo or embryos are destroyed, discarded,

or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses *in utero* under" relevant federal regulations on human subjects protections.[61] This law, known as the "Dickey-Wicker" amendment (named after sponsors Jay Dickey and Roger Wicker) does not limit the practice of ART, though it does prevent federal funding of ART research that runs afoul of its criteria.

For the most part, ART is regulated just as any other branch of medicine, primarily at the state level. The law touches medicine mostly at the front end, at the point of licensure and certification to practice. The primary legal tool to regulate the ongoing practice of medicine is the private law of malpractice. The legal standard for malpractice liability is conduct that falls below the "standard of care"—the type and level of care of an ordinary prudent physician, with the same training and experience, under the same circumstances. The standard is established through expert testimony regarding the practices of the specialty in question. Plaintiffs can also sue doctors in tort for misconduct associated with the failure to obtain proper informed consent. But malpractice litigation is a reactive and ad hoc form of governance.

There is no systematic mechanism for ongoing regulation and oversight of the practice of medicine. There is not, for example, any administrative agency charged with this responsibility. The FDA regulates the drugs, devices, and biological products used by ART physicians for safety and efficacy, but does not regulate the practice of medicine itself. It does administer a statutory framework (established by the Public Health Services Act) for preventing the spread of communicable diseases. Under these auspices it promulgates regulations for the

screening and use of "Human Cells, Tissues, and Cellular and Tissue-Based Products." But FDA has, at the urging of the ART professional societies and "individuals who facilitate embryo donation," carved out very broad exemptions for sperm, egg, and embryos used in IVF.[62]

There have been a few notable exceptions to the FDA's general practice of non-interference with ART. In 1998, Associate Commissioner of the FDA Stuart Nightingale issued a "Dear Colleague" letter asserting that the agency had jurisdiction over any experiment involving cloning to produce a live born child, presumably under its authority to regulate gene transfer research. The letter advised researchers that the agency would not approve such practices, given safety concerns.[63] Later in 2001, Kathryn Zoon, a former head of the agency's Center for Biologics Evaluation and Research (CBER), which oversees human gene therapy research[64] speculated that if such concerns over safety and efficacy were resolved, proposed research on cloning to produce children would be approved.[65] FDA's announcement was criticized as exceeding the agency's authority under the statutes it was created to administer. After the 2001 Zoon statement, the FDA has not reasserted similar claims of authority. Some commentators have speculated that the earlier statements by the agency were meant as a bluff to deter unscrupulous researchers from proceeding; others have suggested that they were meant to discourage Congress from adopting overly restrictive legislation disfavored by the scientific community by assuring members that the agency was in control of the situation.

More recently, Congress adopted an appropriations rider forbidding the FDA from approving "research in which a human

embryo is intentionally created or modified to include a heritable genetic modification."[66] The "Aderholt Amendment" (named for its Congressional sponsor Robert Aderholt) effectively forbids gene editing of embryos as part of IVF treatment, because such changes would be "heritable" to the future generations of genetic descendants of the adults these embryos would later become. The Aderholt Amendment also forbids the various methods of mitochondrial disease treatment that involve the creation and transfer of an embryo with the mitochondrial DNA from two women (usually from a donor and the mother), and the nuclear DNA of the mother and father. Such embryos are sometimes called "Three Parent Embryos." Because mitochondrial DNA is maternally inherited, any female offspring conceived with the aid of these techniques will likewise pass along the donor mitochondrial DNA to her genetic children. All female descendants in this line will likewise pass the genetic change to their offspring.[67] The Aderholt Amendment has been renewed every year since its adoption in 2015.

Putting aside these very atypical examples of FDA involvement in the practice of medicine, ART proceeds largely unregulated by any administrative agency. Physicians are thus left free to practice medicine with a creativity and dynamism that might not be possible with a more cumbersome, comprehensive regime of ongoing oversight. The deference to physicians in the law signals the well-earned respect and esteem in which the profession of medicine is held in American culture. But as applied to ART, which is *sui generis* in both its means and ends, this largely *laissez faire* framework has been a source of consterna-

tion. Novel practices such as ICSI and PGD move from bench to bedside very rapidly and become routine in short order. This passage from the President's Council on Bioethics report is arresting:

> IVF itself was performed on at least 1,200 women before it was reported to have been performed on chimps, although it had been extensively investigated in rabbits, hamsters, and mice. The same is true for ICSI. The reproductive use of ICSI was first introduced by Belgian researchers in 1992. Two years later, relying on a two-study review of safety and efficacy, ASRM [the American Society for Reproductive Medicine] declared ICSI to be a "clinical" rather than "experimental" procedure. Yet the first non-human primate conceived was born only in 1997 and the first successful ICSI procedure in mice was reported in 1995.[68]

Whereas creativity, dynamism, and an entrepreneurial spirit are highly valued when medical practice simply aims to restore a patient to health, the calculus is quite different when the "cure" involves the creation of a new human being. The background facts of IVF's exorbitant cost, the market pressures on clinics to show greater "success" than their competitors, and the human desperation and vulnerability understandably caused by infertility all combine to create strong temptations for everyone involved to push the envelope of innovation when more caution is in order.

## STATE COURTS AND ART

The handful of state supreme court opinions dealing directly with ART involve custody disputes over frozen embryos, usually between former spouses. There are divergent approaches, with some state supreme courts (New York, Washington, Colorado, and Tennessee) signaling a willingness to treat such disputes as straightforward contract cases, applying the terms of any valid prior agreement that sets forth the procedures for embryo disposition under the circumstances.[69] Other state courts of last resort, such as Massachusetts, have refused to enforce such agreements, at least when they appear to require transfer, gestation, and birth against the wishes of one of the parties.[70] Still other state supreme courts, like New Jersey and Iowa, have refused to enforce prior agreements when parties change their minds about embryo custody and disposition.[71]

Despite the disagreement in framing, there are some commonalities among the decisions of these courts of last resort. First, none of them have permitted one partner to implant embryos, gestate, and deliver a baby over the objections of the other.[72] Second, none have treated the frozen embryos as legal persons or children, despite entreaties by one of the parties or the decision of the lower court. Instead, such courts have either deemed frozen embryos to have some "intermediate status" between persons and things, or simply treated them as marital property. Some state courts have explicitly invoked the U.S. Supreme Court's abortion jurisprudence to support their conclusion that the human embryos at issue are not "persons," despite the absence of the unique burdens present in pregnancy. Finally,

the state supreme courts have drawn deeply upon the principles of reproductive liberty, autonomy, and privacy of American abortion jurisprudence as the touchstone for analysis, and all but one have evinced a strong presumption for enforcing the wishes of the party seeking to "avoid procreation" and the unchosen familial relationship with child born as a result.[73]

In the context of surrogacy, there have been some recent high-profile examples of disputes between gestational carriers and intended parents. Two recent instances involved intended parents demanding that the surrogate abort her pregnancy because the child-to-be was diagnosed *in utero* with an adverse but treatable medical condition. In one case, Andrea Ott-Dahl agreed to be a gestational carrier (and an egg donor) for a lesbian couple unable to conceive using ART. When a twelve-week ultrasound revealed that the child-to-be likely had Down Syndrome, the intended parents demanded that Ott-Dahl terminate the pregnancy. Ott-Dahl refused and informed the intended parents that she and her wife Keston planned to keep the baby. The intended parents threatened to sue to try to compel the termination or seek damages, but ultimately did not.[74] In another case, two intended parents demanded that a surrogate terminate her pregnancy when the child-to-be was diagnosed *in utero* with a severe heart defect—Hypoplastic Left Heart Syndrome (HLHS). HLHS is fatal if untreated. However, with a surgical intervention it has a survival rate of 70 percent, though patients may require continued monitoring and care throughout their lives. The surrogate refused to terminate the pregnancy but reported a great deal of anxiety when she learned that the intended parents intended to opt against life-sustaining measures

and let the baby die once they assumed custody of the baby following its birth. In a newspaper interview, the surrogate reported with relief that the intended parents changed their minds and sought treatment for the baby.[75]

There have been other recent cases in which the intended parent or parents directed the surrogate to abort ("reduce") one of the multiple fetuses she was carrying. California resident Melissa Cook contracted to be a gestational carrier for a fifty-year old deaf and mute single man from Georgia who lived alone with his elderly parents. When he discovered that she was carrying triplets, he demanded that she selectively abort one of them to avoid the costs of raising three children. She refused, and he sued. Her parental rights were terminated upon birth and custody was awarded to him. She unsuccessfully sought relief in the California courts and the United States Supreme Court.[76]

Gestational carrier (and California resident) Brandyrose Torres read about the dispute involving Melissa Cook and came forward to tell her story to the press. She was directed by the intended parents to abort one of the triplets she was carrying, even though the pregnancy was healthy and none of the children-to-be were in distress. Torres refused and the intended parents threatened suit for breach of contract. Ultimately, Torres gave birth to the triplets and conveyed custody to the intended parents.[77]

## LEGAL OVERSIGHT OF ART *QUA* ART

The findings of the President's Council on Bioethics in 2004 regarding the legal landscape for ART *qua* ART remain effectively

unchanged. To wit, "there is no uniform, comprehensive, and enforceable system of data collection, monitoring or oversight for the biotechnologies affecting human reproduction."[78] Direct governmental regulation of ART is minimal. The FCSRCA remains a very weak consumer protection law. Most worrisome to the Council was the absence of a legal framework for comprehensive research or regulation focused on the possible effects of ART on the health and well-being of children conceived with its aid, gestational mothers, and egg donors.[79] The Council further observed that in the absence of such regulation, "novel technologies and practices that are successful move from the experimental context to clinical practice with relatively little oversight or deliberation."[80] It noted that PGD is essentially unregulated, with no comprehensive data gathering on the health impact on children born following its use, and no limits on its specific applications, including screening for non-medical criteria such as sex, intelligence, or eye color. The Council observed that there is no comprehensive, uniform legal framework or information gathering system regarding the creation, use, and disposition of human embryos in ART.[81] It further noted that "there is no comprehensive mechanism for regulation of commerce in gametes, embryos, and assisted reproductive technology services."[82]

All of these observations remain true today.

In the absence of comprehensive governmental regulation, the practice standards and ethical guidelines governing ART doctors are promulgated by the profession itself—through professional associations and practitioner societies. Thus, self-regulation is the primary mode of governance for ART. The primary professional societies who set these standards, the

American Society for Reproductive Medicine and the Society for Assisted Reproductive Technologies, have been criticized in some quarters (including by the patient advocacy community) for being too permissive. Supporters of these organizations retort that the purpose is not to police members and that a lighter self-regulatory touch is more likely to keep members aligned with the values of the professional societies. It is very clear that the core animating normative goods driving the prescriptive pronouncements of ASRM (which promulgates ethics and practice guidelines) are patient autonomy and reproductive liberty.

## THE ANTHROPOLOGY OF AMERICAN ART LAW

Like the American jurisprudence of abortion, the anthropology of the legal landscape for ART is expressive individualism. The vision of identity and flourishing assumed by ART law becomes clear when one considers the type of liberty that emerges from the absence of meaningful regulation. From this absence of law arises a very particular kind of freedom, perfectly suited for the atomized individual will seeking to express the originality discovered within itself, and to pursue the life plan of its own authentic design. It is the singular freedom of the unencumbered self, lacking constitutive attachments and unchosen obligations, for whom relationships are either transactional or adversarial, but always instrumental. It does not take embodiment into account, and as anyone who has ever suffered from or has loved someone suffering from infertility understands, it not the kind of freedom that responds fully to the pain of those longing for

a child, who feel betrayed by their bodies. Whereas the American law of abortion responds to the complex crisis of unplanned pregnancy by conferring the simple and brute liberty to eliminate the nascent human life *in utero,* the American law of ART responds to the vulnerability and suffering of infertility by conferring the freedom to create new life by nearly any means necessary. These are rules and remedies designed for persons understood through the imperfect lens of expressive individualism.

A fruitful point of entry into the anthropology of American ART law is through the writings of the man who was arguably the intellectual godfather of the United States framework, the late Professor John Robertson. Robertson, a prolific scholar of the law, was an iconic figure in American public bioethics for decades, serving on numerous influential governmental and private sector advisory committees, including an extended term as Chairman of the American Society for Reproductive Medicine's Ethics Committee. Perhaps more than any single person, Robertson's thought and work is reflected in the modern American legal framework for ART. To understand the anthropology of the law of ART, it is important to explore briefly his conception of human identity and flourishing. Robertson published numerous essays and scholarly articles until his untimely death in 2017, but the most useful and comprehensive source for understanding his vision and the current legal landscape is his 1994 book, aptly titled *Children of Choice.* The themes and concepts he developed in this work recur throughout his whole body of scholarship and advocacy, and have become core animating principles of the current legal paradigm for ART in America.

Robertson's normative framework is squarely anchored in the primacy of "procreative liberty," which in his words is "first and foremost an individual interest."[83] He defines procreative liberty as simply "the freedom to decide whether or not to have offspring."[84] It can often be difficult to determine when Robertson is describing current law and policy or making a moral argument, but this difficulty springs in part from the fact that the law as it currently exists (or, more precisely, the absence of law) broadly mirrors Robertson's approach. He roots the right to procreative liberty explicitly in the Supreme Court jurisprudence of contraception and abortion, styled as the right to avoid procreation.

From this he infers the converse aspect of procreative liberty, namely, the freedom to pursue procreation, both coitally and noncoitally. For Robertson, the right to procreation is a negative right, meaning the government cannot interfere with its exercise. But it is not a positive right; the government is not obliged to facilitate its practice.

Procreative liberty is essential to human flourishing according to Robertson, because it is necessary for self-defining experiences that people greatly value. Maximal freedom to use reproductive technologies is thus crucial because "they are the means to achieve or avoid the reproductive experiences that are central to personal conceptions of meaning and identity."[85] Restrictions on the freedom to avoid procreation unjustly "determine one's self-definition in its most basic sense," whereas limits on the pursuit of procreation through one's chosen means "prevents one from an experience that is central to individual identity and meaning in life."[86] Accordingly, the rights of procreative

liberty should be jealously guarded and walled off from state interference except for the most compelling reasons, which Robertson suggests are "seldom" present.[87]

Framed as an operational legal standard to govern conflicts in this domain, Robertson argues that "procreative liberty should enjoy presumptive primacy when conflicts about its exercise arise because control over whether one reproduces or not is central to personal identity, to dignity, and to the meaning of one's life."[88] Those who would restrict procreative liberty always bear the burden of demonstrating that it is necessary to prevent "substantial harms to the tangible interests of others."[89]

But what kinds of practices fall within the scope of procreative liberty? Here again, Robertson defines the field of protected activities according to their subjective value to the individual involved. "A person's capacity to find significance in reproduction should determine whether one holds the presumptive right."[90]

Even the discrete, isolated actions of gamete donation or gestation without any intent to parent the child born can offer highly valuable and meaningful experiences to donors and gestational carriers. Accordingly, they should be protected from state interference.

When presented with a particular application of reproductive technology, Robertson asks whether the activity is "so central to an individual's procreative identity or life plan" that it deserves protection under the aegis of procreative liberty.[91]

What about screening embryos for preferred traits or conditions? According to Robertson, "Some degree of quality control would seem logically to fall within the realm of procreative

liberty."[92] At points in his writings, Robertson seems to entertain the possibility that certain practices that fall outside the mainstream and to which most people would not ascribe value (for example, genetic enhancement) might lie beyond the scope of procreative liberty, but he always stops short of categorically ruling them out. It is difficult to see how his larger normative framework of maximal procreative liberty would allow such restrictions in the absence of serious harms to others.

What kinds of harms are sufficient for Robertson to curtail procreative freedom? Use and destruction of *in vitro embryos* do not constitute sufficient harms to restrict procreative liberty. Robertson rules out the possibility that they are "persons," but seems to suggest that they should be respected insofar as they have the potential to become a person (if they are transferred, gestated and born), and because of the "symbolic meaning" they hold for "many people."[93] But these interests are easily outweighed in the face of an individual's desire to procreate. Robertson also holds that the fetus *in utero* is likewise not a person, and therefore may be destroyed to vindicate the right of a pregnant woman not to procreate. He states explicitly that in his view, no one has the right to be born.[94]

What about harms to children later born who are injured by the ART techniques from which they are conceived? Or harms to such children caused by their genetic parents' underlying pathologies that required the use of ART to conceive in the first place? For Robertson, it turns out that in almost every instance, such harms are also not sufficient to justify restrictions on procreative liberty. In fact, he does not recognize injuries caused by IVF and adjunct techniques to be a "harm," rightly

understood. In support of this proposition, Robertson invokes philosopher Derek Parfit's "non-identity problem," which holds that if a person is harmed by the very intervention that made his existence possible (such as ICSI), and the only way to prevent such harms is not to use this intervention at all, then such a restriction is not a benefit to the person, because he would not otherwise exist.[95] Moreover, because his life in the injured state is not worse than nonexistence, the use of the harmful technique is, in fact, a benefit to him. Following this reasoning, Robertson concludes that for children harmed by such techniques, "ARTs to enable their birth does not harm them and does not justify restriction on those grounds."[96]

Turning to concrete cases, Robertson applies this principle to the risk of birth defects from ICSI and concludes that children born with these afflictions would not be "harmed," because the alternative future for them is nonexistence.[97] Thus, restrictions on ICSI to prevent birth defects in children are not justifiable restrictions on procreative liberty. For the same reasons, Robertson expresses opposition to bans on the transfer of multiple embryos to prevent harms associated with preterm birth and low birthweight. He likewise opposes bans on novel forms of procreation including the use of gametes derived from stem cells or fetuses, genetic manipulation of embryos, or even cloning to produce a live born child, if the reason for such bans is to protect the well-being of the child born as a result. He does not regard such harm as cognizable. If the freedom to pursue these modes of producing children is to be limited, it must be justified on other grounds. Robertson is doubtful that alternative rationales for bans or restrictions would be compelling.

Robertson does allow the possibility that some intentions of parents, if they do not entail the desire to rear the child, might put the enterprise outside the domain of "procreative liberty." And he notes that state interests (other than preventing harm to children—which he does not recognize) "*might*" warrant regulation when parents' aims are far afield of "traditional reproductive goals."[98] But in making this allowance, it is once again not clear if Robertson is describing the law as it is or as it should be. Moreover, it is difficult to reconcile this solicitude for "traditional reproductive goals" in light of the almost unalloyed libertarian orientation of Robertson's approach.

Surveying the current American legal landscape for ART, it is more or less John Robertson's world. His views have not been constitutionalized by the Supreme Court, but the absence of meaningful, comprehensive regulation and oversight of ART creates conditions that closely approximate his vision of "procreative liberty." There are no legal limitations specific to ART meant to protect the health and well-being of children born with its aid. There are no legal restrictions on techniques that are routinely used that result in a massive increase in risk of preterm births and low birthweight, with associated adverse health consequences for such children. There is no regulation or even federally sponsored longitudinal study of commonly used interventions that appear to increase the risk of birth defects, autism, and other maladies. Parents, *including those who are not infertile,* freely use PGD to select the sex of their children by transferring preferred embryos and discarding others. Parents use PGD to screen and discard those embryos who have a higher probability of contracting treatable diseases that do not appear until

later in life. Organizations advertise predictive testing for low intelligence, with the promise of developing tests for predicting high intelligence in the near term. People screen embryos for eye and hair color. People buy and sell sperm, eggs, and even "batches" of embryos. Intended parents who contract with gestational carriers sometimes demand the abortion of children-to-be with adverse but treatable medical conditions, threatening lawsuits and the withdrawal of financial support. There are a million human embryos stored in freezers as a result of the absence of comprehensive and uniform laws governing their creation, use, and disposition.

All of these practices are legal and unrestricted, creating a domain of free choice and private ordering that replicates Robertson's vison of procreative liberty. And, with Robertson's work as an interpretive guide, it is clear that this particular conception of liberty is firmly rooted in the anthropology of expressive individualism. As Robertson states explicitly, this liberty is meant to serve *individuals* in their quest to pursue reproductive experiences that they highly value as meaningful and essential to self-definition. Human bodies at all stages from embryonic to adult are recruited as instrumentalities of these personal projects. In some cases, the body and its parts are explicitly reduced to articles of commerce. People enter and exit intimate procreative relationships marked by contract and bargained-for exchange. Parental relationships, be they genetic or gestational, are created, avoided, and dissolved through will, choice, and rational ordering. Procreative liberty thus understood alters the role of physician from servant of health and wholeness to a skilled technician enabling the projects of

the will. Thus "health" itself is transformed from a concept connected to the natural functioning of the organism to one nested in will and desire.

This notion of procreative liberty, following its anthropological foundation of expressive individualism, reorients the purposes of reproduction from the aim of bringing about the birth of *one's child* to the satisfaction the self-defining goals of the individuals involved. This transformation of purpose was evident in the 2002 comment of Dr. Gerald Schatten in his testimony to the President's Council on Bioethics: "Reproductive medicine is helping prospective parents realize their own dreams for a disease free legacy."[99] But the version of procreative liberty nested in expressive individualism that arises from the American legal landscape of ART encompasses dreams of more than just a disease-free legacy. It includes a legacy free from a much broader array of imperfection, including even the presence of children of a disfavored sex.

And like all legal frameworks built upon expressive individualism, the current regime is blind to the vulnerability, dependence, and fragility that inexorably attends an embodied life. The American law of ART does not consider the vulnerable and dependent child-to-be in the calculus of interests to be protected and harms to be avoided. Along with John Robertson, American law does not count prevention of harms to children caused by the ART interventions by which they were conceived as grounds for restricting procreative liberty. The law is designed to serve the desires of those seeking to reproduce, despite the risks to the health of the child-to-be discussed above. It likewise fails to adequately protect the health and well-being of the genetic or gestational mothers.

Even evaluated according to the metrics of the law's own aspiration for consumer protection, it does not sufficiently protect ART patients (clients?)—men and women who are profoundly vulnerable by virtue of the deep sadness, exhaustion, and desperation caused by infertility, along with the potentially ruinous financial costs of pursuing treatment for it. The law does nothing to aid their moral imagination—nothing to help them to see the child-to-be at every step of the process as a gift to be treasured and protected. It does nothing to protect them from themselves and the temptation to undertake serious risks to their future child's health and well-being, not to mention their own. The law does not protect patients from making dehumanizing and discriminatory choices like sex selection in bringing their children into the world. The law indulges intolerance of imperfection by allowing unfettered screening for all manner of "flaws." The law fails to teach against the destructive notion that the parent-child relationship is defined by will, control, and mastery rather than unconditional love and gratitude.

And the law as presently constituted does nothing to prevent the community from coarsening and coming to see the entire enterprise not as medically-aided conception and birth of children to be welcomed and loved unconditionally, but rather as a form of manufacture of products subject to quality assurance, and accepted or rejected according to their conformity with the preferences and desires of the "customer" who paid for it.

Here again, the perils of a public bioethics rooted in expressive individualism become apparent. The law is blind to the weak, vulnerable, fragile, and dependent, and all interests and

concerns are crowded out by the law's focus on the desires of the individual will seeking its own way.

## ANTHROPOLOGICAL CORRECTIVE FOR PUBLIC BIOETHICS OF ART

But the law's vision of procreative liberty is not the freedom that patients seeking infertility treatment in the real world want or need. They are not unencumbered selves, but people who are desperately seeking to embrace a role that is defined by a relationship; they want to be a *parent*. And there is no such thing as a parent without *a child*. Despite the weariness, sadness, and even bitterness that comes with experiencing infertility as a betrayal by one's own body, they do not pursue ART to realize any dream of a particular legacy or to assert their atomized will, but to be a mother or a father.

Accordingly, for the public bioethics of ART to respond to their neediness, promote their flourishing, and to protect them and their children from harm (even arising from their own choices), it must begin with the meaning and consequences of embodiment.

Accordingly, just as in the context of abortion, the task for the law is to support, protect, and sustain the networks of uncalculated giving and graceful receiving necessary to respond to the neediness of the vulnerable and dependent, and through which embodied beings come to realize their potential as the kind of persons who are able to make the goods of others their own. By virtue of our individual and shared lives as *embodied* beings, human flourishing is most profoundly achieved through

love and friendship. Of course, where such networks of shared sacrifice and support are missing or become frayed, the law must step in to protect the vulnerable, weak, and marginalized.

More concretely, just as in the context of abortion, the normative paradigm most fitting to the public bioethics of assisted reproduction is *parenthood*. Assisted reproduction, like all reproduction, involves parents and children. The complexity that arises from advances in the medicine and biotechnology of ART does not change this fact, even as it fractures the previously integrated dimensions of procreation. Because of IVF and related techniques and practices, there is the potential for *many* mothers and fathers—genetic, gestational, and rearing. But all are mothers and fathers just the same, albeit in different respects. They are made so by the fact that they are engaged in the business of making and raising *babies*.

Thus understood, the networks of giving and receiving to which the law should respond are those proper to parenthood, which includes, of course, parents and children, but radiates outward to the physicians and health care providers who serve them, extended family members, neighbors, community, and polity (including the government itself), all of whom are reciprocally obliged and entitled to render and receive mutual aid.

An anthropology of embodiment and laws built upon it recognizes that the most vulnerable protagonist of procreation is the child. She depends on the uncalculated giving of her parents—of every sort—who will make her good their own as they engage in whatever role they might play in her life. By virtue of their relationship to her, the genetic, gestational, and rearing parents must act in her best interests, and must make

every effort to protect her from harm, at every stage of her development from conception forward. More deeply, her parents—all of them—must understand that she is a gift, a person who has been conceived, not a product manufactured to serve the desires of another. The proper disposition toward a gift is gratitude and humility, not mastery and exploitation. She was not selected to meet anyone's specifications but emerged from a procreative process possessed of intrinsic and equal dignity. Her "imperfections" or "flaws" are of no consequence, except insofar as they are occasions for unconditional care and support. Doubtless, to see her as she is at every stage of her life from conception forward requires moral imagination. And to honor unchosen obligations to her requires restraint, discipline, and sacrifice. But such is the relationship of parent to child.

Parenting thus requires the virtues of uncalculated giving—just generosity, hospitality, and, when necessary, accompanying the child in suffering as if it were one's own (misericordia). This means subordinating one's desires for the sake of one's child—giving without concern for receiving, in proportion to neediness. It also requires the virtue of gracefully receiving the child who is a gift. This includes gratitude for the child, humility (rather than the hubris of rational mastery), and openness to the unbidden and tolerance of imperfection (rather than the drive to weed out flaws).

The law, then, must support and sustain parents, regardless of type, in discharging these obligations. It must facilitate the understanding and practice of these virtues of parenthood. How and by what means the law might most successfully enable this mindset and the goods and virtues that follow from it are highly

complicated questions requiring consideration of factors well beyond the current inquiry. There are many means—passive and active—that could be deployed to this end. But the law must begin by expanding its anthropological foundation to encompass the meaning and consequences of embodiment. Concretely, the law must offer support, directly and indirectly, for parents of all sorts in fulfilling their duties to children, whom they have a role in conceiving, gestating, and rearing.

Where parents and others fail to meet their obligations to the children, the law must intervene to protect them directly. Again, what this might mean concretely is a large question for another time, but at a minimum, certain principles are clear enough. The law must closely regulate or perhaps even prohibit medical interventions that foreseeably endanger the health and well-being of children conceived with the aid of ARTs. To this end, the government must conduct rigorous longitudinal studies on the impact of ARTs on the flourishing of children, broadly understood. Whether the harm to children is caused by the ART itself, or by the underlying pathology of the infertile parent, the ultimate focus of the law should be on protecting the health and flourishing of children.

Obvious areas of concern are practices that contribute to low birthweight and preterm birth, increased rate of birth defects, as well as the harms wrought by discriminatory and dehumanizing practices such as sex selection, screening for disfavored traits, intolerance of the imperfect and disabled, and the commodification of the body and its parts.[100] States could consider moratoria or bans on practices shown to be harmful.

Moreover, the law must be devised to secure the intrinsic equal dignity of children conceived by ART, and to avoid the risk that others will regard them as unequal and inferior to their "creators" because of how and why they came into the world. They are not creatures devised in a lab to fulfill the dreams of others. They are, in the words of Gil Meilaender, "begotten and not made."[101]

And it may go without saying, but the most fundamental goal of the law in this domain is to ensure that every child born with the aid of ART is received and raised as a son or daughter in a loving family: the network of uncalculated giving and graceful receiving *par excellence.*

Reorienting the purposes of ART regulation toward the well-being of the child will likewise have consequences for how medicine is practiced. From the outset, measures taken must account for the downstream effects on the child-to-be's health and flourishing. In fact, given that the successful culmination of the enterprise is the birth of a child, practitioners would do well to think of the child-to-be *as a patient* in her own right, and make choices with this in mind, even during the preconception stages of the process. Again, how the law might contribute to shaping and directing these behaviors is a complex question for another time.

Vulnerability and exploitation are possible at all stages of the ART process. It is the obligation of the community and the polity to protect these individuals, perhaps even from their own self-destructive decisions or misguided choices that harm the children who are born with their assistance. Areas of concern include the exploitation of gamete donors and gestational sur-

rogates, the commodification of the body and its parts, and the use of IVF techniques and interventions that bear significant risks for the women involved. Developing concrete legal structures responsive to these concerns will, of course, require careful study, reflection, and prudence across a wide spectrum of factors. But the goals, at least, are clear.

The networks of giving and receiving necessary to support the dependent and vulnerable in this context do not merely encompass the parents, children, and health care providers involved, but radiate outward to extended family, community, and polity. The law must have a role in strengthening these bonds and promoting the reciprocal rendering and receiving of care.

It is important to address yet another vulnerable and dependent population that is centrally involved in and affected by the lack of meaningful regulation of ART as such in America, namely, the living human embryos who are conceived, cultured, screened, transferred, intentionally destroyed, donated to other patients, sold in "batches," given to scientists for use and destruction in research, or most often, frozen indefinitely. The moral status of the human embryo is a central question of public bioethics and has been since its inception. The public question has been addressed by government advisory commissions, state legislatures, state courts, administrative agencies, Congress, multiple presidents, and several different intergovernmental bodies including the United Nations, UNESCO, and the Council of Europe.

For present purposes, the narrow question is what (or who), exactly, is the embryo in the context of ART? For commentators

like John Robertson and like-minded advocates of maximal procreative liberty, they are not persons, despite their biological status as living organisms of the human species. For some, they are simply raw biological materials to be used and discarded with impunity; for others they have an "intermediate status" warranting "special respect," which precludes their use and destruction except in compelling circumstances (though this turns out to be a very broad category in practice).

The arguments against the personhood of the living human embryo track the abortion debate somewhat, though the context is distinguishable, as there are no burdens of unplanned pregnancy at issue. Some argue (like Tooley and Warren) that embryos are not persons because they are not yet capable of preferred capacities such as cognition, self-awareness, the formulation of desires, and the creation of future directed plans.[102]

Others argue that embryos that are slated for destruction or indefinite cryostorage are not persons because they will never develop these preferred capacities as they will never enter an environment (namely, the womb) that would support such development. Still others argue that all IVF embryos are not persons based on the assertion that they are incredibly fragile and that most will die of natural causes ("natural embryo loss") before they develop the preferred capacities of personhood. Some argue that they are not persons because they are very small—"a tiny clump of cells no bigger than the period at the end of this sentence."[103] Others assert that they are not yet persons because they are not, in fact, human beings at all but merely "an undifferentiated ball of cells."[104] Finally, there are those who argue that IVF embryos are not persons prior to the formation of the

"primitive streak"—a biological structure that appears around 14 days of development that is the precursor to the nervous system, after which the phenomenon of monozygotic "twinning" is thought to be no longer possible. For such advocates, the primitive streak signals the rudiments of the brain and spinal cord—essential to the cognitive functioning associated with their conception of personhood—and guarantees that the human organism is a stable individual who will not divide into multiple individuals. These arguments are sometimes made individually, sometimes in combination.

As discussed in the previous chapter, an anthropology of embodiment construes the biological origins, structure, and function of the embryo differently. It begins with a posture of great skepticism toward arguments that make "personhood" contingent upon a being's achievement of certain milestones established by others relating to size, strength, cognition, and dependence. This skepticism grows when those setting forth such criteria for personhood are strongly motivated by the desire to use or destroy the being whose moral status they seek to evaluate. Such decisionmakers have a vested interest in a finding of non-personhood; if embryos are not persons, then they are available for recruitment into the projects of others without serious concern for their interests or well-being.

Viewed through the anthropology of embodiment, none of the arguments for IVF embryo non-personhood are persuasive. All human beings, because of their embodiment, exist on a "scale of disability," with their powers waxing and waning according to age, health, and circumstance. As discussed in the last chapter, living members of the human species need not meet

tests for cognitive capacity or possess the abilities of self-reflection and expression necessary to flourish as prescribed by the anthropology of expressive individualism. The vulnerability and dependence of the embryonic human being on others to supply a nurturing environment to support her life and further development (namely, her gestational mother's womb) is no warrant to declare her a non-person available for use or destruction. To the contrary, her vulnerability and dependence—like all human vulnerability and dependence—are a summons for care, concern, and protection. Nor is her small size or fragility a license to treat her as a non-person. The claim that a high rate of embryo demise prior to implantation and birth diminishes the moral worth of embryos is a *non sequitur;* the same logic would lead to the false conclusion that a high infant mortality rate reduces the moral value of babies *in utero.* In any event, the rate of pregnancies initiated per transfer in IVF is quite high—45 percent for nonfrozen embryos and 56 percent for frozen embryos. The overall rate of IVF pregnancies resulting in birth is 81 percent.[105]

Similarly, the claim that IVF embryos are "undifferentiated balls of cells" does not accurately reflect their status as living organisms, biologically or morally. An "organism" is an individual, whole living being composed of parts that function in a coordinated manner to support growth and development of the entity along a species-specific trajectory. Under this definition, the IVF embryo screened and transferred, discarded, or cryogenically stored is manifestly an organism. There is some debate among embryologists about when exactly differentiation and coordination among the component parts of the embryo

occur (for example, within moments following sperm-egg fusion or when the maternal and paternal pro-nuclei fuse at syngamy approximately twenty-four hours later). Despite this uncertainty, there is clear evidence of internally directed, coordinated activity from days one to six, relevant to enabling implantation and further development of the embryo.[106] By virtue of its structure, function, and composition, the IVF embryo is a living human organism.

Similarly, the capacity for embryo twinning does not undermine the embryo's status as an individual living human organism. In rare instances (0.4 percent of births in natural reproduction, and two to twelve times higher in IVF), some portion of the cells of an embryo will split off from the whole, and resolve itself into a new, genetically identical "twin."[107] Some point to this unique capacity for regulation and restitution following developmental disruption as evidence that the embryo is not yet "individuated." But this is not persuasive, given that indivisibility is not necessary for individuation in an organism. The individual flatworm has the bodily resilience to survive similar disruptions, with its severed parts sometimes resolving into a new organism. So too with the human embryo at early stages of development. Its resilience is not surprising given the plasticity of its component parts, which give rise to all the tissue types and structures of the mature body. But despite such plasticity, in the absence of disruption, such parts function as a coordinated, integrated whole. In short, as an individual organism.

From the perspective of an anthropology of embodiment, discussing the human organism at this stage as "the embryo"

fails to capture its essential identity. This nomenclature trades in the notion of atomization and isolation of expressive individualism. It is not "the embryo," but the particular human offspring of specific genetic parents. *This* embryonic human being emerges from the process of fertilization already embedded in a web of relationships, most notably involving his or her biological progenitors—his or her parents. An anthropology of embodiment is mindful of this connectivity and the obligations and privileges that flow from it that comprise one dimension of the network of giving and receiving necessary to human life and flourishing. The relationship of genetic progenitors to the given embryonic human being conceived is, normatively speaking, that of parent and child. It would take more discussion and reflection to do justice to the richness of this relationship and to unfold the contours of obligation and privilege within this network, but at a minimum, the genetic parents have an obligation to protect and promote the flourishing of their embryonic child. How they might discharge this obligation also requires a great deal more thought and discussion, but the end point of any such pathway of care would have to be the birth of a child who has a place of belonging as a genuine son or daughter in a family that loves him or her unconditionally.

The role of the law is to facilitate this end—to help genetic parents to cultivate their moral imaginations so as to see their child in the embryo in the dish, and to understand their obligations as parents. Should the parents fail in this regard, the law must intervene to do what the parents cannot or will not do—seek a resolution where this embryonic human being ultimately finds a place of unconditional belonging as a son or daughter in

a loving family. How the law can accomplish this aspiration, and what kinds of regulatory mechanisms are fitting and appropriate to this end, are a matter for future consideration.

The conclusion as a matter of principle is that embryonic human beings, as embodied living members of the species, must be included in the network of giving and receiving on which all human beings depend for their survival and their flourishing. Their good must be counted as part of the common good, and their vulnerability and dependence are a warrant for protection and support, just as with any other living member of the human family.

How the law might concretely accomplish this end, which of the myriad passive and active tools it should deploy toward these purposes, and what the practice of ART might look like under this new regime are all matters for a future inquiry. One place to start would be to study the rare laws in the United States and abroad that offer protection to all participants in ART through the lens of children and parents. For example, a Louisiana statute declares such embryonic human beings to be "juridical persons," with the attendant privileges and protections owed to such a status.[108] It would be worth knowing whether such a law successfully engenders the understanding that assisted reproduction is a domain of parents and children at all stages of the process. Similar provisions designed to protect parents—genetic, gestational, and rearing—would likewise be worth exploring. These are inquiries for another time, but they must be pursued if the public bioethics of ART is to be responsive to the full range of needs and wants of the embodied beings whose lives are touched by it.

# 10

# Recommendations

Over the past two years, the Council has devoted much time and energy to examining the current oversight and regulation of the uses of biotechnologies that touch the beginnings of human life—practices arising at the intersection of assisted reproduction, genetic screening, and human embryo research. The Council has heard from various experts and stakeholders, engaged in its own diagnostic review of current regulatory mechanisms and institutions, outlined the key findings emerging from that review, and surveyed various general and specific policy options. As the previous chapters indicate, the Council now understands a great deal about today's regulatory landscape and has identified concerns that suggest the need for improved monitoring and oversight and, perhaps, new forms of governmental regulation. Yet we are very far from being able to offer clear and well-considered recommendations regarding major institutional reforms. We do not know the precise costs and benefits of overhauling existing regulatory institutions and practices or of creating new regulatory authorities. We do not even know enough about the incidence and severity of some of the possible risks and harms that we have identified as causes of concern to decide whether they are serious enough to justify changing the present arrangements. We do not accurately know, for example, how the technologies and practices at the heart of our inquiry affect the health of those

whose lives are touched by them—most notably, the children conceived with their aid. Similarly, we do not know how widely preimplantation genetic diagnosis or preconception (and preimplantation) sex selection will be practiced, and for which purposes. Without the answers to such questions, it would be premature at best to recommend dramatic legal or institutional changes. Further research and inquiry, and additional consultations with all those affected, are clearly needed.

Yet even as such inquiry and consultation proceed, the Council believes that some modifications can and should now be implemented to address some of the concerns identified by the present inquiry. The recommendations we offer fall into three general categories: studies and data collection, oversight and self-regulation by professional societies, and targeted legislative measures.

In Sections I and II of this chapter, the Council proposes several measures it believes the federal government and the various relevant professional societies should adopt immediately. Most of these suggestions are aimed precisely at addressing the remaining empirical questions described above. These include a call for comprehensive information gathering, data collection, monitoring, and reporting of the uses and effects of these technologies. They also address the needs for increased consumer protection, improved informed decision-making, and more conscientious enforcement of existing guidelines for practitioners of assisted reproductive technologies (ARTs).

In Section III of this chapter, we identify several matters that may warrant prudent interim legislative action, especially in light of rapidly emerging innovations that signal new departures in human reproduction. Familiar disquiet regarding human cloning or commerce in human embryos and gametes is augmented by recent reports of, for example, fusion of male and female embryos into one chimeric organism and of the derivation of gametes (in animals) from embryonic stem cells (in principle enabling embryos to become biological parents). Accordingly, while policymakers monitor and gather information and while deliberation continues about the need for better and more permanent monitoring and oversight arrangements, it may be necessary and desirable to enact a legislative moratorium on a few boundary-crossing practices, thereby provid-

ing interim prophylactic limitations. Such limitations would prevent the introduction of certain significant innovations into human procreation in the absence of full public discussion and deliberation about their ethical and social implications and consequences.

In offering these interim recommendations for improvements in data collection, monitoring, and professional self-regulation and in proposing limits and restraints on some potential applications of ARTs, the Council does not intend to challenge the current practices or impugn the ethical standards of most practitioners of assisted reproduction. The Council recognizes the efforts of professionals and patient groups working in this field to devise and implement appropriate ethical guidelines and standards of care. Yet we have identified areas of concern that have not been sufficiently studied or addressed. And there are at present no effective mechanisms for monitoring or regulating some of the more problematic practices or for preventing unwelcome innovations introduced by irresponsible practitioners. Indeed, it is our belief that responsible professional participants, patients, policymakers, and interested citizens should be able to recognize the merit of our proposals and work to see them implemented.

The recommendations we offer here are recommendations of the Council as a whole. Though we differ about certain fundamental ethical questions in this field, and especially about the moral standing of human embryos, we have nevertheless been able to agree on several policy suggestions that we believe should command not only the respect but also the assent of most people of common sense, good will, and a public-spirited concern for human freedom and dignity. These recommendations emerge quite naturally from the diagnostic survey and analysis presented in the previous chapters, and they are best understood only when read in that context. We have sought to frame the recommendations with sufficient specificity that they might be adopted by the relevant target audiences.

## I. FEDERAL STUDIES, DATA COLLECTION, REPORTING, AND MONITORING REGARDING THE USES AND EFFECTS OF THESE TECHNOLOGIES

### *A. Undertake a Federally Funded Longitudinal Study of the Impact of ARTs on the Health and Development of Children Born with Their Aid*

A most important unanswered question before the Council concerns the precise effects of ART and adjunct technologies on the health and normal development of children who are now being born or who will in the future be born with their aid. There have been a few studies, mostly undertaken abroad, reaching different and sometimes contradictory results. An effort has been undertaken, by the Genetics and Public Policy Center at the Johns Hopkins University, in collaboration with the American Academy of Pediatrics (AAP) and the American Society for Reproductive Medicine (ASRM), to review all of the existing literature on this question. This retrospective study is a laudable start, capable of identifying harmful health and development outcomes that should be monitored in the future. The Council strongly believes, however, that what is needed now is a *prospective* longitudinal study—national, comprehensive, and federally funded—that looks at both the short-term and the long-term effects of these technologies and practices on the health of children produced with their assistance, including any cognitive, developmental, or physical impairments. Such a study would require an adequate control sample, and a sufficiently large population of subjects to yield meaningful statistical results. Participation in such a study would, of course, be voluntary.

A seemingly ideal vehicle for this study is the National Children's Study (NCS) now being planned by a consortium of federal agencies led by the National Institute of Child Health and Human Development (NICHD). This study, which (if funded) is scheduled to begin in 2005, would track the health and development of 100,000 children across the United States from before birth until age 21. Given its great demographic, temporal, and substantive scope, the NCS would be uniquely suited to studying the health of children conceived with the aid of ART. It would be national in scope, it would not require

the special recruitment of a population of children conceived with the aid of ART, and all participation would be voluntary. Correcting a major defect in other studies of the impact of ART, the NCS would have a built-in control sample, namely, children conceived without the aid of ART. It would allow researchers to observe and consider health impacts that reveal themselves only years after birth. It would analyze an exceptionally wide range of biological, physical, social, cultural, and other factors that may significantly influence a child's health and development. The NCS would have enormous resources at its disposal, as it would be undertaken by a partnership of federal, state, and local agencies; universities; academic and professional societies; medical centers; communities; industries; companies; and other private groups. Finally, the NCS would release its results as the study progresses; thus, it would not be necessary to wait until 2025 to review the information gathered. The study would publicize results as the children reached certain developmental milestones. In short, the NCS would offer an unprecedented and perhaps unrepeatable opportunity to answer questions relating to the well-being of children conceived with the aid of ART.

Should the planned NCS not go forward for any reason (or should it not include a suitable or statistically significant study of children conceived using ARTs), the Council recommends that an independent federally funded longitudinal study be undertaken on the health and development of children who are born with the aid of ARTs.

### *B. Undertake Federally Funded Studies on the Impact of ARTs on the Health and Well-Being of Women*

Another area where better information is needed regards the health and well-being of women who use ARTs and of women who donate their eggs for the use of others. One or more studies, either in conjunction with or separate from the above-mentioned longitudinal study, should be conducted to discover the effects, if any, of the use of ARTs on women's health, including any short-term or long-term hormonal, physical, or psychological impairments. Participation in such a study would, of course, be voluntary.

### *C. Undertake Federally Funded Comprehensive Studies on the Uses of Reproductive Genetic Technologies, and on Their Effects on Children Born with Their Aid*

As noted above, assisted reproduction and genomic knowledge are increasingly converging with one another. Practices such as preimplantation genetic diagnosis (PGD) and gamete sorting represent the first fusion of these disciplines. Before these practices become routine, it is desirable that policymakers and the public understand their present and projected uses and effects. To this end, there should be federally funded comprehensive studies, undertaken ideally with the full participation of ART practitioners and their professional associations, on how and to what extent such practices are currently and may soon be employed, and their effects on the health of children born with their aid. Mechanisms need to be developed for ongoing monitoring of the outcomes of these practices and other practices to which they may lead. Participation in any such studies would, of course, be voluntary.

### *D. Strengthen and Augment the Fertility Clinic Success Rate and Certification Act*

As currently written, the Fertility Clinic Success Rate and Certification Act (FCSRCA) is aimed at providing consumers with key information about the pregnancy and live-birth success rates of assisted reproduction clinics in the United States. We believe that the Act should be augmented and strengthened, both to improve this original function of consumer protection and to allow for better public oversight (through the already existing ART surveillance program at the Centers for Disease Control [CDC]) of the development, uses, and effects of reproductive technologies and practices. Toward these ends, the Act, or the regulations propounded pursuant to it, or both, should be improved and strengthened in the following ways.

*1. Enhance Reporting Requirements.*

*a. Efficacy. Provide more user-friendly reporting of data, including adding "patients" as an additional unit of measure.*

Currently, data are reported only in terms of "cycles" of treatment (beginning when a woman starts ovarian stimulation or monitoring), rather than in terms of individual patients treated. Thus, it is impossible to know how many individuals undergo assisted reproduction procedures in a given year, how many patients achieve success in the first (or second or third) cycle, how many women fail to conceive, and the like. Presenting results in terms of "numbers of individuals" (in addition to "numbers of cycles") would be very helpful to prospective patients and would yield more precise information for policymakers.* Also, this information should be presented with any qualifying language or additional information that would help to avoid confusion for prospective patients or the public.†

*b. Risks and side effects. Require the publication of all reported adverse health effects.* Adequate consumer protection requires informing prospective users of the known hazards connected with the services or products they are using. Yet there is today no mechanism for the publication of information regarding adverse effects of ARTs, either on the health of adult patients or on that of their children. At the present time, the CDC does collect data on complications and adverse outcomes of pregnancy, including low birthweight and birth defects for each live born and stillborn infant, but this information is not made public. Knowledge of such adverse effects is of paramount concern for prospective patients, policymakers, and the public at large. The CDC should publish its data on the incidence of adverse effects on women undergoing treatment, as well as on the health and development of children born with the aid of ART. In order not to confuse or unduly alarm prospective patients or the public, the CDC should include in its publication comparative data on the incidence of such effects in

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* The Council is not calling for the abandonment of "cycles" as a unit of measure. Rather, we urge the inclusion of "patients" as an additional unit of measure.

† The CDC collects but does not publish information regarding ART patients' prior attempts to conceive using assisted reproduction. This information might prove useful in helping the CDC to analyze and present information on a per-patient basis in a way that does not distort success rates and the like.

unassisted births, as well as any other relevant information that could help prevent misimpressions regarding the nature and magnitude of the hazards associated with ART.

*c. Costs to the patients. Require the reporting and publication of the average prices of the procedures and the average cost (to patients) of a successful assisted pregnancy.* There is currently no comprehensive source of information regarding the costs borne by the patients seeking treatment involving assisted reproductive technologies. Not surprisingly, prospective patients are keenly interested in this information. Moreover, policymakers interested in questions regarding equality of access, insurance coverage, and related matters would greatly benefit from such information. It would also shed light on whether incentives currently exist that may induce patients and clinicians to engage in potentially risky behavior, such as the transfer of multiple embryos in each cycle, in an effort to reduce costs (especially in those places where in vitro fertilization (IVF) is not covered by insurance). While the publication of such information may cause some confusion or, worse, may create a perverse incentive to cut costs at the expense of health and safety, the Council believes that the consumer benefits of providing such information outweigh such speculative harms. This is especially true if this information about costs to the patient is published alongside the information, recommended above, regarding patient health and safety.

*d. Innovative techniques. Include information on novel and experimental procedures.* A key area of concern for the Council is the ease and speed with which experimental technologies and procedures (such as intracytoplasmic sperm injection [ICSI] or PGD) move into clinical practice, even in the absence of careful clinical trials regarding their efficacy and their long-term effects on children born with their use. It would be useful for consumers and policymakers to understand more fully how each clinic manages the process of introducing new technologies and practices and what safeguards are employed. Such information would include the human subjects protections in place; the extent to which technologies are first tested in animals; the stan-

dards that must be satisfied before a given procedure is deemed fit for clinical use; and the measures taken to evaluate safety and efficacy.

*e. Adjunct technologies. Require more specific reporting and publication of the frequency of, and reasons for, uses of specialized techniques such as ICSI, PGD, and sperm sorting for sex selection.* Little is understood about the frequency and uses of the various adjunct technologies and practices complementing standard IVF. Under the present system, the CDC already collects and reports information relating to the incidence and uses of some adjunct technologies.* The present approach could be greatly improved, however, by modestly changing the relevant law to require information on additional adjunct procedures (particularly those that combine assisted reproduction with human genetic technologies), as well as to require the reporting and publication of somewhat more detailed information relating to the reasons patients elect to use those procedures that are already subject to reporting requirements. For example, the present system of reporting sheds little light on precisely *why* patients chose ICSI as their preferred method of fertilization. Also, because results are reported in terms of cycles rather than patients (as discussed above), it is impossible to know how many *individuals* used ICSI.

Other techniques, particularly those fusing reproductive technology and genomic knowledge, are not reported at all under the present version of the Act. There is no requirement to report the number of cycles using PGD, much less the reasons for using PGD. For example, how many patients using PGD are infertile? How many have family histories of genetic disorders? What sort of genetic screening is being done? For aneuploidy and single-gene mutations? For donor siblings? For non-disease-related traits? There is also no reporting of any practices in which sex selection occurs or of the reasons for undertaking them. Consumer protection and public policy would be enhanced if this information

* For example, the CDC publishes information on the percentage of IVF cycles involving ICSI (49.4 percent in 2001); the CDC also reports the percentage of the cycles using ICSI that involve patients with male factor infertility (57.8 percent in 2001).

were available and published. Consumers would benefit from knowing how much experience a given clinic has in performing such procedures. The public would benefit from knowing how, why, and to what effect genomic knowledge is being used in human reproduction.

*2. Enhance Patient Protections: Informed Decision-Making.*

*a. Provide model forms for decision-making.* The present Act would be greatly improved by providing for the promulgation of easy-to-read model consent forms that include information on the possible health risks to mother and child, the novelty of the various procedures used, the number of procedures performed to date, the outcomes, and the various safeguards in place to ensure that such procedures are safe and effective.

*3. Improve Implementation.*

*a. Enforcement. Provide stronger penalties to enhance compliance with the Act's reporting requirements.* Under the Act as currently written the only penalty for noncompliance is the publication of the names of nonreporting clinics. This is insufficient, given the importance of clinic compliance to ART consumers and the greater public. The penalties should reflect the magnitude of harms to be avoided. We leave to legislators the question of what precisely these should be.

*b. Funding. Increase funding for implementation of the Act.* CDC's budget should be augmented sufficiently to enable it to undertake the additional measures suggested above. In this way, the increased oversight called for will be borne by the government rather than by the individual patient. We leave to legislators the question of how much additional funding would be required.

## II. INCREASED OVERSIGHT BY PROFESSIONAL SOCIETIES AND PRACTITIONERS

Professional oversight has traditionally been the principal mechanism of regulation for the practice of medicine, and the practice of reproductive medicine is no exception. There is a well-developed body of professional guidelines and standards for the clinical practice of assisted reproduction, and as far as the Council can determine (in the absence of a more comprehensive investigation of physicians' actual conduct), the vast majority of practitioners abide by these guidelines and standards and are dedicated to the welfare of their patients. Yet the Council has identified the following substantive areas that it believes require attention and improvement:

### *A. Strengthen Informed Patient Decision-Making*

Clinicians and their professional societies should make efforts to improve the current system of informed decision-making by patients to conform to the concerns and suggestions described above. ASRM and SART (the Society for Assisted Reproductive Technology) should pay attention not only to helping devise improved consent forms, but also to recommending procedures to their members for discussing the subject properly with patients and for securing their meaningful consent. For this purpose, they should consider making training sessions on this subject a requirement of membership.

### *B. Treat the Child Born with the Aid of Assisted Reproductive Procedures as a Patient*

ART clinicians should take additional measures to ensure the health and safety of all participants in the ART process, *including the children who are born as a result*. Thus, in making decisions and undertaking clinical interventions, such practitioners should carefully consider how these actions will affect the health and well-being of these children. We recognize, of course, that health care services tend in general to be disaggregated among different specialties, and that collaboration is not always feasible. In the domain of assisted reproduction, once pregnancy has been achieved, the prenatal care of the

pregnant woman is transferred to her obstetrician. But the Council urges clinicians and professional societies to seek out ways to improve the continuity of the services offered to their patients and their children. ART clinicians and their professional societies should consult with pediatricians (and their professional societies) to learn how their practices may be affecting the health and safety of the children born as a result. Clinicians and professional societies should also cooperate fully and vigorously with any efforts (such as the studies described in Section I of this chapter) to ascertain the effects of ART and related practices on the health and development of such children. In addition, the Council strongly endorses a specific substantive recommendation: clinicians and professional societies should take additional concrete steps to *reduce the incidence of multiple embryo transfers* and resulting multiple births, a known source of high risk and discernible harm to the resulting children.

### *C. Improve Enforcement of Existing Guidelines*

There are today a host of reasonable guidelines in place for clinicians and practitioners engaged in ART, and, to repeat, they are apparently followed by most practitioners. However, the relevant professional societies need to take stronger steps to ensure that these guidelines are followed. For example, one such professional society "actively discourages" the use of PGD for sex selection for nonmedical purposes, yet several prominent members of that society openly advertise the practice. Professional societies must clarify the contours of appropriate conduct and adopt reasonable mechanisms of enforcement.

### *D. Improve Procedures for Movement of Experimental Procedures into Clinical Practice*

Professional societies and clinicians should develop a more systematic mechanism for reviewing experimental procedures before they become part of standard clinical practice. Such a system might include requirements for animal studies, institutional review board (IRB) oversight, and formal discussion and

ongoing (and prospective) monitoring of the significance and results of novel procedures.

### *E. Create and Enforce Minimum Uniform Standards for the Protection of Human Subjects Affected by Assisted Reproduction*

At present there is no systematic, mandatory mechanism for protecting human subjects who are engaged in experimental ART protocols not affiliated with institutions receiving federal funds. This problem is compounded by the fact that in the practice of assisted reproduction (as in the practice of medicine more generally), there is not a clear distinction between research and innovative clinical practice. Investigational interventions that could affect the health and well-being of children born with the aid of ART should be subjected to at least as much ethical scrutiny and regulatory oversight as investigational interventions affecting other human subjects of research. Current research policies establish special protections for children and fetuses in research. For similar reasons, there is a need for special protections when research involves interventions in embryos that could later affect the health and welfare of the resulting live-born children. Clinicians and their professional societies should adopt measures (such as IRB-like oversight) to provide necessary safeguards.

### *F. Develop Additional Self-Imposed Ethical Boundaries*

Clinicians and professional societies would be well-advised to establish for themselves additional clear boundaries defining what is and what is not ethically appropriate conduct, regarding both research and clinical practice. Without such guidance, irresponsible clinicians and scientists may engage in practices that will, fairly or unfairly, bring opprobrium on the discipline as a whole. Practices such as, among others, the fusion of male and female embryos, the use of gametes harvested from fetuses (or produced from stem cells) to create embryos, and the transfer of human embryos to nonhuman uteri for purposes of research fall squarely into this category. The relevant professional societies should preemptively take a

firm stand against such practices and back that stand up with meaningful enforcement.

## III. TARGETED LEGISLATIVE MEASURES

In the course of our review, discussion, and findings, we have encountered and highlighted several particular practices and techniques (some already in use, others likely to be tried in the foreseeable future) touching human procreation that raise new and distinctive challenges. Given the importance of the matter, we believe these practices and techniques require special attention, not only from professional societies but also from the people's representatives. Especially because technological innovations are coming quickly and because there are today no other public institutions charged with setting appropriate limits, we believe Congress should consider some limited targeted measures—bundled together perhaps as a "Reproduction and Responsibility Act"—that might erect boundaries against certain particularly questionable practices.* These measures, proposed as moratoria, would remain operative at least until policymakers and the public can discuss the possible impact and human significance of these new possibilities and deliberate about how they should be governed or regulated.

The benefits of such congressional legislation, as we see it, are multiple:

(a) It could help educate the public about the transformative character of some new reproductive biotechnologies; and it could enhance public awareness of the need for research and practice in this area to be guided by respect for the women using assisted reproduction and for the children born with its aid (on which see below).

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* The listing (below) of these activities should not be taken to imply that we believe that the reputable practitioners of assisted reproduction are interested in engaging in them. Our goal is rather to establish boundaries and guidelines for future practice, and barriers against those irresponsible practitioners who, indifferent to the standards of the profession and the community, might not only endanger patients and the public, but also unfairly cast a pall over the entire field.

(b) It would institute a temporary moratorium on certain practices, imposing a few carefully defined boundaries on what may be done and preventing any individual from committing acts that could radically alter what the community regards as acceptable in human reproduction without prior public discussion and debate.

(c) If carefully drafted, it would not interfere with important scientific research. On the contrary, it could serve to protect the reputation of honorable scientists and practitioners of assisted reproduction against the mischief done by "rogues," whose misconduct might invite harsh and crippling legislative responses.

(d) Practically, it would place the burden of persuasion on those innovators who are inclined to transgress these important boundaries without adequate prior public discussion or due regard for social or moral norms.

(e) It would show that there is a way forward for continuing public oversight in these areas, and it would demonstrate that scientists and humanists, physicians and laymen, liberals and conservatives, "pro-lifers" and "pro-choicers," can find certain shared core values that they are willing to defend collectively and by deliberate agreement.

Legislative interest in responsible reproductive practices might give rise to a fairly wide range of specific provisions, and Congress should consider these in their full array. But the concerns we have taken up in this report, and which emerge from our findings, suggest to us a few that are especially crucial, and also especially likely to command fairly broad assent. They may be usefully grouped under four principles or desiderata, each pointing to one or two particular provisions that we believe to be in order and that we now recommend*:

* The particular provisions that follow below (in boldface type) have been carefully drafted, with a view to specifying accurately the Council's concerns. Yet they are to be read not as precise legislative provisions but as articulations of possible boundaries that we would like to see erected and defended.

### *A. Preserving a Reasonable Boundary between the Human and the Nonhuman (or, between the Human and the Animal) in Human Procreation*

The question of the human-animal boundary in general can, in some respects, be quite complex and subtle, and the "mixing" of human and animal tissues and materials is not, in the Council's view, by itself objectionable. In the *context of therapy and preventive medicine*, we accept the transplantation of animal organs or their parts to replace defective human ones; and we welcome the use of vaccines and drugs produced from animals. Looking to the future, we do not see any overriding objection to the insertion of animal-derived genes or cells into a human body—or even into human fetuses—where the aim would be to treat or prevent a dread disease in the patient or the developing child (although issues would remain about indirect genetic modification of egg and sperm that could adversely affect future generations). Likewise in the *context of biomedical research*, we now see nothing objectionable in the practice of inserting human stem cells into animals—though we admit that this is a scientifically and morally complicated matter. But in the *context of procreation*—of actually mixing human and nonhuman gametes or blastomeres at the very earliest stages of biological development—we believe that the ethical concerns raised by violating that boundary are especially acute, and at the same time that the prospects for drawing clear lines limiting permissible research are especially favorable. One bright line should be drawn at the creation of animal-human hybrid embryos, produced ex vivo by fertilization of human egg by animal (for example, chimpanzee) sperm (or the reverse): we do not wish to have to judge the humanity or moral worth of such an ambiguous hybrid entity (for example, a "humanzee," the analog of the mule); we do not want a possibly human being to have other than human progenitors. A second bright line would be at the insertion of ex vivo human embryos into the bodies of animals: an ex vivo human embryo entering a uterus belongs *only* in a *human* uterus. If these lines should be crossed, it should only be after clear public deliberation and assent, not by the private decision of some adventurous or renegade researchers. We therefore recommend that Congress should:

- **Prohibit the transfer, for any purpose, of any human embryo into the body of any member of a nonhuman species; and**

- **Prohibit the production of a hybrid human-animal embryo by fertilization of human egg by animal sperm or of animal egg by human sperm.***

### *B. Respect for Women and Human Pregnancy, Preventing Certain Exploitative and Degrading Practices*

Respect for women with regard to assisted reproduction encompasses many things, including respect for their health, autonomy, and privacy; these are by and large properly attended to in current assisted-reproduction practices. But in the face of some new technological possibilities, we recognize that respect for women also involves respecting their bodily integrity. A number of animal experiments using assisted reproductive technologies have shown the value of initiating pregnancies solely for the purpose of research on embryonic and fetal development or for the purpose of securing tissues or organs for transplantation. We generally do not object to such procedures being performed on other animals, but we do not believe they should, under any circumstances, be undertaken with humans, or that human pregnancy should be initiated using assisted reproductive technologies for any purpose other than to seek the birth of a child. A woman and her uterus should not be regarded or used as a piece of laboratory equipment, as an "incubator" for growing research materials, or as a "field" for growing and harvesting body parts. We therefore recommend that, in an effort to express our society's profound regard for human pregnancy and pregnant women, Congress should:

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* It bears noting that, in testing for male-factor infertility, practitioners of assisted reproduction now use hamster eggs to test the capacity of human sperm to penetrate an egg; yet there is no intent to produce a human-animal hybrid embryo and there is a negligible likelihood that one might be formed, given the wide gap between the species. Thus, we do not believe that such procedures run afoul of the letter or spirit of the above recommendations.

- **Prohibit the transfer of a human embryo (produced ex vivo) to a woman's uterus for any purpose other than to attempt to produce a live-born child.**

### *C. Respect for Children Conceived with the Aid of Assisted Reproductive Technologies, Securing for Them the Same Rights and Human Attachments Naturally Available to Children Conceived In Vivo*

We believe that children conceived with the aid of ARTs deserve to be treated like all other children and to be afforded the same opportunities, benefits, and human attachments available to children conceived without such assistance. If some care is taken, this can surely be accomplished, as it largely has been for twenty-five years with IVF as ordinarily practiced. But as we have seen, certain applications of embryo manipulation and assisted reproductive techniques could deny to children born with their aid a full and equal share in our common human origins, for instance by denying them the direct biological connection to *two* human genetic parents or by giving them a fetal or embryonic progenitor. We believe that such departures and inequities in human origins should not be inflicted on any child. We therefore recommend that, in an effort to secure for children who are born with the help of ARTs the same rights and human attachments naturally available to children conceived in vivo, Congress should:

- **Prohibit attempts to conceive a child by any means other than the union of egg and sperm.***

- **Prohibit attempts to conceive a child by using gametes obtained from a human fetus or derived from human embryonic stem cells.***

- **Prohibit attempts to conceive a child by fusing blastomeres from two or more embryos.***

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* Operationally, in each of the three cases listed, the prohibited act comprises the creation ex vivo of any such human embryo *with the intent* to transfer it to a woman's body to initiate a pregnancy.

### *D. Setting Some Agreed-Upon Boundaries on How Embryos May Be Used and Treated*

What degree of respect is owed to early human embryos will almost certainly continue to arouse great controversy, as it does among members of this Council. But we all agree that human embryos deserve, as we have said, "(at least) special respect." Accordingly, we believe some measures setting upper age limits on the use of embryos in research and limits on commerce in human embryos may be agreeable to all parties to the ongoing dispute over the moral status of human embryos. Along these lines, we believe that Congress should:

- **Prohibit the use of human embryos in research beyond a designated stage in their development (between 10 and 14 days after fertilization);[*] and**

- **Prohibit the buying and selling of human embryos.[†]**

Furthermore, these concerns about commerce in the domain of human reproduction suggest to us the need for legislation

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[*] Some members of the Council are opposed to any experimentation that harms or destroys human embryos, but, recognizing that it is legal and active, they see the value in limiting the practice. Other members of the Council favor allowing such experimentation during the early stages of embryonic development, but nonetheless recognize the need to establish an upper age limit beyond which such research should not proceed. Some Council members believe that this upper limit should be 14 days after the first cell division; others favor 10 (or fewer). *This recommendation should not be construed as silently endorsing (or opposing) embryo research at earlier stages.*

[†] This provision is not intended to preclude those patients who receive donated embryos from reimbursing donors for reasonable expenses, storage costs, and the like. Also, because the compensated giving of sperm is a long-established practice, and because payment to egg donors is now also fairly common, efforts to ban payment to gamete providers would likely prove controversial and untenable for purposes of actual legislation. Thus, we decline to recommend such a ban here. That is not to say, however, that the Council approves of the buying and selling of gametes. Indeed, many Council members have raised serious concerns regarding this species of commercialization in the domain of human reproduction.

instructing the United States Patent and Trademark Office **not to issue patents on claims directed to or encompassing human embryos or fetuses at any stage of development**; and amending Title 35, United States Code, section 271(g) (which extends patent protections to products resulting from a patented process) **to exclude these items from patentability**. The language of any such statute would in our view need to take some care not to exclude from patentability the processes that result in these items, but only the products themselves. Similar language has been included in a component of the federal budget for fiscal year 2004 (the Consolidated Appropriations Act of 2004, H.R. 2673, 108th Congress [January 23, 2004], Division B, § 634), but we believe this provision should also be made a clear and permanent element of the patent law.

These recommendations indicate the kinds of specific measures that could give concrete expression to widely shared goals and that might serve as safe interim boundaries, as public deliberation tries to catch up with rapidly changing technologies. We do not presume here to make detailed suggestions regarding specific legislative language or the assignment of penalties, as Congress, should it choose to take up these recommendations, would most appropriately determine these in accordance with its usual procedures. Also, of course, these are by no means the only possible legislative measures Congress might take up to limit practices that put at risk important shared public values. But we offer these recommendations for what in our view are reasonable and moderate measures, which could do genuine good and which might command relatively broad assent across the usual spectrum of opinion on these subjects.

Questions for the Record from Senator Charles Grassley
U.S. Senate Committee on the Judiciary
"The Continued Assault on Reproductive Freedoms in a Post-*Dobbs* America"
March 20, 2024

Questions for Doctor Monique C. Wubbenhorst:

*(1) Medical facilities of all sorts have security measures limiting who can access certain areas. For example, a hospital's nursery has tight security measures to ensure the safety and security of the newborn infants in the hospital's care. Similarly, operating rooms in medical facilities have safeguards to ensure patient safety and security during procedures.*

*Is there a minimum level of security in vitro fertilization (IVF) facilities should have to ensure the safety of embryos? If so, what security factors ought to be considered?*

Thank you for this question. It is my opinion that IVF facilities should have several types and layers of security, because there are two types of security to be considered. One is concerned with access to embryos by unauthorized people, including those with potentially malicious intent. The other is concerned with preserving the safety and physical integrity of embryos. The latter can be compromised by equipment failures or staff errors.

Physical security can be promoted by introducing the following regulations, many of which are in place at many health facilities:

a. At a minimum, the embryology laboratory should have a separate, locked entrance within the hospital or clinic. There should not be access to the laboratory from outside the building.
b. Consideration should be given to hiring a receptionist for physical presence in the clinic near the access door to the laboratory.
c. Only staff with proper identification should have access to the embryology laboratory and freezers.
d. Badge access should be used to enter the laboratory and to enter the freezer area.
e. Freezers should be locked (physically or electronically). Access to the freezer should be recorded.
f. Cameras should be installed to monitor activity within the laboratory.
g. Monitoring of the IVF laboratory and freezer area by building security staff (i.e., walk-through on watchman's rounds) should be included as part of general facility security measures.

The protection of embryos can be promoted by introducing the following regulations:

a. IVF clinics and laboratories should adopt federal biobanking standards. These standards provide guidance as to the handling, transportation and storage of biospecimens. Although an embryo is a human being, not a biospecimen,

federal biobanking standards should be updated and expanded to apply to IVF laboratories so as to protect embryos.

b. An alarm system should be installed to notify staff of unauthorized access to the laboratory or freezer area.
c. Freezers should be set up in such a way that, if they begin to warm, alarms will go off.
d. All freezers should be connected to a generator as a backup power supply (e.g. a generator), in the event of a prolonged power failure, which could result in the thawing and death of embryos.
e. Routine infection control and sterility protocols should be in place in IVF clinics.
f. As noted above, building security staff (i.e., walk-through on watchman's rounds) should monitor the IVF laboratory and freezer area to check for high temperature or other environmental problems as part of general facility security measures.

*(2) Based on your experience, does the IVF industry need better regulation to protect women, would-be mothers, and the embryos created? If so, what types of measures ought be considered by the Federal Government or by the states?*

Again, thank you for this question. Media reports show, and the IVF industry itself admits (https://news.virginia.edu/content/uva-law-professor-examines-wild-west-fertility-industry; https://www.nytimes.com/roomfordebate/2011/09/13/making-laws-about-making-babies/fertility-industry-is-a-wild-west indicate that better regulation is needed to protect women and men seeking to become mothers and fathers, and their embryos. The Alabama case is one example of how a basic lack of adequate security related to laboratory and freezer access led to the death of multiple embryos. As noted, the IVF industry has been called the "Wild West". A study of lawsuits against IVF clinics for lost, damaged and destroyed embryos, from the medical journal *Fertility and Sterility*, noted that for the cases seen "Allegations range from business practices to product liability and are seldom for medical malpractice. Our results suggest that best practices in storage of frozen embryos should include not only improvements in hardware and monitoring of storage conditions of specimens but also setting standards for communications among patients, providers, and embryology laboratories regarding disposition of embryos" (Letterie G, Fox D. Lawsuit frequency and claims basis over lost, damaged, and destroyed frozen embryos over a 10-year period. *Fertil Steril Rep* 2020;1:78–82. 2020).

These and other problems identified in, and by, the IVF industry could effectively be addressed through federal or state legislation. Such problems include:

1. **A lack of standards and accreditation of IVF clinics and laboratories by an independent regulatory body.** Voluntary self-regulation of ART programs has not been shown to be effective. Not all ART programs or facilities are members of professional organizations, such as the Society for Assisted Reproductive Technology (SART) or the American Society for Reproductive Medicine (ASRM). Moreover, these professional organizations do not independently confirm that their members follow their voluntary guidelines. At present, unlike other laboratories involved with human health, IVF clinics and laboratories are not accountable to standards and accreditation by an independent regulatory body. The implications are obvious. In addition, prospective parents have no data regarding clinic safety and adherence to good clinical practice standards.
2. **A lack of standards and accreditation for laboratory equipment**. Similarly, there are no standards for equipment used in IVF, specifically the cryogenic storage tanks used to hold frozen eggs and embryos. As noted above, according to Professor Dov Fox of the UCSD Law School, these devices are currently less regulated than kitchen equipment or farm tools. Equipment failures for cryogenic tanks have led to catastrophic outcomes, including the loss of embryos, and egg and sperm cells.

3. **A lack of standards for laboratory security**, such as were seen in the Alabama case.

4. **A lack of oversight and mandated data collection for IVF clinic outcomes, complications and demographic characteristics of women and men who utilize IVF.** There are currently no mechanisms for data collection from IVF clinics, despite the pressing need to understand outcomes for IVF. While clinics publish data on success rates from IVF, what constitutes success is measured in terms of live births. There is no mention of adverse effects and complications for mothers undergoing IVF, or of long-term outcomes in children.

5. **A lack of restrictions on the number of embryos that can be conceived through IVF, and no laws regulating the fate of embryos who are abandoned.** This is one of the most serious problems related to IVF. The lack of IVF regulation has led to the large-scale conception of embryonic human beings without oversight or accountability. IVF clinics continue to allow families to create multiple embryos, despite the fact that many will not be implanted and will end up either frozen indefinitely or destroyed. The variety of "options" for parents with embryos that they do not wish to be transferred shows the need for legislation to address this pressing issue, which has implications for both mothers and children. "With the average number of stored embryos averaging 6 per individual, approximately 1.5 million embryos are currently cryopreserved in the United States, many stored for 5 years or longer" (Michele Martens, et al. Disposition Options for Cryopreserved Embryos: Results of an Educational Program, 19 j. *Nurse Practitioners* 104646 (June 2023). It is estimated that 1/3 of these embryos are abandoned, either being left frozen or destroyed. Families may inform the clinic that they do not wish to use any "extra" embryos, or they may stop responding to communications, or paying storage fees. "Research suggests that education and counseling about the donation process and benefits could increase donation rates. However, very few frozen embryos are actually donated to infertile individuals (Martens et al, 2023). "[I]ndividuals often reported that a lack of education and poorly timed conversations related to embryo disposition were barriers that resulted in low donation rates." "Upon the initial informed consent at the beginning of the IVF process, most individuals intend to donate or store embryos. However, when a decision was required, approximately 72% of individuals decided to forgo donation, increasing the number of cryopreserved embryos" (Martens et al, 2023). Notably, although many countries limit the number of embryos that can be created or transferred during the IVF process, the U.S. does not. Thus, millions of human embryonic children are stored in "cryogenic nurseries"; for many of these children, the facilities could more accurately be called "cryogenic orphanages". Many are ultimately either destroyed outright, or sold or donated for experimental purposes.
6. **A lack of restrictions on the number of embryos that can be implanted.** The number of embryos implanted in an IVF cycle is directly related to maternal and fetal outcome. While there has been a steady decline in the number of embryos transferred per cycle, society guidelines fail to recommend a maximum number of embryos to transfer. Multiple gestations are associated with increased maternal, fetal and

newborn morbidity and mortality. In some situations, "selective termination", or abortion of one twin or triplet, is recommended or performed, even though, according to the American Society for Reproductive Medicine, "the procedure may result in the loss of all fetuses, it does not completely eliminate the risks associated with multiple pregnancies, and it may have adverse psychological consequences…Moreover, multifetal pregnancy reduction is not an acceptable option for many women" (Practice Committee of the American Society for Reproductive Medicine and the Practice Committee for the Society for Assisted Reproductive Technologies, Guidance on the limits to the number of embryos to transfer: a committee opinion. *Fertility and Sterility*, vol. 116, No. 3, September 2021).

7. **A lack of regulation of sperm and egg cell donors.** Recent reports of sperm donors fathering dozens of children (in one case, 150 of them; in another case 200), or transmitting genetic abnormalities to their children, show the problems associated with this unregulated industry. Similarly, the process of "egg harvesting" represents a commodification of reproduction and women's bodies. The IVF industry seeks women between the ages of 18 and 25 for "egg harvesting" because they produce the healthiest and most efficient eggs for use in ART and research. A typical egg donor for eggs used in IVF procedures can expect to be paid between $5,000 and $10,000 per cycle (How Much Money Do Egg Donors Get Paid?, Bright Expectations (June 29, 2018), https://www.brightexpectationsagency.com/blog/how-much-money-egg-donors-paid/). Women on college campuses are promised large sums of money for their eggs, and it is not clear whether adequate informed consent is given for the procedure. During the process, ovarian hyperstimulation is used to obtain 10 or more eggs per treatment. Over several cycles, this represents a significant portion of a woman's total complement of eggs, which cannot be recovered. The risks of hyperstimulation and egg retrieval include infertility, infection, ovarian torsion, blood clots, kidney failure, premature menopause, ovarian cysts, chronic pelvic pain, stroke, reproductive cancers, and death (Kathleen Sloan, The Dark Side of Third-Party Reproduction, *Pub. Discourse* (Aug. 3, 2015), https://www.thepublicdiscourse.com/2015/08/15413/. Few states mandate disclosure of risk and procurement of informed consent prior to performing "egg harvesting" procedures, and even fewer limit advertisements and solicitations related to egg harvesting. There is "little to no peer-reviewed medical research on the effects of egg procurement on women's health" (Kallie Fell & Paul Ramsey, A Comprehensive Report on the Risks of ART, Ctr. For Bioethics & Culture Network, May 2023, available at https://cbc-network.org/wp-content/uploads/2023/05/Comprehensive-Paper-on-ART-Final.pdf).
8. **No laws restricting the destruction and disposal of embryos.** As noted earlier, embryos are disposed of literally by being discarded as laboratory medical waste; heated; killed by chemicals or disinfectants; or otherwise disposed of.
9. **No laws regulating human experimentation on embryos.** Because embryos cannot by definition give consent, they are subject to being used in a variety of experiments, including the creation of chimeras (human-animal hybrids) and engineered embryos. There are clear ethical and moral problems related to this topic.
10. **No laws regarding sex selection or preimplantation genetic testing of embryos.** Such testing, as noted earlier, is eugenics in its purest form, and leads to the selective

targeting and destruction of human beings. This occurs even where the reasons for screening are not medical, for example, when a specific eye color may be desired.

11. **No laws requiring informed consent.** IVF is associated with significant risks to mothers, even in a singleton pregnancy. Obstetricians caring for mothers who conceived using IVF, manage them as high-risk patients. Risks include significantly delivery complications, risk of uterine rupture, need for transfusion, and higher rates of preeclampsia and gestational diabetes. Another study examining in-hospital complications of women who conceived using ART found that "pregnancies conceived by ART have higher risks of adverse obstetric outcomes and vascular complications compared with spontaneous conception" (Pensee Wu, et al., In-Hospital Complications in Pregnancies Conceived by Assisted Reproductive Technology. *J. Am. Heart Assoc.* e022658. (Mar. 2022). In this study, women using ART to conceive had higher rates of comorbidities such as diabetes, hypertension, obesity, hyperlipidemia, and other medical problems. These women also were at higher risk of cesarean delivery, preterm birth, and placental abruption than those who conceived spontaneously, with increased risk of preeclampsia, acute kidney injury, ischemic stroke, arrhythmia, and venous thromboembolism. Another study found similar results, finding that ART pregnancies had "significantly increased risk of pregnancy-induced hypertension, gestational diabetes mellitus, placenta previa, placental abruption, antepartum hemorrhage, postpartum hemorrhage, polyhydramnios, oligohydramnios, cesarean sections, preterm and very preterm birth, low and very low birth weight, small for gestational age, perinatal mortality, and congenital malformation when compared to singleton pregnancies conceived naturally" (Fell et al). The risk for severe maternal and fetal morbidities is increased for women utilizing IVF with donor eggs, including increased risks for unplanned hysterectomy, pregestational and gestational hypertension, and intensive care (ICU) admissions for the mother.

    IVF is also associated with adverse effects in children. In a 2020 international study, it was found that "[t]he risk of congenital malformations is approximately one-third higher in children conceived with the aid of IVF technology than in other children". This includes cardiac malformations, musculoskeletal malformations, and genitourinary malformations. The study also found that "the risks of preterm birth and low birth weight are, respectively 1.7 and 1.5 times higher in IVF singleton pregnancies than in non-IVF pregnancies" (M. Wolff & T. Haaf, In Vitro Fertilization Technology and Child Health, 117 *Deutsches Ärzteblatt International* 23-30, 23 (2020). A 2017 study found that "IVF has been associated with an increased risk of adverse obstetric and perinatal outcomes including hypertensive disorders of pregnancy, preterm labor and preterm delivery, and low birth weight. IVF pregnancies have also been associated with congenital anomalies, imprinting disorders, and neurodevelopmental disorders" (C. Sullivan-Pyke et al., In Vitro Fertilization and Adverse Obstetric and Perinatal Outcomes, *Seminars in Perinatology* 345-53, 345 (October 2017). Low birth weight children are also at increased risk for adverse metabolic outcomes throughout life including obesity, hypertension, and diabetes. Other studies have found that children conceived through IVF may have higher blood pressure, adiposity, glucose levels, more generalized vascular dysfunction, higher risks for certain muscle and liver cancers, and

premature cardiovascular disease (E. Kamphuis, et al., Are we overusing IVF?, 348 *British Med. J.* g252 (2014); C. Williams, et al., Cancer Risk among Children Born after Assisted Conception. *NEJM* Vol 369: 1819-27 (2013); U. Scherrer, et al., Systemic and Pulmonary Vascular Dysfunction in Children Conceived by Assisted Reproductive Technologies, 125 *Circulation* 1890-96, 1890 (2012). These risks must be spelled out clearly and in detail in informed consent.

Legislative measures that could be considered include:

1. Establish standards for obtaining informed consent from couples and individuals seeking ART.
2. Establish facility standards for IVF laboratories.
3. Establish standards for IVF equipment.
4. Require collection and dissemination of data on outcomes from IVF.
5. Limit the number of embryos that can be created in any reproductive cycle.
6. Reduce multiple gestations and the risk of fetal reduction by limiting the number of embryos transferred in any reproductive cycle.
7. Institute annual reporting requirements for IVF.
8. Prohibit eugenic testing of embryos.
9. Prohibit the experimental use of embryos.
10. Prohibit the sale of gametes.
11. Prohibit the sale of embryos.
12. Develop regulations to protect embryos that have been abandoned.

Federal laws (from other countries) have attempted to address some of the above concerns. For example, several countries limit the number of embryos that can be conceived through IVF. Belgium, Brazil, Denmark, Germany, Hungary, Italy, Saudi Arabia, Singapore, Spain, Sweden, Switzerland, and the United Kingdom limit the number of embryos that can be transferred in a cycle, usually to two or three.

In Germany, the "Act for the Protection of Embryos" (attached) provides a wide range of protections for prospective mothers and fathers, and embryos, including by forbidding the fertilization of more than three embryos, the transfer of more than one embryo to a woman. It bans surrogacy, sex selection, preimplantation testing (with some exceptions), and the creation of human embryos for experimental purposes. It also prohibits the creation of human-animal chimeras, the use of more than one couple's gametes to create an embryo, artificial modification of human germ cell lines, and the sale of embryos. Penalties are described for violations of the Law. The Law does not address the disposition of embryos. However, under the law, more embryos cannot be created than are to be transferred to the mother.

At the state level, Louisiana's IVF law recognizes the humanity of the embryo, but still allows IVF. Model legislation using the principles embodied in Louisiana's law could help States to develop their own laws, which would protect prospective parents and embryos.

To summarize, it is clear from recent history that, as noted, voluntary self-regulation of IVF programs is not effective, despite the efforts of professional societies. Because prospective

parents often feel a sense of desperation and even hopelessness when infertility is an obstacle to building their families; they are vulnerable to potential exploitation, inadequate informed consent, and severe financial burdens. Parents have the right to full disclosure of the risks as well as the benefits of IVF. Embryos, as human beings, should not be destroyed, manipulated or subject to eugenic procedures. Addressing the problems outlined above represents an opportunity for elected officials to intervene to protect families and their children, and to uphold human dignity.

Monique Chireau Wubbenhorst, M.D., M.P.H., FACOG, FAHA

Federal Law Gazette, Part I, No. 69, issued in Bonn, 19th December 1990, page 2746

# Act for the Protection of Embryos (The Embryo Protection Act)*

## Gesetz zum Schutz von Embryonen (*Embryonenschutzgesetz – ESchG*)

**Of 13th December 1990 (BGBl. I p. 2746), last amended by Article 1 of the Law of 21st November 2011 (BGBl. I p. 2228)**

Section 1

**Improper use of reproduction technology**

(1) Whosoever

1. transfers to a woman an unfertilised egg cell collected from another woman,
2. undertakes to fertilise artificially an egg cell for any purpose other than bringing about a pregnancy in the woman from whom the egg cell was collected,
3. undertakes, within one treatment cycle, to transfer more than three embryos to a woman,
4. undertakes, by gamete intrafallopian transfer, to fertilise more than three egg cells within one treatment cycle,
5. undertakes to fertilise more egg cells from a woman than may be transferred to her within one treatment cycle,
6. removes an embryo from a woman before its implantation in the uterus is completed, in order to transfer it to another woman or to use it for a purpose other than its preservation, or
7. undertakes to carry out an artificial fertilisation of a woman who is prepared to give up her child permanently after birth to third parties (surrogate mother) or to transfer a human embryo to her.

shall be punished with up to three years' imprisonment or a fine.

(2) Likewise anyone shall be punished who

1. brings about artificially the penetration of a human egg cell by a human sperm cell, or
2. inserts a human sperm cell into a human egg cell artificially,

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* Disclaimer: Translations of any materials into languages other than German are intended solely as a convenience to the non-German-reading public. If any questions arise related to the accuracy of the information contained in the translation, please refer to the German version of the document which is the official version of the document. Any discrepancies or differences created in the translation are not binding and have no legal effect for compliance or enforcement purposes.

without intending to bring about a pregnancy in the woman from whom the egg cell was collected.

(3)

1. In the cases of subsection 1, numbers 1, 2 and 6, the woman from whom the egg cell or embryo was collected, and likewise the woman to whom the egg cell or embryo will be transferred, and

2. in the cases of subsection 1, number 7, the surrogate mother and likewise the person who wishes to permanently take care of the child,

shall not be liable to punishment.

(4) In the cases of subsection 1, number 6, and subsection 2, any attempt shall be punishable.

Section 2

**Improper use of human embryos**

(1) Whosoever sells a human embryo created outside the woman's body, or removed from the woman before the completion of implantation in the uterus, or makes it available, or acquires or uses it for a purpose other than its preservation, shall be punished with up to three years' imprisonment or a fine.

(2) Likewise anyone shall be punished who causes a human embryo to develop further outside the woman's body for any purpose other than the bringing about of a pregnancy.

(3) Any attempt shall be punishable.

Section 3

**Forbidden sex selection**

Whosoever undertakes to fertilise artificially a human egg cell with a sperm cell that is selected for the sex chromosome contained in it, shall be punished with up to one year's imprisonment or a fine. This shall not apply when the selection of a sperm cell is made by a physician in order to preserve the child from developing Duchenne-type muscular dystrophy or a similarly severe sex-linked genetic illness, and the illness threatening the child is recognised as being of appropriate severity by the body responsible according to Land legislation.

Section 3a

**Pre-implantation genetic diagnosis; Authority to issue ordinances**

(1) Whosoever subjects the cells of an embryo to *in vitro* genetic screening prior to its intrauterine transfer (pre-implantation genetic diagnosis) shall be punished with up to one year's imprisonment or a fine.

(2) Where the genetic pre-disposition of the woman from whom the egg cell was collected, or that of the man producing the sperm cell, or both, suggest that their offspring will be highly

likely to have a serious genetic illness, it shall not be an offence for anyone who intends to bring about a pregnancy to subject the cells of the embryo to state-of-the-art *in-vitro* genetic screening for this illness prior to intrauterine transfer, if the woman from whom the egg cell was collected gives her written consent.
Nor shall it be an offence for anyone to carry out, with the written consent of the woman from whom the egg cell was collected, pre-implantation genetic diagnosis in an embryo to identify an abnormality that would be highly likely to lead to still-birth or miscarriage.

(3) Pre-implantation genetic diagnosis as set out in subsection 2 may only be performed

1. when the woman has given her informed consent after having been informed and counselled on the medical, psychological and social implications of the genetic screening of the embryonic cells requested by her,

2. after an interdisciplinary ethics committee at the approved centres for pre-implantation genetic diagnosis has verified compliance with the requirements of subsection 2 and delivered a favourable opinion and

3. by a specifically qualified physician in centres approved for pre-implantation genetic diagnosis that have the diagnostic, medical and technological resources necessary to carry out the procedures involved in pre-implantation genetic diagnosis.

The approved centres shall report, in an anonymised form, the measures carried out within the framework of pre-implantation genetic diagnosis, including the cases dismissed by the ethics committees, to a central body for documentation purposes. The Federal Government shall issue an ordinance with the approval of the *Bundesrat*, to stipulate the details regarding

1. the number of and the approval requirements for the centres where pre-implantation genetic diagnosis may be performed, including the qualification of the physicians working there and the period of validity of the approval,

2. the establishment, composition, functioning and financing of the ethics committees for pre-implantation genetic diagnosis,

3. the establishment, structure and organisation of the central body that will be responsible for documenting the measures performed within the framework of pre-implantation genetic diagnosis,

4. the requirements for the reporting of measures performed within the framework of pre-implantation genetic diagnosis to the central body and the requirements for documentation.

(4) Whosoever, in breach of subsection 3 sentence 1, performs pre-implantation genetic diagnosis commits an administrative offence. The administrative offence shall be punishable with a fine of up to fifty-thousand euros.

(5) No physician shall be under an obligation to perform or take part in a measure as set out in subsection 2.
Non-participation may not lead to any disadvantage for the physician concerned.

(6) The Federal Government shall draw up, every four years, a report on the experience with pre-implantation genetic diagnosis. Based on central documentation and anonymised data, the report shall contain the number of measures performed each year as well as a scientific evaluation.

**Unauthorised fertilisation, unauthorised embryo transfer and artificial fertilisation after death**

(1) Whosoever

1. undertakes artificially to fertilise an egg cell without the woman whose egg cell is to be fertilised, and the man whose sperm cell will be used for fertilisation, having given consent,

2. undertakes to transfer an embryo to a woman without her consent, or

3. knowingly fertilises artificially an egg cell with the sperm of a man after his death

shall be punished with up to three years' imprisonment or a fine.

(2) In the case of subsection 1 number 3, the woman in whom the artificial fertilisation was performed shall not be liable to punishment.

Section 5

**Artificial alteration of human germ line cells**

(1) Whosoever artificially alters the genetic information of a human germ line cell shall be punished with up to five years' imprisonment or a fine.

(2) Likewise anyone shall be punished who uses a human germ cell with artificially altered genetic information for fertilisation.

(3) Any attempt shall be punishable.

(4) Subsection 1 shall not apply to

1. the artificial alteration of the genetic information of a germ cell situated outside the body, if any use of it for fertilisation is ruled out,

2. the artificial alteration of the genetic information of any other autologous germ line cell that has been removed from a dead embryo or fetus, a human being or a deceased person, if it is ruled out that

   a) it will be transferred to an embryo, fetus or human being or

   b) a germ cell will originate from it,

   and likewise

3. vaccinations, radiation, chemotherapeutic or other treatments which are not intended to alter the genetic information of germ line cells.

Section 6

**Cloning**

(1) Whosoever causes artificially a human embryo to develop with the same genetic information as another embryo, fetus, human being or deceased person shall be punished with up to five years' imprisonment or a fine.

(2) Likewise anyone shall be punished who transfers to a woman an embryo as specified in subsection 1.

(3) Any attempt shall be punishable.

Section 7

**Creation of chimeras and hybrids**

(1) Whosoever undertakes

1. to combine embryos with different genetic information to form a cluster of cells, using at least one human embryo,

2. to combine a human embryo with a cell that contains genetic information different from the embryo cells and, so combined, is able to differentiate further, or

3. by fertilisation of a human egg cell with the sperm of an animal or by fertilisation of an animal's egg cell with human sperm, to engineer an embryo that is able to differentiate,

shall be punished with up to five years' imprisonment or a fine.

(2) Likewise anyone shall be punished who undertakes

1. to transfer an embryo arising out of a procedure defined in subsection 1 to

   a) a woman or

   b) an animal

   or

2. to transfer a human embryo to an animal.

Section 8

**Definition**

(1) For the purposes of this Act, an embryo shall already mean the human egg cell, fertilised and capable of developing, from the time of fusion of the nuclei, and further, each totipotent cell removed from an embryo that is assumed to be able to divide and to develop into an individual under the appropriate conditions.

(2) In the first twenty-four hours after nuclear fusion, the fertilised human egg cell shall be held to be capable of development unless it is established before the expiry of this time period that it will not develop beyond the one-cell stage.

(3) Germ line cells, for the purpose of this Act, shall be all cells that, in one cell-line, lead from the fertilised egg and sperm cells to the resultant human being and, further, the egg cell from the insertion of or penetration by the sperm cell until the completion of fertilisation by fusion of the nuclei.

Section 9

**Medical prerogative**

Only a physician shall be entitled to carry out

1. artificial fertilisation,
2. pre-implantation genetic diagnosis,
3. transfer of a human embryo to a woman,
4. preservation of a human embryo or human egg cell which has already been penetrated by a human sperm cell or into which a human sperm cell has been artificially inserted.

Section 10

**Voluntary participation**

No one shall be under an obligation to carry out the measures described in section 9 above or to take part in them.

Section 11

**Offences against the medical prerogative**

(1) Whosoever, without being a physician,

1. carries out an artificial fertilisation contrary to section 9 number 1,
2. carries out pre-implantation genetic diagnosis contrary to section 9 number 2, or
3. transfers a human embryo to a woman contrary to section 9 number 3,

shall be punished with up to one year's imprisonment or a fine.

(2) In the case of section 9 number 1, a woman who carries out an artificial insemination on herself, and the man whose sperm is used for artificial insemination shall not be liable to punishment.

Section 12

**Administrative fines**

(1) An administrative offence shall be deemed to have been committed by a person who, without being a physician, in violation of section 9 number 4, preserves a human embryo or a human egg cell as described therein.

(2) The commission of an administrative offence may be punished with a fine not exceeding two thousand five hundred euros.

Section 13

**Entry into force**

This Act shall enter into force on 1st January 1991.

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The constitutional rights of the *Bundesrat* have been observed.

The above Act is herewith signed and will be published in the Federal Law Gazette (*Bundesgesetzblatt*).

Bonn, 13th December 1990

The Federal President
Weizsäcker

The Federal Chancellor
Dr. Helmut Kohl

The Federal Minister of Justice
Engelhard

The Federal Minister for Youth, Family and Health
Ursula Lehr

The Federal Minister for Research and Technology
Riesenhuber

Bundesministerium der Justiz Bundesamt für Justiz

# Law on the Protection of Embryos (Embryo Protection Act - ESchG)

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ESchG

Date of issue: 13.12.1990

Full quote:

"Embryo Protection Act of 13 December 1990 (Federal Law Gazette I p. 2746), last amended by Article 1 of the Act of 21 November 2011 (Federal Law Gazette I p. 2228)"

**Status:** last amended by Art. 1 G v. 21.11.2011 I 2228

Further information on the stand can be found in the menu under Notes

**footnote**

(+++ Text reference from: 1.1.1991 +++)

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## § 1 Abusive use of reproductive techniques

(1) Any person shall be punished with imprisonment for a term not exceeding three years or with a fine

1st transfers a foreign unfertilized egg cell to a woman,

2nd it undertakes to artificially fertilise an ovum for a purpose other than to bring about pregnancy in the woman from whom the ovum was derived,

3. it attempts to transfer more than three embryos to a woman within one cycle,

4th it attempts to fertilise more than three oocytes within one cycle by intratubal gamete transfer,

5th it attempts to fertilize more eggs from a woman than are to be transferred to her within one cycle,

6th removes an embryo from a woman before it has been implanted in the uterus in order to transfer it to another woman or to use it for a purpose other than its preservation, or

7th it undertakes to carry out artificial insemination or to transfer a human embryo to a woman who is willing to permanently hand over her child to a third party after birth (surrogate mother).

(2) The same penalty shall be imposed on anyone who

1st artificially causes a human sperm cell to penetrate a human egg cell, or

2nd artificially transfers a human sperm cell into a human egg cell,

without intending to induce pregnancy in the woman from whom the egg cell originated.

(3) Not to be punished

1st in the cases referred to in paragraph 1 numbers 1, 2 and 6, the woman from whom the egg cell or embryo originates and the woman to whom the egg cell is transferred or the embryo is to be transferred, and

2nd in the cases referred to in paragraph 1, number 7, the surrogate mother and the person who wishes to take permanent care of the child.

(4) In the cases referred to in paragraph 1, number 6, and in paragraph 2, the attempt is punishable.

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## § 2 Abusive use of human embryos

(1) Whoever sells a human embryo created extracorporeally or removed from a woman before its implantation in the uterus has been completed, or gives it away, acquires or uses it for a purpose other than its preservation, shall be punished with imprisonment for a term not exceeding three years or with a fine.

(2) Any person who causes the extracorporeal development of a human embryo for a purpose other than the initiation of pregnancy shall be punished in the same way.

(3) The attempt is punishable by law.

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### § 3 Prohibited Sex Selection

Anyone who attempts to artificially fertilise a human egg cell with a sperm cell that has been selected according to the sex chromosome it contains shall be punished with imprisonment of up to one year or a fine. This shall not apply if the selection of the sperm cell by a doctor serves to protect the child from developing Duchenne muscular dystrophy or a similarly serious sex-linked hereditary disease, and the disease threatening the child has been recognised as sufficiently serious by the competent authority under state law.

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### § 3a Preimplantation genetic diagnosis; authorization to issue regulations

(1) Anyone who genetically examines cells of an embryo in vitro prior to its intrauterine transfer (preimplantation genetic diagnosis) shall be punished with imprisonment for a term not exceeding one year or with a fine.

(2) If, due to the genetic disposition of the woman from whom the egg cell was derived, or of the man from whom the sperm cell was derived, or of both, there is a high risk of a serious hereditary disease for their offspring, it is not unlawful for a person to carry out a genetic examination of embryo cells in vitro for the risk of that disease prior to intrauterine transfer in order to bring about a pregnancy with the written consent of the woman from whom the egg cell was derived, in accordance with the generally accepted state of medical science and technology. It is also not unlawful for a person to carry out preimplantation genetic diagnosis with the written consent of the woman from whom the egg cell was derived, in order to determine whether there is serious damage to the embryo which is highly likely to result in stillbirth or miscarriage.

(3) Preimplantation genetic diagnosis pursuant to paragraph 2 may only be

1st after information and advice on the medical, psychological and social consequences of the genetic examination of embryo cells requested by the woman, whereby the information must be provided before consent is obtained,

2nd after an interdisciplinary ethics committee at the approved centres for preimplantation genetic diagnosis has examined compliance with the requirements of paragraph 2 and has given a favourable assessment, and

3. by a qualified doctor in centres approved for preimplantation genetic diagnosis that have the diagnostic, medical and technical facilities necessary to carry out preimplantation genetic diagnosis,

The measures carried out within the framework of preimplantation genetic diagnosis, including cases rejected by the ethics committees, are reported by the approved centres to a central office in anonymised form and documented there. The Federal Government shall determine the details by means of a legal order with the consent of the Federal Council.

1st on the number and conditions for authorisation of centres in which preimplantation genetic diagnosis may be carried out, including the qualifications of the doctors working there and the duration of authorisation,

2nd on the establishment, composition, procedures and financing of ethics committees for preimplantation genetic diagnosis,

3. for the establishment and design of the central office responsible for the documentation of measures carried out within the framework of preimplantation genetic diagnosis,

4th on the requirements for reporting measures carried out within the framework of preimplantation genetic diagnosis to the central office and the requirements for documentation.

(4) Anyone who carries out preimplantation diagnostics contrary to paragraph 3, sentence 1, commits an administrative offence. The administrative offence may be punished with a fine of up to fifty thousand euros.

(5) No doctor shall be obliged to carry out or cooperate in a measure referred to in paragraph 2. Failure to cooperate shall not result in any disadvantage to the person concerned.

(6) Every four years, the Federal Government shall prepare a report on the experience gained with preimplantation genetic diagnosis. The report shall contain, on the basis of central documentation and anonymised data, the number of measures carried out each year and a scientific evaluation.

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### § 4 Unauthorized fertilization, unauthorized embryo transfer and artificial insemination after death

(1) Any person shall be punished with imprisonment for a term not exceeding three years or with a fine

1st it attempts to artificially fertilise an egg cell without the consent of the woman whose egg cell is to be fertilised and the man whose sperm cell is to be used for the fertilisation,

2nd attempts to transfer an embryo to a woman without her consent, or

3. knowingly artificially fertilizes an egg cell with the sperm of a man after his death.

(2) In the case referred to in paragraph 1, number 3, the woman on whom artificial insemination is performed shall not be punished.

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### § 5 Artificial modification of human germline cells

(1) Anyone who artificially alters the genetic information of a human germ cell shall be punished by imprisonment for a term not exceeding five years or by a fine.

(2) Any person who uses a human gamete with artificially modified genetic information for fertilisation shall be punished in the same way.

(3) The attempt is punishable by law.

(4) Paragraph 1 shall not apply to

1st an artificial alteration of the genetic information of a germ cell located outside the body, if it is excluded that this will be used for fertilization,

2nd an artificial alteration of the genetic information of another endogenous germ cell taken from a dead fetus, a human being or a deceased person, if it is excluded that

a) it is transferred to an embryo, fetus or human being or

b) a germ cell develops from it,

as well as

3. Vaccinations, radiotherapy, chemotherapy or other treatments that do not intend to alter the genetic information of germ cells.

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### § 6 Cloning

(1) Whoever artificially causes the creation of a human embryo with the same genetic information as another embryo, a foetus, a human being or a deceased person shall be punished with imprisonment for a term not exceeding five years or with a fine.

(2) Any person who transfers an embryo referred to in paragraph 1 to a woman shall be punished in the same way.

(3) The attempt is punishable by law.

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### § 7 Chimera and hybrid formation

(1) Whoever undertakes

1st To combine embryos with different genetic information into a cell group using at least one human embryo,

2nd to connect a cell with a human embryo that contains different genetic information than the cells of the embryo and is capable of further differentiation with it, or

3. to produce an embryo capable of differentiation by fertilising a human egg cell with the sperm of an animal or by fertilising an animal egg cell with the sperm of a human,

shall be punishable by imprisonment for up to five years or a fine.

(2) Any person who undertakes to

1st an embryo resulting from an act pursuant to paragraph 1 on

a) a woman or

b) an animal

to transfer or

2nd to transfer a human embryo to an animal.

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### § 8 Definition

(1) For the purposes of this Act, an embryo shall be any fertilised human egg cell capable of development from the time of nuclear fusion, as well as any totipotent cell taken from an embryo which, if the necessary further conditions are met, is capable of dividing and developing into an individual.

(2) During the first twenty-four hours after nuclear fusion, the fertilised human ovum shall be considered to be capable of development, unless it is established before the expiry of that period that it is incapable of developing beyond the single-cell stage.

(3) For the purposes of this Act, germ cells are all cells which lead in a cell line from the fertilised egg cell to the egg and sperm cells of the human being resulting from it, and also the egg cell from the introduction or penetration of the sperm cell until fertilisation which is completed with nuclear fusion.

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### § 9 Doctor's reservation

Only a doctor may perform:

1st artificial insemination,

2nd preimplantation genetic diagnosis,

3. the transfer of a human embryo to a woman,

4th the preservation of a human embryo and a human egg cell into which a human sperm cell has already been penetrated or artificially introduced.

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### § 10 Voluntary Participation

No one is obliged to take measures of the kind referred to in Section 9 or to participate in them.

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### § 11 Violation of the doctor's reservation

(1) Anyone who, without being a doctor,

1st carries out artificial insemination contrary to Section 9 No. 1,

2nd carries out preimplantation genetic diagnosis contrary to Section 9 No. 2 or

3. transfers a human embryo to a woman in contravention of Section 9 No. 3,

shall be punishable by imprisonment for up to one year or a fine.

(2) In the case referred to in paragraph 1 of Section 9, the woman who undergoes artificial insemination and the man whose semen is used for artificial insemination shall not be punished.

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### § 12 Fines

(1) Any person who, without being a medical practitioner, preserves a human embryo or a human egg cell as defined in section 9(4) in contravention of paragraph 4 shall commit an administrative offence.

(2) The administrative offence may be punished with a fine of up to two thousand five hundred euros.

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### § 13 Entry into force

This law comes into force on 1 January 1991.

# APPENDIX

**The following submissions are available at:**

*https://www.govinfo.gov/content/pkg/CHRG-118shrg58675/pdf/CHRG-118shrg58675-add1.pdf*

**Submitted by Chair Durbin:**



**Submitted by Ranking Member Graham:**