

# E

## **The Impact of *Dobbs v. Jackson Women's Health Organization* on Clinical Research with Pregnant and Lactating Persons**

### **AUTHOR**

Allison M. Whelan, J.D., M.A., Georgia State University College of Law, Consultant to the Committee, 2024

This report assesses the current and potential future consequences on clinical research with pregnant and lactating persons of the U.S. Supreme Court's 2022 decision in *Dobbs v. Jackson Women's Health Organization* (*Dobbs v. Jackson women's health organization*, 2022). The report is organized as follows: The first section introduces the issue and key terms. The second section describes the general legal and regulatory landscape governing clinical trials and human subjects research, including a section focused specifically on the laws, regulations, and policies governing research involving pregnant and lactating persons. The third section unpacks some of the likely consequences of *Dobbs* on clinical research involving pregnant and lactating persons. The final section concludes by suggesting mechanisms that may mitigate the possible effects of *Dobbs* on clinical research involving pregnant and lactating persons.

The consequences of *Dobbs* in the clinical and research context remain in flux, making much of this document predictive and somewhat speculative. The consequences predicted in this document are not guaranteed to transpire. Federal and state laws surrounding abortion and reproductive health care continue to evolve, making it difficult to predict consequences with a high degree of certainty. Nevertheless, such uncertainty requires that all stakeholders remain flexible and informed of ongoing changes in the law so they can adapt accordingly.

## SUMMARY

The *Dobbs* decision is unlikely to have a significant effect on research involving lactating persons. The effect of *Dobbs* and the state laws and regulations that have transpired after the constitutional right to abortion was overruled in *Dobbs* focus primarily on activities that occur during the *prenatal* period, such as abortion and fetal harm. Yet *Dobbs*—and the laws that have or may flow from the decision—are likely to make research involving pregnant persons more difficult, costly, and rife with legal uncertainties and risks. Despite the incremental progress in recent years towards greater inclusion of pregnant persons in clinical trials, *Dobbs* places that progress in jeopardy.

In the context of clinical research, the most immediate effect will be experienced by sponsors of clinical trials studying various methods of medication or procedural abortion. But as this report describes, the effect of *Dobbs* on research involving pregnant women may extend beyond clinical trials studying medication and procedural abortions and affect the study of other reproductive medicines and technologies or perhaps even any drug that has the potential to cause fetal harm or spontaneous abortion. The consequences may affect trial sponsors, individual investigators, participants, participants' health care providers, and funders of clinical research. If *Dobbs* has consequences for broader swaths of research, the consequences may be felt more broadly by the health care system and society.

If clinical research involving pregnant persons becomes more difficult in the wake of *Dobbs*, pregnant persons themselves may experience short- and long-term harms. Although antiabortion policy makers typically defend their positions as necessary to prevent fetal harm or death, the collateral consequences of those laws may defeat their very purpose, resulting in a continued lack of evidence and knowledge about how medical products affect pregnant persons and their fetuses. As stated by Dr. Catherine Spong, a professor and chair of the Department of Obstetrics and Gynecology at the University of Texas Southwestern Medical Center, although researchers think they are protecting pregnant persons and their fetuses by excluding them from trials, “what [they] are doing is making them more vulnerable. Now you are going to be treating them based on no data and no evidence. By not including them, you are almost to the point of experimenting each time” (Balch, 2022).

A pregnant person's need for medication does not disappear during pregnancy. Pregnant persons will, and often must, continue to take medications during pregnancy. Ninety percent of women report taking some type of medicine during pregnancy, and seventy percent report taking at least one prescription medicine. From 1976 to 2008, women's use of prescription medicines during their first trimester of pregnancy

increased by more than 60 percent. Yet problematically, many of the medications used have not been studied in pregnant persons (CDC, 2023). Data and evidence are needed to ensure medications are safe for use during pregnancy. Clinical trials help provide that data, yet they often remain legally and ethically difficult to perform, issues that have been compounded by *Dobbs*. Relatedly, harms may result if pregnant persons avoid necessary and beneficial medical interventions during pregnancy because of lack of evidence, a situation that transpired during the COVID-19 pandemic with the COVID-19 vaccines (Lampton, 2022).

Many of the questions and considerations raised in this report do not yet have clear answers. There are many new and emerging issues that must be considered in the clinical trials community in terms of how the *Dobbs* decision may affect clinical research in the United States and whether there are ways to minimize the potential consequences. There remains much to learn about the full effect of *Dobbs*, and it may be years before we know the true scope of the harm.

## INTRODUCTION

### Key Terms

This report focuses on the effect of *Dobbs* on clinical research involving pregnant and lactating persons. It does not address the effects on the broader population of persons capable of pregnancy, although research on that population will likely also be affected by *Dobbs*. Key terms used in this report include:

- *Lactating persons*—persons feeding an infant with their own breast milk after giving birth.
- *Medication abortion*—abortion caused by medications (e.g., pills) that are intended to be used to induce an abortion. Example: mifepristone, approved by the U.S. Food and Drug Administration (FDA) in combination with misoprostol to induce an abortion through 10 weeks gestation.
- *Persons capable of pregnancy*—persons with a uterus in which a fertilized egg can be implanted.
- *Pregnant persons*—a human person at any stage of pregnancy (i.e., postimplantation of an egg that has been fertilized by sperm). This report aims to use gender-neutral language whenever possible. Abortion is often framed as a “women’s” issue, but transgender, nonbinary, and gender-nonconforming people may also become pregnant and need abortions. The term *woman* or *women* may be used, however, particularly where the sources use that terminology.

- *Procedural abortion*—abortion caused by a medical procedure that removes the embryo or fetus and the placenta from the pregnant person’s uterus. Sometimes called *surgical abortion*.
- *Stillbirth*—death of a fetus after 20 weeks gestation (CDC, 2022).
- *Spontaneous abortion*—the loss of a pregnancy at less than 20 weeks gestation. Often referred to as a miscarriage (Dugas and Slane, 2022).

### Background: Abortion in America

On June 24, 2022, the U.S. Supreme Court issued its decision in *Dobbs v. Jackson Women’s Health Organization*, thereby overturning *Roe v. Wade*, 1973, and *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 1992. In short, *Dobbs* held that the Due Process Clause of the Fourteenth Amendment does not protect the right to abortion. Without constitutional protection, the states now possess even greater freedom to ban or severely restrict access to abortion care. *Dobbs* does not, however, foreclose the possibility of courts finding that another provision of the U.S. Constitution protects the right to abortion, nor does it prevent the federal government or individual state governments from enshrining the right to abortion in federal laws, state laws, or state constitutions.

Other constitutional theories, such as federal preemption, also provide a strong argument against restrictive state laws, particularly with respect to mifepristone, a drug approved by FDA for use in combination with misoprostol for medication abortion. The Supremacy Clause, found in Article VI, Clause 2, of the U.S. Constitution, provides that the “Constitution, and the Laws of the United States which shall be made in Pursuance thereof. . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” This language provides the foundation for the doctrine of federal preemption, under which federal law supersedes conflicting state laws. Essentially, the argument is that FDA’s authorization and regulation of mifepristone—which is done pursuant to federal law—preempt state laws banning the use of mifepristone or enacting greater restrictions on its use than provided for under FDA regulation.

As of July 2023, there are numerous cases working their way through the courts relying, at least in part, on preemption. Two cases getting much attention involve conflicting rulings issued by two separate federal court judges. The first, *Alliance for Hippocratic Medicine v. FDA*, 2023, was issued on April 7, 2023, by Judge Matthew Kacsmaryk in the U.S. District Court for the Northern District of Texas. Judge Kacsmaryk issued a preliminary injunction that suspended FDA’s 23-year approval

of mifepristone. He also endorsed the view that a previously dormant, 150-year old law—the Comstock Act—“plainly forecloses mail-order abortion.” The Biden Administration appealed this ruling to the Fifth Circuit Court of Appeals. In a 2-1 decision, the U.S. Court of Appeals for the Fifth Circuit blocked the portion of Judge Kacsmaryk’s ruling that overturned FDA’s 2000 approval of mifepristone but allowed the reimposition of restrictions on mifepristone previously lifted by FDA. These reimposed restrictions include limiting mifepristone’s approved use to 7 (instead of 10) weeks’ gestation and requiring that patients pick up the medication in person (i.e., prohibiting the use of mail pharmacies). The Biden Administration again appealed, this time to the U.S. Supreme Court, which temporarily blocked the decisions of both lower courts, returning the case to the Fifth Circuit. The Supreme Court ruled that access to mifepristone will remain unchanged for the duration of the lawsuit, which is expected to ultimately make its way back before the Supreme Court (Center for Reproductive Rights, 2023). Despite the back-and-forth nature of the courts’ actions, the Supreme Court’s recent ruling means that access to mifepristone remains unchanged and the drug is still considered approved by FDA.

The second, and conflicting, ruling was issued that same day—April 7, 2023—in the U.S. District Court in the Eastern District of Washington by Judge Thomas O. Rice. This case—*Washington v. FDA, 2023*—was filed by 18 attorneys general from 17 states and the District of Columbia and challenges FDA’s decision to impose restrictions on the dispensing and prescribing of mifepristone through what is known as a Risk Evaluation and Mitigation Strategy (REMS). Essentially, this case is the mirror image of the Texas case, arguing that FDA must *remove* restrictions rather than reimpose restrictions or ban the drug. In this case, the court ordered FDA to maintain the current availability of mifepristone in the 17 states and the District of Columbia.

As of this writing, attempts to protect abortion through federal legislation have largely been unsuccessful, and while some states have recognized the right to abortion in their state constitutions or laws, many states have also banned or severely restricted access to abortion. The legality and accessibility of abortion in the United States remain in a constant state of flux. The overall absence of any current federal protection for abortion means that a person’s access to abortion depends in large part on their geographic location, financial resources, and ability to travel to a state where abortion care remains available.

Yet even before *Dobbs*, states used many direct and indirect mechanisms to restrict abortion, often with the Supreme Court’s blessing. As the number and severity of restrictions mounted, their cumulative effect often rendered abortion out of reach for many pregnant persons (Whelan, 2023).

*Dobbs* has magnified the challenges associated with accessing safe abortion care, even in life-threatening situations. The *Dobbs* decision has—and will continue to—affect the lives of many Americans—forcing some to make agonizing choices, eliminating choices for many others, and placing many in danger. Many consequences have already been seen, yet it will likely take years to understand the full consequences of *Dobbs*.

### **Background: Fetal Personhood**

When the Supreme Court decided *Roe v. Wade* in 1973, it rejected the argument by the state of Texas that a fetus is a “person” within the language and meaning of the Fourteenth Amendment. In overturning *Roe*, the Supreme Court in *Dobbs* did not address the issue of fetal personhood, thus leaving the question open for states to decide. As the term implies, fetal personhood laws grant the rights of personhood to the unborn, some time from the moment of conception or detection of a fetal heartbeat.

The state of Georgia, for example, enacted the Living Infants Fairness and Equality (LIFE) Act in 2019. Among other things, this law defines an unborn child as “a member of the species *Homo sapiens* at any stage of development who is carried in the womb.” The law qualifies this in various sections, granting certain rights and privileges solely to unborn children with a “detectable heartbeat,” which can occur as early as 6 weeks gestation. Although most fetal personhood laws are being passed with an intent to target and ban abortion, the implications are broader, both explicitly and implicitly. Explicitly, under Georgia law, for example, an unborn child with a detectable human heartbeat can now be claimed as a dependent on income taxes (Living Infants Fairness and Equality [LIFE] Act, 2019). Implicitly, contraception and treatments for infertility such as in vitro fertilization may be affected (Manninen, 2023). As described further below, fetal personhood laws may also affect research involving pregnant persons.

The remainder of this report focuses on the regulation and performance of clinical research, and specifically focuses on an often-overlooked consequence of *Dobbs*: the effect of the decision on clinical research with pregnant and lactating persons. The vast majority of clinical trials do not involve the explicit performance or study of medication or procedural abortions, and state restrictions on abortion have thus far not addressed clinical trials explicitly. Nevertheless, abortion bans, restrictions, and other similar laws that prioritize the prevention of fetal harm or pregnancy loss from any cause may pose difficulties for clinical trials involving pregnant and lactating persons. This is attributable, in part, to the broader effects of antiabortion laws. Antiabortion laws and policies have and may lead to the possibility of any fetal harm or death (e.g., spontaneous abortion,

stillbirth, in utero exposures resulting in fetal anomalies that may prompt the pursuit of an abortion, premature labor that could result in neonatal death) being viewed with suspicion and potentially prosecuted as an illegal abortion, feticide, or homicide.

This report concludes that the effect of *Dobbs* on research involving pregnant persons will likely be far greater than the effect on research involving lactating persons. Barriers remain to including lactating persons in clinical trials, but there is little reason to believe that *Dobbs* will significantly increase the difficulties or add new ones. The same cannot be said for pregnant persons.

## **LAWS AND REGULATIONS GOVERNING CLINICAL TRIALS AND HUMAN SUBJECTS RESEARCH**

This section first provides a brief overview of the legal and policy landscape for clinical trials and human subjects research generally. It then describes the rules and policies specific to research involving pregnant and lactating persons.

### **General Regulatory Landscape of Clinical Trials and Human Subjects Research**

#### *Federal Laws and Regulations*

The Federal Policy for the Protection of Human Subjects—often referred to as the “Common Rule”—was published in 1991 and revised in 2018. The Common Rule was heavily influenced by the Belmont Report, which was issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Protections, 2022).

The Common Rule applies to human subjects research conducted or supported by one of the federal departments or agencies that have codified the policy, such as the Department of Health and Human Services (HHS). HHS, for example, has codified the Common Rule in the Code of Federal Regulations (CFR) at 45 CFR Part 46, with four subparts (Subparts A–D). Many nongovernmental entities have also elected to apply parts of the Common Rule to their research, regardless of whether they receive funding from one of the relevant agencies (Office for Human Research Protections, 2022).

Clinical trials that produce data that will be submitted to FDA in support of product approval by FDA must be designed, conducted, analyzed, and reported in compliance with a separate set of regulations, codified at 21 CFR Parts 50 and 56. These regulations are similar but not identical to the Common Rule. In the fall of 2022, two notices of proposed rulemaking



were issued to harmonize the human subject protection regulations of HHS and FDA (FDA, 2022).

Additionally, many clinical trials are conducted by hospitals or academic medical centers (AMCs), which are subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology and Economic Clinical Health Act of 2009 (HITECH Act). At a high level, these laws outline the lawful use and disclosure of protected health information (PHI). Hospitals and AMCs that are subject to these laws must comply with their requirements, which establish conditions under which PHI may be used or disclosed for research purposes.

### *State Laws and Regulations*

In addition to federal laws and regulations, states may also enact laws that affect clinical trials, including laws that regulate the conduct of human subjects research and those that relate to informed consent, age of consent, legal representatives, and government notification, among other things (Protection of Human Subjects in Medical Experimentation Act, 2023). Some states also impose specific consent, confidentiality, and privacy requirements on particular types of activities, such as those involving genetic, mental health, substance use, or reproductive health information (Acheson and Halaiko, 2023). State laws often provide *greater* protection for the confidentiality of health information than HIPAA, and thus are not preempted by HIPAA.

### *Institutional Policies*

Many institutions, including AMCs, have policies that mirror or supplement federal and state regulations governing clinical trials and human subjects research. At a minimum, institutions must adhere to federal and state requirements, but they can also supplement them with their own institutional policies. For example, the Catholic University of America does not conduct research, nor does it allow students to be placed in off-campus academic situations (e.g., internships) that involve human embryonic stem cells or other primary human fetal or embryo cells (The Catholic University of America, 2020).

## **Regulatory Landscape for Research Involving Pregnant and Lactating Persons**

In addition to the general laws and regulations governing clinical research discussed previously, various rules and policies have been issued by HHS and FDA concerning research involving pregnant and lactating persons.



These policies were not developed in a vacuum. Paternalism and concerns for potential adverse effects on pregnant and lactating persons, persons capable of pregnancy, and fetuses have played a significant role in the development of federal regulations governing clinical research involving these populations. Clinical research and its regulation have long been affected by the abortion debate (Liu and Mager, 2016; Waggoner and Lyerly, 2022). As explained by Waggoner and Lyerly, (2022), “The basis of research protections as we know them was developed during [the 1970s],” the same decade when *Roe v. Wade* was decided. *Roe*, which held that the Due Process Clause of the Fourteenth Amendment of the U.S. Constitution protects a person’s liberty to choose to have an abortion (subject to some limitations that increase as the pregnancy progresses), provided a key backdrop to the deliberations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which considered the issue of research involving the fetus. The tensions are obvious: Conversations about concerns for fetal life and well-being were occurring in tandem with debates about abortion, women’s right to choose, and women’s autonomy more generally.

Catalysts for protectionist research policies included the thalidomide and diethylstilbestrol (DES) tragedies exposed in the 1960s. Thalidomide, used primarily as a sedative and treatment for nausea in early pregnancy, caused a rare set of deformities in children born to women who used the drug, including severe limb malformations. DES, widely prescribed in the 1940s and 1950s to prevent miscarriages, has now been linked to adenocarcinoma in the children of women who took DES during pregnancy (NASEM, 1994). Controversy over the Dalkon Shield, an intrauterine device, also likely played a role. Women claimed it failed to protect them from unwanted pregnancies, ectopic pregnancies, septic abortions, miscarriages, birth defects, excessive bleeding and cramping, pelvic inflammatory disease, infertility, or death (Menkel-Meadow, 1998; Parekh et al., 2011). Ironically, these tragedies, which resulted in part because the products were *not* studied in pregnant persons, caused even more resistance to test medications in pregnant populations. The response to these tragedies may have exacerbated the problems by causing underrepresentation of pregnant and lactating persons, thereby increasing knowledge gaps.

The formalization of these protectionist policies began in 1975, with the promulgation of federal regulations that restricted pregnant women from being involved in research unless specific criteria were met. The restrictive policies were broadened further when FDA issued “General Considerations for the Clinical Evaluation of Drugs” in 1977 (“the 1977 Guidelines”). The 1977 Guidelines set forth acceptable approaches to

clinical trials with investigational drugs and recommended that “females who are pregnant, or at risk of becoming pregnant” (i.e., of childbearing potential), be excluded from early-stage research (i.e., Phase I trials).

The 1977 Guidelines also stated that women of childbearing potential “may be included” in later stage, Phase III, studies “[i]f adequate information on efficacy and relative safety has been amassed during Phase II” studies and if animal reproductive studies have been completed. For women of childbearing potential enrolled in a study, the 1977 Guidelines recommended that pregnancy tests be performed and that the women be advised about suitable methods of contraception. According to Waggoner and Lyerly (2022), these policies “promulgated the notion of the fetus as uniquely vulnerable to research harms.”

The 1977 Guidelines did not provide much guidance regarding whether lactating persons may or may not be included in clinical trials. Instead, the 1977 Guidelines simply stated that “[e]xcretion of the drug or its metabolites in the milk of lactating women should be determined, when feasible, prior to the use of the drug in nursing mothers.”

Over time, the restrictions have been relaxed. In 1993, FDA published new guidelines and withdrew the restrictions on the participation of women of childbearing potential in early clinical trials (e.g., Phase I) (FDA, 1993). These revisions were a response to growing concerns that the drug development process did not produce adequate information about the safety and efficacy of drugs in women. FDA itself acknowledged that the 1977 Guidelines were viewed as “rigid,” “paternalistic,” and “overprotective”; left “virtually no room for the exercise of judgment by responsible female research subjects, physician investigators, and [investigational review boards (IRBs)]”; and denied “young women the opportunity available to young men and older women to participate in early drug development research.” FDA did not, however, require inclusion of women in general or women of childbearing potential, and recognized that drug companies and/or IRBs may not change their restrictions.

In 1998, FDA sought to address the problem further by issuing a Final Rule amending its regulations pertaining to Investigational New Drug Applications (INDs) and New Drug Applications (NDAs). Among other things, this Final Rule amended FDA regulations to require sponsors of NDAs to include in their applications analyses of safety and effectiveness data for certain subgroups, including gender. FDA has the authority to refuse to file an NDA that lacks such data (21 cfr 314.101(d)(3), 2020). In 2000, FDA promulgated another Final Rule that gives FDA the authority to place a trial for a life-threatening disease or condition on clinical hold if the sponsor excludes men or women only because of reproductive potential (FDA, 2000). This rule only applies to trials for a life-threatening disease or condition in which the subjects

have the disease or condition; it does not apply to trials only involving healthy volunteers or for diseases or conditions that are not considered “life-threatening.”

Many of the regulations discussed previously referred broadly to “women of childbearing potential.” In 2018, FDA addressed the specific subgroup of pregnant persons when it issued draft guidance titled “Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials” (FDA, 2018). The draft guidance is intended to “[support] an informed and balanced approach to gathering data on the use of drugs and biological products during pregnancy through judicious inclusion of pregnant women in clinical trials and careful attention to potential fetal risk” (FDA, 2019, 2020). In addition to these and other changes, the FDA Office of Women’s Health (OWH) was established by congressional mandate in 1994, with a mission to, among other things, promote the inclusion of women in clinical trials and the implementation of guidelines concerning the representation of women in clinical trials and completion of sex or gender analysis.

Another set of regulations that applies to research involving pregnant and lactating persons is found in Subpart B of the HHS regulations entitled “Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research.” Furthermore, the provisions of Subpart D are applicable to research with children, including viable neonates, and therefore may be implicated in research involving lactating persons who may transfer some of a medication they take to a breastfeeding child.

Despite this progress, much work remains. The COVID-19 pandemic brought the issue into the spotlight once again. Despite the increased risk of severe illness in pregnant persons, along with other risks such as preterm birth, initial trials of the COVID-19 vaccines excluded pregnant and lactating women. As a result, pregnant and lactating persons were left to decide whether to get the vaccine without much, or any, evidence of its safety for pregnant persons. Health care providers were likewise left in the dark. This lack of data likely decreased vaccine uptake in pregnant persons, as lack of trust in COVID-19 vaccines and concern about safety and side effects are predictors of low vaccine uptake (Galanis et al., 2022). Data now show that low vaccine uptake among pregnant persons resulted in harm to pregnant persons and fetuses. Unvaccinated pregnant persons had higher rates of maternal mortality, and SARS-CoV-2 infection in pregnant persons has been associated with higher risks of admission to the neonatal intensive care unit, intrauterine fetal death, perinatal mortality, preeclampsia, and preterm labor (Grunebaum and Chervenak, 2022; Watanabe et al., 2022). For lactating persons, administration of the COVID-19 vaccine has resulted in temporary decreased milk supply, an effect that was not discovered until the vaccine was being widely used,

due to the exclusion of lactating persons in the initial clinical studies (Kachikis et al., 2021).

Waggoner and Lyerly (2022) emphasize that most research regulations in the United States were developed after 1973, and thus during a time when abortion was legal. Waggoner and Lyerly “fear that the changing legal landscape in the U.S. threatens progress in addressing key evidence gaps in the care of women and pregnant persons. Just as *Roe* had consequences for the evolution of research with these populations, so, too, will its reversal.”

### **DOBBS: THE CONSEQUENCES AND IMPLICATIONS FOR CLINICAL RESEARCH**

As noted in the second section of this document, much progress has been made in recent years toward recognizing the importance of and improving knowledge about how medical products, such as drugs, affect pregnant and lactating persons, who were historically excluded from clinical trials. Yet, much work remains to mitigate the harms that result from the lack of evidence and knowledge that remains. *Dobbs* jeopardizes the incremental progress made and risks stalling further progress.

This section describes how the *Dobbs* decision has or may affect clinical research involving pregnant and lactating persons. Some of the consequences listed are more likely than others to transpire. Moreover, an important caveat to the findings of this report is that at this time, much remains unknown about the full impact of *Dobbs*. With time, the scope of the consequences of *Dobbs* will become clearer.

#### **Lactating Persons**

The direct result of *Dobbs* is greater restrictions on access to abortion throughout the United States. The goals of some abortion opponents, however, extend beyond merely returning the legality of abortion to the states, and include complete elimination of abortion in the United States and the legal recognition of fetal personhood.

The goals of abortion opponents are thus focused principally on *prenatal* activities and outcomes, which will primarily affect pregnant persons but not lactating persons (unless that lactating person is also pregnant). In short, *Dobbs*, and the antiabortion movement more generally, are about *fetal* protection. The movement does not focus on protections for newborns no longer in utero.

A main reason why lactating persons are excluded from clinical research is because of concerns about how medications may affect nursing infants. Laws that restrict access to or eliminate abortion or laws that protect fetuses should not affect clinical trials on lactating persons.

## Pregnant Persons

In contrast to lactating persons, *Dobbs* is likely to affect clinical research involving pregnant persons. This section outlines how *Dobbs* and the restrictions, bans, and fetal protection laws promulgated as a result of that decision may make clinical trials involving pregnant persons more difficult and may increase the risk of liability of performing such trials.

### *Trials in Progress*

Sponsors of trials in progress will need to consider whether any of these trials need to be halted or whether protocols will need to be amended. In making these decisions, sponsors will need to consider the location of their trial sites, whether and how the site's abortion laws have changed since *Dobbs*, and whether and how that affects the performance of their trial or collection of specific types of data. Sponsors should also consider whether there is a need to obtain new consent from participants to address legal restrictions on abortion access given a change in law after enrollment and initial consent.

The frequent, often back-and-forth changes being seen in abortion laws, particularly as some laws are being challenged in courts, means that sponsors should engage experienced legal counsel to ensure their trials remain compliant with changing state laws, which remain in a constant state of flux. Given the evolving nature of state abortion laws, sponsors should also consider establishing a process that requires periodic review of their trials in conjunction with any new or amended state or federal laws and regulations.

### *Limitations on What Can Be Studied*

Clinical trials studying abortion drugs, methods, and services will experience the most direct and significant consequences. The studies will be subject to the same state requirements as those services when provided at the clinical level. Thus, if there is a ban on providing medication abortion or procedural abortions in the clinical context in a state, there will also be a ban on providing abortion in the research setting in that state. This will make studying new methods of medication abortion more difficult and even impossible in some states. Studying medicines like mifepristone, as well as other drugs known to increase the risk of pregnancy loss for nonabortion purposes, will also be legally difficult.

As noted by Sugarman et al., "fear of legal risks associated with facilitating an abortion, or uncertainty about the rapidly evolving legal status of abortion, might leave researchers reluctant to obtain rigorous data

on pregnancy, possibly including adverse pregnancy-related outcomes.” If that occurs, data will be incomplete and less valuable to researchers and society more generally.

### *The Comstock Act*

The Comstock Act was not mentioned in *Dobbs*, but recent court cases involving medication abortion attempt to bring back to life this relatively dormant antivice law. The Comstock Act of 1873 made it illegal to send “obscene, lewd or lascivious,” “immoral,” or “indecent” publications through the mail. The Act also made it a misdemeanor for anyone to sell, give away, or possess an obscene book, pamphlet, picture, drawing, or advertisement (*An act for the suppression of trade in, and circulation of, obscene literature and articles of immoral use*, 1873).

The Act’s prohibitions include writings or instruments pertaining to contraception and abortion. Specifically, the Act bans the mailing of articles, including drugs and medicines, or things “designed or intended” to procure an abortion. The Comstock Act’s prohibitions extend not only to the United States Postal Service, but also to “any letter carrier” or “common carrier,” including the United Parcel Service or Federal Express.<sup>1</sup> The Supreme Court overturned the Act’s restrictions on contraception in the 1965 case (*Griswold v. Connecticut*, 1965) and Congress subsequently amended the law to remove the reference to contraception. Furthermore, in December 2022, the Department of Justice (DOJ) issued an opinion stating that the Comstock Act:

does not prohibit the mailing of certain drugs that can be used to perform abortions where the sender lacks the intent that the recipient of the drugs will use them unlawfully. Because there are manifold ways in which recipients in every state may lawfully use such drugs, including to produce an abortion, the mere mailing of such drugs to a particular jurisdiction is an insufficient basis for concluding that the sender intends them to be used unlawfully. (Schroeder, 2022)

Thus, under this interpretation, because mifepristone has been approved by FDA for termination of pregnancy through 10 weeks gestation, the Comstock Act does not prevent the mailing of that drug if the intent is to use the drug to terminate a pregnancy as approved by FDA.

Even while *Dobbs* did not address or involve claims relating to the Comstock Act, the decision paved the way for new and ongoing litigation involving the Comstock Act. For example, litigation has been brought

---

<sup>1</sup> Mailing obscene or crime-inciting matter; and importation or transportation of obscene literature. 18 U.S.C. 1461-62.



challenging FDA's approval of mifepristone, one of the drugs approved by FDA in the medication abortion regimen. Among other claims, this lawsuit claims that the Comstock Act prohibits the mailing of mifepristone. This lawsuit and prominent antiabortion lawyers are focused on how the law applies to the mailing of abortion drugs. The broadest interpretations being put forward by some opponents of abortion would mean that even tools and medical instruments that facilitate abortion procedures that are shipped in the mail to clinics and other facilities would be caught in the Comstock Act's net (Sneed, 2023).

Should enforcement of a broader reading of the Comstock Act transpire, there could be serious implications for clinical trials. The significance, however, will depend largely on how expansive an interpretation is adopted. Many drugs and devices are designed in ways that could, if used in particular ways, cause an abortion. Such a broad view would implicate most, if not all, clinical trials. A narrower interpretation, which only affects drugs and devices specifically *intended* to cause an abortion, would implicate far fewer clinical trials—primarily those involving drugs and devices being studied for the precise purpose of causing a medical or procedural abortion. As a federal law, its enforcement would, for all intents and purposes, prevent the study of any drug intended to induce an abortion because it is almost certain that a clinical trial would require some of the drugs to be shipped through the mail system.

### *Clinical Trial Location*

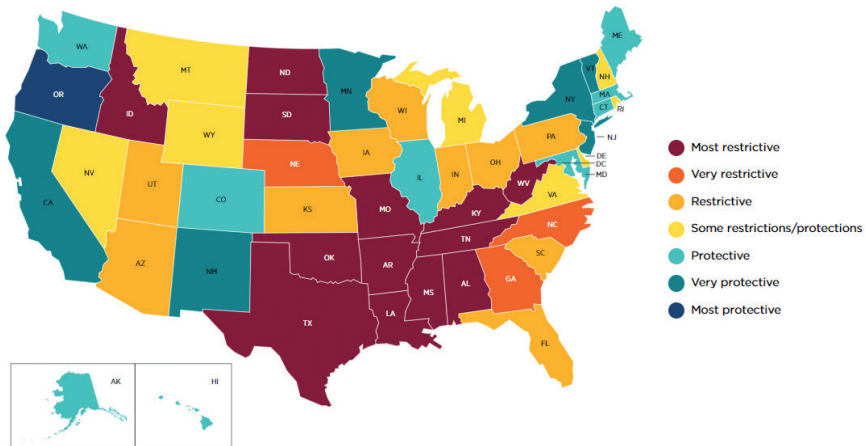
*Dobbs* may affect the location of clinical trial sites, which may detrimentally effect the diversity of clinical trials.

Current guidelines from the Council for International Organizations of Medical Sciences (CIOMS) state: "Research with pregnant women must be conducted only in settings where these women can be guaranteed access to safe, legal abortion." Sponsors following those guidelines would thus not be able to perform clinical trials in the many states that have banned or severely restricted abortion (CIOMS and WHO, 2016).

According to Waggoner and Lyerly (2022), "Trial participants may desire termination of pregnancy in the rare circumstance where participation in the study is associated either with fetal harm or with prolonging a pregnancy where maternal health is in danger (e.g., severe preeclampsia)." If abortion is not available to these participants, they may have to drop out of the trial.

If clinical trials cannot be held in certain states, the diversity of clinical trials may decrease, making it more difficult for sponsors to achieve adequate racial, ethnic, and socioeconomic diversity. According to Sugarman





**FIGURE E-1** U.S. abortion policies and access after *Dobbs* (as of July 25, 2023)  
SOURCE: Institute, 2023c.

et al. (2023), sponsors must consider whether the risks of performing trials at certain sites outweigh the benefits, but that “such decisions should not be taken lightly because such a choice obviates the opportunity for people who can become pregnant to participate in research and generate locally relevant data.”

Many of the southern states with the most severe abortion laws in the country are also densely populated by people of color, including the majority of Black Americans, as depicted in Figure E-1 (Abrams, 2023; U.S. Census Bureau, 2021). Sponsors will continue to be able to conduct trials in states with large populations of people of color, such as California, which currently protects access to abortion, but the pool of participants will be far smaller. According to the 2020 Census, for example, roughly 3.3 million Blacks live in Georgia, whereas approximately 2.2 million Blacks live in California. The 2020 Census data show that southern states like Georgia, Louisiana, Mississippi, Alabama, and South Carolina have some of the highest percentages of Black populations. These same states have all banned or severely restricted access to abortion as of the date of this report; some of these bans are currently blocked by court order (*New York Times*, 2023) (see Table E-1).

### *Informed Consent Issues*

Sponsors will need to consider whether and how their informed consent procedures need to be amended to describe the risks of pregnancy loss; availability of abortion or contraception; possible effects on a fetus; and the risks of pregnancy information and outcomes being

**TABLE E-1** Ten States with Highest Percentage of Black or African American Alone<sup>2</sup> Population (2020 Census)

State or District	Black or African American Alone (2020 Census)	Abortion Policies
District of Columbia	41.4% (285,810 people)	No bans
Mississippi	36.6% (1,084,481 people)	Abortion banned with very limited exceptions
Louisiana	31.4% (1,464,023 people)	Abortion banned with very limited exceptions
Georgia	31.0% (3,320,513 people)	Abortion banned at 6 weeks
Maryland	29.5% (1,820,472 people)	Abortion banned at fetal viability (~24–26 weeks gestation)
Alabama	25.8% (1,296,162 people)	Abortion banned with very limited exceptions
South Carolina	25.0% (1,280,531 people)	Abortion banned at 22 weeks gestation (6-week ban on hold while legal challenges continue)
Delaware	22.1% (218,899 people)	Abortion banned at fetal viability (~24–26 weeks gestation)
North Carolina	20.5% (2,140,217 people)	Abortion banned after 12 weeks
Virginia	18.6% (1,607,581 people)	Banned starting at third trimester

NOTE: Red rows are states that have banned abortion at or less than 6 weeks. The yellow row indicates an abortion ban after 12 weeks.

SOURCE: U.S. Census Bureau, 2021; Guttmacher Institute, 2023b; *New York Times*, 2023.

recorded, reported, or accessed by state officials. Participants should also be informed of whether there is a potential risk of prosecution or other legal liability should their fetus be harmed or should they decide to terminate a pregnancy after a positive pregnancy test so they can continue the trial or if their fetus is harmed by the product being tested.

If sponsors are conducting trials in states where abortion is banned or severely restricted, sponsors should also strongly consider providing this information explicitly to participants during the informed consent process. For example, if pregnancy is an exclusion criterion, sponsors should consider whether to inform participants that if they become pregnant during the study and want to get an abortion so they can remain in the trial, it may be difficult for them to access abortion care, meaning they will have to drop out of the study.

<sup>2</sup> Black or African American alone includes respondents who reported only one response to the race question in the U.S. Census.

Sponsors should also consider whether they intend to provide participants with information about how to access an abortion should they become pregnant during the course of the trial and they want to obtain an abortion so they can remain in the trial (if pregnancy is an exclusion criterion). In states where abortion is banned or severely restricted, there could be legal liability for doing so, which could affect the pregnant persons, the sponsor, and study staff. Such risks are more acute where the language of the law suggests that those who “aid and abet” an abortion can be held liable. For example, Texas law provides civil liability for any person who “knowingly engages in conduct that aids or abets the performance or inducement of an abortion” that is otherwise illegal under Texas law (*Civil liability for violation or aiding or abetting violation*, 2021).

The potential expansion of fetal personhood laws made possible by *Dobbs* may also affect informed consent for trials that include pregnant persons. Even though clinical trials enrolling pregnant persons remain relatively rare, they have increased in recent years amid the push to expand medical knowledge about how drugs affect pregnant persons and fetuses. Thus far, the pregnant person has the legal and ethical authority to consent to their participation in research (assuming they meet the other criteria for giving informed consent). Where fetal personhood laws exist, the issue of consent may become more complicated.

For example, if a state considers a fetus a person under the law, sponsors will need to determine whether *two* separate consents must be obtained before a pregnant person can enroll in a clinical trial. If two consents are needed, sponsors must also consider whether the pregnant person, as the “parent” of the fetus, will have the authority to consent to the fetus’s participation, just as the parent of a born minor child would. This raises the question of whether the fetus’s other biological or legal parent should also have a role in the consent process.

The consent process may be complicated if the pregnant person wants to enroll in the clinical trial but the other parent is concerned about the fetus and refuses to consent to the fetus’s participation in the research. Subject to some exceptions, federal regulations already require the consent of the father “if the research holds out the direct benefit solely to the fetus” (HHS, 2018). But in situations where the research also or solely holds out a possible direct benefit to the *pregnant person*, and not the fetus, the father’s consent is not explicitly required. Yet in a post-*Dobbs* world, more states may consider adopting fetal personhood laws or state laws requiring the other parent’s consent when a pregnant person enrolls in a clinical trial. If a state’s law considers a fetus a person, and thus analogous to a *child*, sponsors may have to comply with the requirements specific to consent for a *child’s* involvement in clinical trials. Under federal regulations, IRBs may require the permission of both

parents for certain types of research involving children (HHS, 2018). A specific state's personhood laws will matter, however, because these same federal regulations provide that "children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, *under the applicable law of the jurisdiction in which the research will be conducted*" (HHS, 1983).

### *Documentation and Privacy Concerns*

**Background:** Complicated privacy concerns have long been an issue for research involving pregnant persons, often stemming from the state's purported interest in protecting fetal life. For example, an IRB at the University of South Dakota encountered such privacy issues when the IRB was presented with a protocol for a five-state study of fetal alcohol syndrome that involved identifying and monitoring women who drink during pregnancy. South Dakota law, however, requires officials to report potentially abusive behavior toward a fetus, which includes drinking alcohol. Investigators were unable to offer research participants a certificate of confidentiality or other privacy protection because of state law. As a result, women who volunteered for the study were at risk of being reported to state officials and potentially facing legal repercussions because of their substance abuse while pregnant. Ultimately, the governor's office wanted the study to proceed because its objectives involved a positive intervention—helping pregnant persons with drinking problems with educational interventions intended to help them maintain sobriety. Under the state's decision, the women would still be reported to the state, but the state would take no action against any individual participants of the study (IRB Advisor, 2003).

**Post-Dobbs:** The breadth of privacy issues may increase as states propose and enact news laws aimed at preventing abortion, protecting fetal life, and policing the bodies and choices of pregnant persons. The current legal environment, including its instability, underscores the importance of protecting the confidentiality of all information about trial participants' pregnancies and use of abortion services.

*Dobbs* may affect how researchers record pregnancies among subjects and whether and how that information is protected from disclosure. In many clinical trials involving nonpregnant subjects, initial and periodic pregnancy tests are a standard part of trial protocol. These tests are deemed necessary when a trial's protocol requires exclusion of pregnant persons, yet they may also detect early pregnancies that would have otherwise gone unnoticed because of high rates of first trimester miscarriages. A positive pregnancy test during the course of a trial is

typically considered a “reportable event,” so participants must be willing to report their pregnancies and feel secure doing so, particularly if they are considering an abortion. According to Aoife Brennan, CEO of Synlogic, Inc., *Dobbs* “is forcing people involved in clinical research to rethink something as simple as pregnancy tests, which had once been taken for granted, and plan for the possibility that research sponsors and study sites will be required to share pregnancy and outcome data with state officials” (Skerret, 2022). Sugarman et al. (2023) agree, stating: “The simple fact that a research participant is not pregnant nor has given birth, but a test indicates that they were pregnant during research, could put them at risk of legal action.”

For the last 4 decades, the Centers for Disease Control and Prevention (CDC) has partnered with states to collect aggregate statistics about abortion. States are not required to submit their abortion data to CDC, but the majority do report. Moreover, even though states are not required to submit their abortion data to CDC, the majority of states require hospitals, facilities, and physicians to submit regular reports to the state with various information about abortions performed. Some of these states also require reporters to provide some information about the reason the person sought an abortion (Guttmacher Institute, 2023a). Some states have attempted to go further, proposing laws that would require reporting of miscarriages and stillbirths (Weigel et al., 2019).

These existing and proposed laws suggest that states could attempt to expand their reporting requirements to other entities, including clinical trial sponsors, who become aware of an induced or spontaneous abortion that occurs during the course of a clinical trial. Such information may already be provided in those states that require providers to list the reason for the abortion (e.g., in the case of a clinical trial participant, the reason may be so they can remain in the trial). States may argue that compiling this information relates to their legitimate interest in compiling vital statistics about births and deaths. Such reporting requirements are perhaps most likely to be proposed in states with fetal personhood laws, as the death of a fetus will be considered on par with the death of any person after birth.

States could justify the collection of such information by arguing that it is related to their interest in maternal health. The Supreme Court has recognized that “[r]ecordkeeping and reporting requirements that are reasonably related to the preservation of maternal health and that properly respect a patient’s confidentiality and privacy are permissible” (Danforth, 1976).

If states were to require clinical trial sponsors to report pregnancy and abortion data about their trial participants, and if any abortions occurred in violation of state law, states could seek to hold the sponsor

civily or criminally liable, depending on the scope and language of the state's abortion laws. As noted previously, some states provide for civil liability of those who "aid and abet" an abortion. If sponsors provide information to clinical trial participants about abortions, or even if they simply inform a participant that they must drop out of the trial if they remain pregnant, states with aiding and abetting laws could adopt a broad reading of these statutes and impose liability on trial sponsors.

In most if not all cases, the information reported to states maintains the patient's confidentiality and does not provide their name or other personally identifiable information. However, where a state has banned or severely restricted abortion, they may seek such identifiable information in pursuit of criminal charges. And even if the pregnant person is not identifiable and thus not at risk for legal consequences, the sponsor could still be subject to liability if, for example, they help participants obtain an abortion, and there is evidence that participants did in fact terminate their pregnancies. Whether any legal consequences transpire will be a matter for a court to decide. The Supreme Court has held that states have a compelling interest in pursuing criminal investigations (Branzburg, 1972). Furthermore, an individual's right to privacy is not necessarily "absolute; rather, it is a conditional right which may be infringed upon a showing of proper governmental interest" (Lawell, 2002). As described in the final section of this document, certificates of confidentiality may provide some protection against this.

The possibility of compelled reporting or disclosure of such information to a state entity may depend in part on the type of entity sponsoring the trial. In many cases, the federal government, such as the National Institutes of Health (NIH), sponsors clinical trials, raising the question of whether the state can compel a federal entity to provide it with information. This appears to be an open question in the clinical trial context. As noted above, although the primary regulatory framework for conducting clinical trials in the United States is set forth in Title 21 of the *Code of Federal Regulations*, these regulations do not preclude states from imposing their own requirements in such areas as informed consent (FDA, 2011). With respect to clinical trial registration and reporting requirements, federal law provides that "no State or political subdivision of a State may establish or continue in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database" (Food and Drug Administration Amendments Act of 2007, 2007). Yet, even while states may not require additional *result* reporting requirements, the laws and regulations do not, however, appear to address whether or not states may request or compel information from federal government sponsors of clinical trials for purposes outside of these public reporting requirements.



Privacy concerns may make it more difficult to enroll participants. In the context of cancer research, for example, Mittal and colleagues remark that

With the overturning of *Roe v. Wade*, women of childbearing age with a cancer diagnosis may feel discouraged and/or threatened by participating in clinical trials as therapeutic interventional studies would require documentation of regular pregnancy screening. We are concerned that the recent ruling [in *Dobbs*] will curtail the therapeutic armamentarium for oncology patients in the reproductive age group, by restricting clinical trial options for women and disempowering them from making personal health care decisions. (Mittal et al., 2023)

Sugarman et al. similarly note that “If risks to research participation that result from legal restrictions on abortion access are not sufficiently addressed, people who can become pregnant might be deterred from enrolling in clinical research.” This may have serious consequences, “compromise[ing] the scientific and social value of research [and reinforcing longstanding gender disparities, which are due in part to longstanding underrepresentation of people who can become pregnant in research” (Sugarman et al., 2023).

In addition to reinforcing gender disparities, ethnic and racial disparities may also be reinforced and exacerbated. Enrollment difficulties are particularly likely for participants from historically marginalized and vulnerable populations who may have less trust in government, medical, and research institutions in light of a long history of exploitation and abuse. Individuals with lower levels of trust in the health care system and researchers are less likely to participate in various kinds of research (Sanderson et al., 2017). The effects may be magnified particularly for women of color, who have experienced a long history of being unknowingly or unwillingly subjected to unethical medical experiments and procedures, such as those carried out by doctors like James Marian Sims who performed myriad gynecological experiments on Black enslaved women, often without providing them any anesthesia (Whelan, 2021). Furthermore, communities of color are already susceptible to discriminatory oversurveillance and policing, including state prosecution of women for their behaviors during pregnancy (Dirks, 2022; Whelan, 2023). Communities of color are thus likely to have heightened and well-founded fears about the confidentiality of their information.

### *Liability*

Overall, the risk of liability will likely increase post-*Dobbs* for all entities involved in research with pregnant persons. This includes the sponsor, funders, investigators/study staff, and participants. This will be particularly true in states with fetal personhood laws. As noted by



Waggoner and Lyerly (2022), “It is easy to imagine that in a legal context where fetal harm is more likely to result in criminal penalties, especially among women of color . . . the research community might conclude that a study with pregnant persons is too risky to justify—to funders, to research oversight boards, or to pregnant persons themselves.”

The potential for liability depends on how far states are willing to push their antiabortion and fetal protection laws. While some states may limit their actions to research explicitly studying drugs intended to induce an abortion, others could go further, seeking to impose liability on those involved in clinical research that harms a fetus or results in fetal death. The liability could stem from a state’s abortion laws, fetal personhood laws, children endangerment/abuse laws, or other criminal laws.

In the event a participant becomes pregnant but wants to remain in a trial where pregnancy is an exclusion criterion, sponsors will need to consider whether to provide participants with any information or resources about abortion. Doing so would increase their risk of being held liable for aiding and abetting an abortion.

### *Higher Costs*

Trial sponsors may have to spend more time and resources obtaining legal advice to ensure they do not run afoul of any state’s antiabortion or fetal personhood laws. They may also need to amend their informed consent documents and procedures. If sponsors encounter difficulties enrolling adequate numbers of participants, the trial may need to run longer than initially expected in order for the sponsor to collect the volume of data needed. The extra time and money may have downstream effects on the price of medication if the product makes it through trials and is ultimately approved by FDA.

### *Stifling Innovation*

As noted in previous sections, *Dobbs* may make it more difficult to enroll pregnant persons in clinical trials and to study certain types of medical products. This may stifle innovation, both generally and specifically with respect to medications that aim to treat or prevent pregnancy-related conditions, such as gestational diabetes, preeclampsia, preterm birth, maternal–fetal disease transmission, and more.

Clinical trials for such products could be shifted to other jurisdictions in the United States or another country where abortion laws do not impose these extra hurdles. However, as noted previously, some of the states with the greatest restrictions are also the states with the highest populations of communities of color and low-income populations.

These same populations are also more likely to experience some of the diseases and conditions listed in the prior paragraph (Osuebi, 2023). As FDA acknowledges, broader and

more-inclusive enrollment practices should improve the quality of studies by ensuring that the study population that will use the drug if the drug is approved by facilitating the discovery of important safety information about use of the investigational drug in patients who will take the drug after approval; and by increasing the ability to understand the therapy's benefit-risk profile in later stages of drug development for the Phase III population across the patient population likely to use the drug in clinical practice. (HHS and FDA, 2020)

Other areas of innovation that may be affected include: (1) research and development of infertility treatments and artificial reproductive technologies, particularly any that involve the creation and potential destruction of embryos;<sup>3</sup> (2) research involving fetal tissue and embryonic materials; (3) pre- and postimplantation gene editing; (4) research into new and potentially safer and more effective methods of medication abortion and contraception; and (5) research and development of period tracking or other fertility-related apps.

## MITIGATING THE CONSEQUENCES OF *DOBBS*

This section discusses existing and new mechanisms that may help mitigate the effects of *Dobbs* on clinical research. Given that much remains unknown at this time, sponsors and other stakeholders will need to remain flexible as new or unexpected challenges arise and as laws and policies continue to evolve in the post-*Dobbs* world.

### Certificates of Confidentiality

Certificates of confidentiality (CoCs) provide an important opportunity to protect against the privacy issues discussed in the previous section. The privacy and legal risks encountered post-*Dobbs* represent precisely what CoCs are intended for: to protect researchers and health care providers and research participants from unintended legal consequences.

---

<sup>3</sup> In November 2022, the Tennessee attorney general issued an opinion clarifying that disposing fertilized preimplantation embryos, such as those created in the course of IVF treatment, would not constitute a criminal abortion under the state's Human Life Protection Act, even though the Act includes preimplantation embryos in its definition of an "unborn child" (Stockard, 2022). However, it is unclear if disposal of preimplantation embryos in IVF context is the same as actively destroying an embryo in course of human embryonic stem cell (HESC) research.

The CoC is a federal statutory device that protects identifiable, sensitive information collected during “biomedical, behavioral, clinical, or other research” from compelled disclosure. Specifically, if a law enforcement officer, prosecutor, legislator, civil litigant, or other party seeks to compel information about a research participant through a subpoena or warrant, a CoC prohibits the researcher from making the disclosure and bars the use of that information as evidence. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, a CoC can help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to subjects.

The statutory scheme providing for CoCs has been amended numerous times since first enacted in 1970. Every time Congress has revisited the statute, it has not only reaffirmed the importance of CoCs, but *broadened* their reach and scope. The CoC statutory scheme represents Congress’s view that research is very important and should be facilitated.

The statute itself is surprisingly broad. Initially, it applied only to certain types of research. Today, that is no longer the case. The statute no longer distinguishes between different types of research; it applies to *all* types of research. In short, the law today mandates the issuance of CoCs for all federally funded research; researchers not engaged in federally funded research are eligible to apply for a CoC. As a result of this law, large volumes of research data are now covered by CoCs and therefore beyond the reach of state and federal law enforcement, legislative, and other authorities. CoCs help reassure participants that their data are safe and protected from disclosure or use in legal proceedings.

The protections offered by CoCs are broad, but not absolute. Although they protect individually identifiable research data against compelled disclosure in any “Federal, State, or local, civil, criminal, administrative, legislative, or other proceeding,” they do not prevent disclosures that are “required by Federal, State, or local laws” outside of the “compelled” context. So, if a state law requires the disclosure or collection of research data for public health purposes, such as vital statistics about pregnancy outcomes, a CoC will not likely protect them from being disclosed to the state for such purposes. Importantly, however, if the information can be obtained elsewhere, the researcher can always direct the requester elsewhere.

As noted by Sugarman et al. (2023), CoCs have yet to be tested in this context in court. It is possible that antiabortion policy makers could view the post-*Dobbs* landscape as an opportunity to challenge CoCs. States may argue that such data concern public health, which has been deemed “a quintessential concern of [a state’s] police power” (*Terkel v. CDC*, 2021). States could attempt to challenge the constitutionality of CoCs, alleging that law enforcement within its borders also represents a quintessential

police power that the Tenth Amendment of the U.S. Constitution reserved to the states. Essentially, states could argue that Congress lacks the constitutional authority to statutorily disable state warrants and subpoenas that are otherwise valid.

Strong arguments can be made, however, to support the constitutionality of CoCs. These arguments would be grounded primarily in the Commerce Clause, with additional support from Congress's power to tax and spend. Using these constitutional authorities in a forthcoming law review article, Natalie Ram, Jorge L. Contreras, Laura M. Beskow, and Leslie E. Wolf, make a strong case for the constitutionality of CoCs (Ram et al., 2023).

Should the states seek the disclosure of research data under one of the legitimate exceptions to a CoC's protections, one might be concerned that the state could then later use that information in a legal proceeding, even if they originally used it for a valid purpose. In this situation, there is a strong argument that the information should be inadmissible. The statute was amended under the 21st Century Cures Act to apply to *all* copies in perpetuity. Therefore, a copy of the information initially obtained for a valid reason could not later be used for an invalid reason (e.g., in a legal proceeding).

One potential and important loophole in the context of clinical trials involving pregnant persons and CoCs is mandatory reporting laws. A CoC protects research subjects from legally *compelled* disclosure of their identity and sensitive information. It does not, however, restrict voluntary disclosure. For example, a CoC does not prevent researchers from voluntarily disclosing to appropriate authorities such matters as child abuse, a subject's threatened violence to self or others, or reporting a communicable disease. If researchers intend to make such disclosures, that should be clearly stated in the consent forms that research participants are required to sign. Child abuse reporting laws could come into play in states with fetal personhood laws or that criminalize certain behaviors of pregnant persons, classifying things like drug or alcohol use as child abuse. But importantly, these disclosures are *voluntary*—researchers are not *required* to report them.

In sum, despite some limitations, CoCs appear to provide a very strong mechanism currently available to protect against the many concerns addressed in the previous section.

### **Congressional Action**

Congress has historically shown support for research involving human subjects. Congress illustrates its support in various ways, such as through the passage of laws, the establishment of agencies that govern or conduct biomedical research, and the provision of significant funds to

support biomedical research. NIH, for example, invests most of its multi-billion dollar annual budget in medical research (NIH, 2022). Recent congressional support for research is shown by the creation of the Advanced Research Projects Agency for Health (ARPA-H), which was established in March 2022 to support the development of high-impact research to drive biomedical and health breakthroughs to deliver transformative, sustainable, and equitable health solutions (*Consolidated Appropriations Act, 2022*, 2022).

Executive agencies also play a role in protecting health privacy, and recent actions by HHS illustrate concerns about the privacy of reproductive health information. HHS has issued a notice of proposed rulemaking that would modify the Standards for Privacy of Individually Identifiable Health Information (i.e., the “Privacy Rule”) under HIPAA and the HITECH Act. The proposed rule would modify existing standards permitting uses and disclosures of PHI for certain purposes where the use or disclosure of information is about reproductive health care that is lawful under the circumstances in which such health care is provided. The proposal would modify existing standards by prohibiting uses and disclosures of PHI for criminal, civil, or administrative investigations or proceedings against individuals, covered entities or their business associates (collectively, “regulated entities”), or other persons for seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it is provided.

An important limitation of the proposed rule is that it only prevents the use and disclosure of PHI that relates to reproductive health care that is *lawful under the circumstances in which such health care is provided*. So if a state seeks the information because they believe an abortion was performed or a fetus was harmed in violation of a state law, the proposed rule would not protect that information from disclosure. Under this rule, a CoC, as described above, would still be needed to protect the information from disclosures made for purposes of various types of legal proceedings.

### **Institutional Review Boards (IRBs)**

IRBs should consider specifically reviewing *Dobbs*-related risks, such as risks related to restrictions on abortion access to participants who may become pregnant. IRBs should also consider ways to minimize any such risks. To perform their oversight responsibilities, IRB members will need to understand and have a working knowledge of relevant state law that will apply to the trial protocol, and they should consult with those with appropriate expertise when necessary.

IRBs should consider, for example, whether *Dobbs*, or any new state laws that have been enacted in the wake of *Dobbs*, make it illegal or extremely risky to conduct certain studies in certain states. Informed consent procedures should also be reviewed with an eye toward *Dobbs*. These may be complicated and time-consuming obligations, given the variability and evolving nature of laws across the states, but they remain necessary.

According to William Alford at Public Responsibility in Medicine and Research (PRIM&R), a nonprofit organization that provides education, membership, and other professional resources to the research and research oversight community, the organization has not provided any information to IRBs about abortion/*Dobbs*-related factors (e.g., legality of abortion) when assessing whether to approve certain studies.

Sponsors and other stakeholders should consider whether all research with the potential to affect a pregnancy should be governed by IRBs comprised of members with adequate expertise to determine the myriad risks associated with new state laws, including privacy risks. Currently, IRB approval for research involving deidentified data is not required unless the researcher has access to a link allowing reidentification (HHS, 2017). However, evolutions in technology make it increasingly easy to reidentify deidentified information, so it would be wise for sponsors to engage an IRB or other privacy experts to ensure their data are protected adequately.

### **Compensation and Reimbursements for Participants**

Sponsors of clinical trials often reimburse patients for costs related to their participation in research (e.g., travel). Given the increasing number of states enacting abortion bans and restrictions that may make it difficult to conduct certain types of clinical research in that state, sponsors will need to consider whether they have the resources to reimburse participants for longer-distance travel, hotel stays, and overnight stays. This approach may help mitigate the effect of *Dobbs* on clinical trial diversity discussed in the previous section. Yet even if these costs are reimbursed, requiring persons to uproot their lives and essentially move temporarily during the duration of the trial still represents a substantial burden that would be likely to discourage enrollment. There is also a sustainability issue—will sponsors be able to sustain such levels of reimbursement in the long term?

As always, sponsors will need to keep abreast of state laws that attempt to criminalize abortion-related travel. Sponsors must also ensure that any reimbursement or compensation provided to participants do not cross a line so as to become coercive (Largent et al., 2012).

## Liability Insurance

Sponsors should work closely with insurers to develop insurance policies that provide broad liability and/or indemnity coverage. An important limitation here is that many abortion laws now impose criminal penalties, which are likely beyond the scope of any protection from insurance policies.

## Lawsuits

If a state law attempts to collect confidential information from trial sponsors or other parties, a lawsuit could challenge the law on the grounds that the state does not have legitimate need or reason for collecting such information. Trial sponsors, investigators, health care providers involved in the participant's care, and/or the participants might, for example, challenge the constitutionality of these laws, specifically as they relate to the constitutional right to privacy.

States may, however, have relatively strong arguments in support of their laws, even if the laws include the collection of identifiable information. States will argue that these laws are a valid and reasonable exercise of their broad police powers. The Supreme Court has long recognized the breadth of the states' police powers, which provide states with broad authority "to establish and enforce standards of conduct within [their] borders relative to the health of everyone there" (*Barsky*, 1954). Back in 1909, for example, in *District of Columbia v. Brooke*, 1909, the Court stated that the "exercise of the police power" represents "one of the least limitable powers of the powers of government." The Court's recognition of strong state police powers may make it difficult to overcome the state's argument in these cases.

These lawsuits might make similar claims to those made by the petitioners in *Whalen v. Roe* (1977), a 1977 Supreme Court case that challenged New York statutes that classified potentially harmful drugs and provided that the prescriptions for Schedule II drugs (the most dangerous legitimate drugs) be prepared on an official form. One copy of the form, which identified the prescribing physician; dispensing pharmacy; drug and dosage; and the patient's name, address, and age, was required to be filed with the State Health Department, where data were recorded on tapes for computer processing. All forms were retained for a 5-year period and thereafter destroyed. Public disclosure of the patient's identity was prohibited and access to the files was confined to a limited number of state personnel. Prescribing physicians and a group of patients regularly prescribed these drugs challenged the constitutionality of the Schedule II patient-identification requirements. The Supreme Court, however, upheld



the laws, concluding: (1) the patient identification requirement was a reasonable exercise of the State's broad police powers, (2) neither the immediate nor threatened impact of the patient identification requirement on either the reputation or independent of patients sufficed to constitution an investigation of any right or liberty protected by the Fourteenth Amendment, and (3) there was no merit to the prescribing doctors' contention that the law impaired their right to practice medicine free from unwarranted state interference.

In the case of clinical trial information about pregnancy outcomes, the state could reasonably claim an interest in protecting maternal and fetal health. And now that *Roe* has been overturned, there is no countervailing constitutional right to abortion to counteract that state interest. A state also has an interest in maintaining a vast array of vital statistics, including data on pregnancy outcomes, maternal health, and fetal health. Moreover, in the case of clinical trial data, courts may not view pregnancy-related information from clinical trial sponsors as implicating the physician-patient relationship, so those interests may not even come into play as a countervailing interest to the state's interest. Courts generally have not recognized researchers as having a researcher-participant privilege, which might offer similar protection as the doctor-patient privilege.

## CONCLUSION

This report described how the U.S. Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization* may affect clinical research involving pregnant and lactating persons. On the one hand, this report concludes that *Dobbs*, and the state laws and regulations that have transpired or may transpire from that decision, are unlikely to have a significant effect on research involving lactating persons. On the other hand, they are likely to make research involving pregnant persons more difficult, costly, and rife with legal uncertainties and risks.

All stakeholders involved in clinical research must remain abreast of the evolving legal landscape. This report has described some potential considerations and mitigation strategies for sponsors. The most important tool currently at the disposal of trial sponsors is certificates of confidentiality, which should be used and defended rigorously. Importantly, sponsors must remain vigilant and flexible as the reproductive health care landscape continues to change.

## REFERENCES

- Abrams, Z. 2023. Abortion bans cause outsized harm for people of color. *Monitor on Psychology* 54(4).
- Acheson, M., and M. Halaiko. 2023. Data privacy and clinical trials: The complicated intersection of protecting patient data and clinical research. *Nelson Mullins Idea Exchange*, [https://www.nelsonmullins.com/idea\\_exchange/alerts/privacy\\_and\\_data\\_security\\_alert/all/data-privacy-laws-and-clinical-trials-the-complicated-intersection-of-protecting-patient-data-and-clinical-research](https://www.nelsonmullins.com/idea_exchange/alerts/privacy_and_data_security_alert/all/data-privacy-laws-and-clinical-trials-the-complicated-intersection-of-protecting-patient-data-and-clinical-research) (accessed December 29, 2023).
- An act for the suppression of trade in, and circulation of, obscene literature and articles of immoral use*, 1873. 17 Statute 598.
- Alliance for hippocratic medicine v. FDA*, 2023 WL 2825871, (United States District Court, N.D. Texas 2023).
- Balch, B. 2022. Prescribing without data: Doctors advocate for the inclusion of pregnant people in clinical research. *AAMC News*, <https://www.aamc.org/news/prescribing-without-data-doctors-advocate-inclusion-pregnant-people-clinical-research> (accessed May 18, 2023).
- Barsky v. Board of Regents* 347 442 (Supreme Court 1954).
- Branzburg v. Hayes*, 408 665 (Supreme Court 1972).
- CDC (Centers for Disease Control and Prevention). 2022. *What is stillbirth?* <https://www.cdc.gov/ncbddd/stillbirth/facts.html> (accessed June 1, 2023).
- CDC. 2023. *Facts about medicine and pregnancy*. <https://www.cdc.gov/pregnancy/meds/treating-fortwo/facts.html> (accessed June 1, 2023).
- Center for Reproductive Rights. 2023. *Alliance for hippocratic medicine v. FDA*. <https://reproductive-rights.org/case/alliance-for-hippocratic-medicine-v-fda/> (accessed July 28, 2023).
- Civil Liability for Violation or Aiding or Abetting Violation*. (September 1, 2021).
- Consolidated Appropriations Act, 2022*. 117-103.
- CIOMS (Council for International Organizations of Medical Sciences) and WHO (World Health Organization). 2016. International guidelines for health-related research involving humans. <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf> (accessed December 15, 2023).
- Dirks, S. 2022. Criminalization of pregnancy has already been happening to the poor and women of color. *Oregon Public Broadcasting*, (accessed June 1, 2023).
- District of Columbia v. Brooke*, 214 138 (Supreme Court 1909).
- Dobbs v. Jackson Women's Health Organization*, 142 Supreme Court, 2288 (Supreme Court 2022).
- Dugas, C., and V. H. Slane. 2022. *Miscarriage*. Place Published: StatPearls Publishing. <https://www.ncbi.nlm.nih.gov/books/NBK532992/> (accessed June 1, 2023).
- FDA (U.S. Food and Drug Administration). 2011. Elements of informed consent. In 21. Code of Federal Regulations.
- FDA. 1993. *Guidelines for the study and evaluation of gender differences in the clinical evaluation of drugs*.
- FDA. 2000. *Investigational new drug applications: Amendment to clinical hold regulations for products intended for life-threatening diseases and conditions*.
- FDA. 2018. *Pregnant women: Scientific and ethical considerations for inclusion in clinical trials, guidance for industry*. <https://www.fda.gov/media/112195/download> (accessed December 29, 2023).
- FDA. 2019. *Office of women's health*. <https://www.fda.gov/about-fda/office-commissioner/office-womens-health> (accessed May 18, 2023).
- FDA. 2020. *Women's health research*. <https://www.fda.gov/science-research/science-and-research-special-topics/womens-health-research> (accessed May 18, 2023).

- FDA. 2022. *FDA takes steps to further harmonize clinical research regulations with HHS common rule*. <https://www.fda.gov/news-events/fda-voices/fda-takes-steps-further-harmonize-clinical-research-regulations-hhs-common-rule> (accessed May 18, 2023).
- Food and Drug Administration Amendments Act of 2007*. 110-85.
- Galanis, P., I. Vranka, O. Siskou, O. Konstantakopoulou, A. Katsiouroumpa, and D. Kaitelidou. 2022. Uptake of COVID-19 vaccines among pregnant women: A systematic review and meta-analysis. *Vaccines (Basel)* 10(5).
- Griswold v. Connecticut*, 381 479 (U.S. Supreme Court 1965).
- Grunebaum, A., and F. A. Chervenak. 2022. Physician hesitancy to recommend COVID-19 vaccination in pregnancy as a cause of maternal deaths—Robert Brent was prescient. *Birth Defects Res* 115(14):1255–1260. <https://doi.org/10.1002/bdr2.2136>.
- Guttmacher Institute. 2023a. *Abortion reporting requirements*. <https://www.guttmacher.org/state-policy/explore/abortion-reporting-requirements> (accessed June 2, 2023).
- Guttmacher Institute. 2023b. *Interactive map: US abortion policies and access after Roe*. <https://states.guttmacher.org/policies/delaware/abortion-policies> (accessed June 1, 2023).
- Guttmacher Institute. 2023c. *Interactive map: US abortion policies and access after Roe*. <https://states.guttmacher.org/policies/> (accessed July 28, 2023).
- HHS (U.S. Department of Health and Human Services). 1983. Definitions. In 45, CFR 46.
- HHS. 2017. Definitions for purposes of this policy. In 45, CFR 46.
- HHS. 2018. Subpart B—Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research. In 45 CFR 46.
- HHS and FDA. 2020. *Enhancing the diversity of clinical trial populations—Eligibility criteria, enrollment practices, and trial designs, guidance for industry*. <https://www.fda.gov/media/127712/download> (accessed December 29, 2023).
- IRB Advisor. 2003. Consult fathers, too, in research involving fetuses. *IRB Advisor*, <https://www.reliamedia.com/articles/27466-consult-fathers-too-in-research-involving-fetuses> (accessed June 6, 2023).
- Kachikis, A., J. A. Englund, M. Singleton, I. Covelli, A. L. Drake, and L. O. Eckert. 2021. Short-term reactions among pregnant and lactating individuals in the first wave of the COVID-19 vaccine rollout. *JAMA Network Open* 4(8):e2121310-e2121310. <https://doi.org/10.1001/jamanetworkopen.2021.21310>.
- Lamprey, E. 2022. Overcoming barriers to COVID-19 vaccination of pregnant women. *Gynecology and Obstetrics Clinical Medicine* 2(1):29-33.
- Largent, E. A., C. Grady, F. G. Miller, and A. Wertheimer. 2012. Money, coercion, and undue inducement: Attitudes about payments to research participants. *IRB* 34(1):1-8.
- Liu, K. A., and N. A. Mager. 2016. Women's involvement in clinical trials: Historical perspective and future implications. *Pharm Pract (Granada)* 14(1):708.
- General Assembly of Georgia. *Living Infants Fairness and Equality (LIFE) Act*. HB 481. 2019-2020 (2019).
- Manninen, B. A. 2023. A critical analysis of *Dobbs v. Jackson Women's Health Organization* and the consequences of fetal personhood. *Cambridge Quarterly of Healthcare Ethics* 1-11.
- Menkel-Meadow, C. 1998. Taking the mass out of mass torts: Reflections of a dalkon shield arbitrator on alternative dispute resolution, judging, neutrality, gender, and process. *Loyola Los Angeles Law Review* 31.
- Mittal, K., M. Sheen, M. Wheelden, R. Faramand, E. Teplinsky, and M. Joshi. 2023. *Dobbs v Jackson—Rewriting women's autonomy in cancer care*. *JCO Oncology Practice* 19(4):157-159.
- NASEM (National Academies of Sciences, Engineering, and Medicine). 1994. In *Women and health research: Ethical and legal issues of including women in clinical studies: Volume I*, edited by A. C. Mastroianni, R. Faden, and D. Federman. Washington (DC): National Academies Press.
- New York Times. 2023. Tracking the states where abortion is now banned. *N.Y. Times*. <https://www.nytimes.com/interactive/2022/us/abortion-laws-roe-v-wade.html> (accessed June 1, 2023).

- NIH (National Institutes of Health). 2022. *Budget*. <https://www.nih.gov/about-nih/what-we-do/budget> (accessed June 1, 2023).
- Office for Human Research Protections. 2022. *Federal policy for the protection of human subjects ("common rule")*. <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html> (accessed May 11, 2023).
- Osuebi, O. 2023. Maternal-fetal health in African American women. *Speaking of Health*, <https://www.mayoclinichealthsystem.org/hometown-health/speaking-of-health/maternal-fetal-health> (accessed July 28, 2023).
- Parekh, A., E. O. Fadiran, K. Uhl, and D. C. Throckmorton. 2011. Adverse effects in women: Implications for drug development and regulatory policies. *Expert Rev Clin Pharmacol* 4(4):453-466.
- Planned Parenthood of Central Missouri v. Danforth* 428 52 (Supreme Court 1976).
- Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 United States, 833 (Supreme Court 1992).
- Planned Parenthood of Southern Arizona v. Lawall*, 307 783 (9th Circuit 2002).
- Protection of Human Subjects in Medical Experimentation Act*.
- Ram, N., J. L. Contreras, L. M. Beskow, and L. E. Wolf. 2023 (unpublished). *Constitutional confidentiality*.
- Roe v. Wade*, 410 United States (Supreme Court 1973).
- Sanderson, S. C., K. B. Brothers, N. D. Mercaldo, E. W. Clayton, A. H. M. Antommara, S. A. Aufox, M. H. Brilliant, D. Campos, D. S. Carrell, J. Connolly, P. Conway, S. M. Fullerton, N. A. Garrison, C. R. Horowitz, G. P. Jarvik, D. Kaufman, T. E. Kitchner, R. Li, E. J. Ludman, C. A. McCarty, J. B. McCormick, V. D. McManus, M. F. Myers, A. Scrol, J. L. Williams, M. J. Shrubsole, J. S. Schildcrout, M. E. Smith, and I. A. Holm. 2017. Public attitudes toward consent and data sharing in biobank research: A large multi-site experimental survey in the US. *Am J Hum Genet* 100(3):414-427.
- Schroeder, C. H. 2022. Application of the Comstock Act to the mailing of prescription drugs that can be used for abortions, 12/23/2022.
- Skerret, P. 2022. First opinion podcast. In *How the Dobbs decision could affect how and where clinical trials are conducted*: STAT.
- Sneed, T. 2023. The 150-year-old chastity law that may be the next big fight over abortion. CNN, <https://www.cnn.com/2023/04/28/politics/comstock-act-abortion-ban-legal-fight/index.html> (accessed July 29, 2023).
- Stockard, S. 2022. AG opinion: Disposal of human embryos not transferred to uterus doesn't violate law. *Tennessee Lookout*, <https://tennesseelookout.com/2022/11/01/ag-opinion-disposal-of-human-embryos-not-transferred-to-uterus-doesnt-violate-law/> (accessed May 18, 2023).
- Sugarman, J., D. M. Wenner, A. Rid, L. M. Henry, F. Luna, R. Klitzman, K. M. MacQueen, S. Rennie, J. A. Singh, and L. O. Gostin. 2023. Ethical research when abortion access is legally restricted. *Science* 380(6651):1224-1226.
- TCU (The Catholic University of America). 2020. *Use of biological materials in research policy*. <https://policies.catholic.edu/use-of-biological-materials-in-research-policy.html> (accessed May 24, 2023).
- Terkel v. CDC*, 521 662 (Eastern District of Texas 2021).
- U.S. Census Bureau. 2021. *Race and ethnicity in the United States: 2010 Census and 2020 Census*. <https://www.census.gov/library/visualizations/interactive/race-and-ethnicity-in-the-united-state-2010-and-2020-census.html> (accessed June 1, 2023).
- Waggoner, M. R., and A. D. Lyerly. 2022. Another consequence of overturning *Roe*: Imperiling progress on clinical research in pregnancy. *Am J Bioeth* 22(8):59-62.
- Washington v. FDA*, 2023 WL 2825861 (E.D. Washington 2023).
- Watanabe, A., J. Yasuhara, M. Iwagami, Y. Miyamoto, Y. Yamada, Y. Suzuki, H. Takagi, and T. Kuno. 2022. Peripartum outcomes associated with COVID-19 vaccination during pregnancy: A systematic review and meta-analysis. *JAMA Pediatrics* 176(11):1098-1106.

- Weigel, G., L. Sobel, and A. Salganicoff. 2019. *Understanding pregnancy loss in the context of abortion restrictions and fetal harm laws*. Kaiser Family Foundation.
- Whalen v. Roe*, 589 (Supreme Court 1977).
- Whelan, A. M. 2021. Unequal representation: Women in clinical research. *Cornell Law Review Online* 106(3).
- Whelan, A. M. 2023. Aggravating inequalities: State regulation of abortion and contraception. *Harvard Journal of Law & Gender* 46(1):131-204.