Life Sciences Health Industry

Health Care

Unanswered Questions after Dobbs Part III: Fertility

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Unanswered Questions Part III: Fertility Treatments and Reproductive Health in a Post-Dobbs World

The Supreme Court's forthcoming opinion in *Dobbs v. Jackson Women's Health Organization* – in which the Court, according to a leaked draft, plans to overturn *Roe v. Wade* and *Planned Parenthood of Southeast Pennsylvania v. Casey* – raises significant issues and potential unintended consequences in the fertility space for providers, pharmacies, practitioners, laboratories, genetic counselors, ambulatory surgery centers (ASCs), storage facilities, transportation companies, and other participants in the health care and adjacent industries. Of particular relevance to the impact of *Dobbs* on fertility treatments are so-called "personhood" laws, by which states may classify fertilized eggs, zygotes, embryos, and/or fetuses as "persons," thereby granting them, among other things, the right to life from the moment of conception.

"Personhood" laws have been introduced into Congress and state legislatures hundreds of times since *Roe* was decided in 1973 and have begun to re-emerge. In the past year alone, at least six states – Iowa, Oklahoma, South Carolina, Vermont, West Virginia, and Louisiana – have introduced "personhood" laws, with Louisiana's law approved by committee and Oklahoma's law passing in one chamber. Many other states are considering "personhood" legislation, which has the potential to transform fertility treatment as we know it – whether intended or not.

Currently, a number of different fertility treatments are available, ranging from limited interventions, such as the use of fertility drugs to induce ovulation, to more invasive procedures that assist in conception, such as intrauterine insemination (IUI), invitro fertilization (IVF), and surrogacy. These avenues for treatment can involve a number of different interventions and steps, including the prescription and dispensation of specialized hormonal medication, surgical procedures, laboratory testing, creation of embryos, and storage and shipping of eggs, sperm, and embryos.

In our third installment of "Unanswered Questions," we consider the implications and potential unintended consequences of the anticipated *Dobbs* opinion and, specifically, the possible proliferation of "personhood" laws on people and companies operating in the fertility space, and on the spectrum of available fertility treatments.

Unanswered Questions Post-Dobbs

Applicability of Personhood Laws to Embryos

- If embryos are persons, is there an affirmative obligation to transfer every embryo created? Must they be transferred at a time that optimizes their potential for implantation and viability?
- Would "personhood" laws be implicated in situations where an embryo fails to develop? For example, could the law be used to hold providers or laboratories liable for, say, neglect if the embryo does not survive?
- Will these laws provide any exceptions or considerations for embryos that are determined to be unviable or unsuitable for safe/successful transfer?
- What are the implications of discarding or destroying otherwise viable embryos based on genetic testing results showing material risk of illness or disability to the fetus? What actors could be liable (e.g., genetic counselors, laboratories, patients, providers)?

- Are unused, viable embryos required to be stored indefinitely? Who is obligated to pay for the storage and for how long?
- What if embryos are accidentally destroyed (e.g., freezer malfunction, transportation accident, etc.)? Could these laws be used to hold medical storage, transportation, and shipping providers liable?
- · What are the potential implications under these laws for failed transfers?

Conflicts of Laws

- Laboratory testing, including genetic screening, is not always performed in the state where the patient resides, and genetic counselors may provide services and guidance regarding the impact of screening results via telehealth. Which state's laws govern the genetic counselor's ability to advise regarding recommended actions following genetic screening, particularly where the recommendation involves discarding or not transferring the embryo?
- · Can states with "personhood" laws enforce their laws extraterritorially?
 - For example, if embryos are created in a state with a personhood law, but stored/maintained in a state without such a law, would destruction of the embryos in the state where they are stored implicate the other state's personhood laws?

Conscientious and Religious Objectors

• Will *Dobbs* change the rights of providers and other personnel involved in the IVF process to refuse to participate in the destruction of embryos or other aspects of IVF based on religious objections?

Embryo Bank Storage Licensing and Accreditation: As discussed above, there are a number of questions regarding whether a "personhood" law could extend to embryos in storage.

- With these potential changes, will more states create state licensing standards for embryo storage and transportation?
- Will these standards have heightened requirements for handling and storing embryos if state law considers them a person?
- Will the entire embryo bank storage and transportation industry accreditation standards change everywhere if only a few states implement these "personhood" laws?

Non-Personhood Considerations

- Fertility-Related Medication: Fertility treatments involve the use of various hormonal medications, including, in some cases, oral contraceptives to control the patient's ovulation cycle and other hormones that might require dispensation by a specialty pharmacy. How will the use of these medications be impacted by the *Dobbs* decision and state laws implemented in its wake?
- Risk Calculation: What impact will the Dobbs decision have on patients' risk calculation in deciding to proceed with fertility treatments?
 - For example, fertility treatments can create risks that make carrying the pregnancy to term undesirable, unsafe, or unviable (e.g., multiple implantations/births, ectopic pregnancies, and birth defects) and patients may be left without adequate means of managing these risks post-*Dobbs*.
 - Moreover, providers may be limited in their ability to counsel patients, particularly if one of the recommendations may include traveling out of state to obtain an abortion.
 - Will providers have a heightened responsibility to make patients fully aware of their legal as well as medical risks?
- Privacy Issues: Fertility treatment requires extensive monitoring and the need to capture detailed health information daily, which is often aided by helpful third party applications. How this data is collected and maintained may implicate health privacy laws. Please see our recent alert, "<u>California AG Urges Health Apps to Safeguard User's Reproductive Health Information</u>," for more information on these issues.

Please reach out to a member of the <u>Reed Smith Reproductive Health Working Group</u> or the Reed Smith attorneys with whom you regularly work for more information or guidance on these or related issues. Reed Smith will continue to monitor developments as we anticipate the release of the *Dobbs* opinion.

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