UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

WHOLE WOMAN'S HEALTH ALLIANCE, *et al.*,	)	
Plaintiffs,	)	
v.	)	Case No. 1:18-cv-01904-SEB-MJD
CURTIS T. HILL, JR., Attorney General of the State of Indiana, in his official capacity, *et al.*,	)	
Defendants.	)	

DEFENDANTS' MEMORANDUM
IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT

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Defendants Curtis T. Hill, Jr., Attorney General of Indiana; Kristina Box, M.D., Commissioner of the Indiana State Department of Health; John Strobel, M.D., President of the Medical Licensing Board of Indiana; and Kenneth P. Cotter, St. Joseph County Prosecutor (the State) respectfully submit this memorandum supporting their Motion for Summary Judgment.

INTRODUCTION

Plaintiffs—Whole Woman's Health Alliance, All-Options, Inc., and Jeffrey Glazer, M.D. (Whole Woman's Health or Plaintiffs)—are abortion providers and intermediaries who challenge Indiana laws designed to protect women seeking abortion; unsurprisingly, there are not among the plaintiffs any pregnant women seeking to invalidate such safeguards. Plaintiffs attack nearly every Indiana abortion statute and regulation—from licensing to physical examination—including some that do not even affect them. And while Plaintiffs invoke the rights of patients, their interests as abortion providers diverge from pregnant women, which makes their third-party standing claims highly suspect—an issue likely to be resolved in *June Medical Services, LLC v. Gee*, No. 18-1323, 2019 WL 4889929 (U.S. Oct. 4, 2019). Regardless, Plaintiffs' claims fail as a matter of law. Their broad theory is that, under *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016), the benefits and burdens of all abortion restrictions are subject to judicial factfinding and rebalancing. But as already confirmed in this very case, controlling precedents upholding abortion restrictions remain good law, which negates most claims. And while *Hellerstedt* questioned the benefits of two new Texas laws threatening extreme disruption, it did not negate the usual rule, embraced in *Gonzales v. Carhart*, 550 U.S. 124, 163 (2007), that courts defer to legislative judgments on reasonably disputed questions of medical science. Accordingly, and because two of Plaintiffs' critical experts should be excluded on key points, summary judgment is appropriate against *all* claims.

STATEMENT OF MATERIAL FACTS NOT IN DISPUTE

I. Regulation of Abortion Providers

A. Risks and complications of surgical and medication abortions

Surgical abortions carry risks such as "bleeding, infection, or injury to the cervix, vagina, or uterus." Exhibit 1, Expert Report of Christopher Stroud, M.D. ¶ 8; *see also* Exhibit 2, Expert Report of Nancy Goodwine-Wozniak, M.D. ¶ 64 (listing "anesthesia complications, hemorrhage, blood clot, uterine perforation, [and] vessel injury" as possible complications of surgical abortion). These complications "could lead to serious long-term ramifications such as cervical incompetence and/or the inability to achieve pregnancy in the future." Ex. 1 ¶ 8. A "[f]orced dilation of an unripe cervix," for example, can weaken the cervix and lead to cervical incompetence, where the cervix dilates early in the woman's next pregnancy. Exhibit 3, Expert Report of Byron C. Calhoun, M.D. ¶ 50. This "predisposes a woman to premature rupture of membranes, intrauterine infections, and premature delivery." *Id.*

Medication abortions also incur significant risks. According to Dr. Nancy Goodwine-Wozniak, "[m]ifepristone use in ectopic pregnancy has been associated with sepsis and cases of maternal death." Ex. 2 ¶ 55. Dr. Donna Harrison testifies that medication abortion is also contraindicated for women with an "undiagnosed adnexal mass," "chronic adrenal failure," "concurrent long-term corticosteroid therapy," "history of allergy to mifepristone, misoprostol, or other prostaglandins," "hemorrhagic disorders or concurring anticoagulant therapy," "inherited porphyria," or an "intrauterine device." Exhibit 4, Expert Report of Donna Harrison, M.D. ¶ 25. Detection of these disorders requires "a physical examination by a physician capable of diagnosing" possible contraindications. *Id.* ¶ 26. And a physician must evaluate whether the patient is "capable of withstanding the emotional and physical stresses she will have to endure while passing the fetus and its placenta, and the

considerable vaginal bleeding that will follow," and whether a patient has "the necessary resources to help her seek emergency care" in case of a hemorrhage or "the necessary support to cope with the isolation and potential depression that may follow the termination of her pregnancy." Ex. 1 ¶ 39.

The risks associated with medication abortions can be mitigated if physicians performing them use only FDA-approved abortion-inducing drugs and ensure the drugs are used only as specified by the FDA. Using regimens "other than those approved by the FDA . . . would risk the health and safety of women in Indiana." Ex. 4 ¶ 23. Indeed, "[t]he FDA considers the off-label use of Mifeprex prohibited due to serious concerns about safety." *Id.* ¶ 23. The risk of Mifeprex complications increases with gestational age: "Large studies have documented increasing failure and complication rates at gestational ages over 49 days" such as the "rate of infection and the rate of failure requiring surgical intervention." *Id.* ¶ 16. The Mifeprex FDA label acknowledges that the failure rate more than triples when comparing successful abortions at 49 days' gestation to 63 days' gestation: "by 63 days gestation you have nearly one out of 13 women fail their Mifeprex abortion and require surgical completion" and there is a "10-fold increase in ongoing pregnancies when comparing Mifeprex abortions at 49 days with Mifeprex abortions at 63 days." *Id.* ¶ 18. The FDA label also warns that Mifeprex use can also produce bleeding and fatal infections. *Id.* ¶ 20.

Even when medication abortion works properly, many women experience far worse pain and bleeding than expected. *See, e.g.*, Exhibit 5, Declaration of Taylor Darnell in Support of Defendants' Motion for Summary Judgment ¶ 8 ("Once I took the second pill, I got even sicker. It was like a heavy period, but with lots of pain and constant diarrhea. "); ECF No. 96 ¶ 10 ("There was so much pain and blood that I thought I might die."); ECF No. 96-1 ¶ 11 ("It hurt so much that I was screaming in pain."); ECF No. 96-2 ¶ 13 ("I was stunned that it hurt so bad. It was nothing like they had told me."); ECF No. 97 ¶ 8 ("I bled so much that the pill I had inserted came back out. I

had to re-insert it, which was difficult to do because I was in so much pain."); ECF No. 97-1 ¶ 9 ("I lost so much blood that my friend wanted to take me to the hospital.").

Some women even see their baby when they pass the fetus, causing emotional pain that often remains with them for years after. Ex. 5 ¶ 9 ("The thing I remember most is when I passed the baby. . . . I sat on the bathroom floor and cried. Then I had to flush my baby down the toilet because that was what the clinic had told me to do."); ECF No. 96 ¶ 11 ("He looked like a little gummy bear. I sat and held him and cried."); ECF No. 96-2 ¶¶ 14–15 ("I had given birth to what looked like a fully-formed, intact 14-week old fetus covered in blood. . . . I sat on the floor and held him and cried.").

Women often experience physical and emotional pain accompanying medication abortion while home alone. Ex. 5 ¶ 8 ("I was home alone at the time. I asked the father of my baby to come over, but he told me he didn't feel like stopping by."); ECF No. 96-1 ¶ 11 ("My boyfriend asked a friend to pick him up because he couldn't handle my screaming."). It should therefore be uncontroversial to observe that abortion is a serious choice "that not only carries medical risks, but has implications for a patient's emotions, mental well-being, and personal relationships." Ex. 2 ¶ 62. The decision to obtain an abortion "is by nature difficult and highly stressful for a significant percentage of women." Exhibit 6, Expert Report of Priscilla K. Coleman, Ph.D. ¶¶ 54, 193.

Substantial, reliable scientific evidence backs up these common-sense observations. Dr. Priscilla Coleman, a developmental psychologist and professor at Bowling Green State University whose published work focuses on the psychology of abortion, testifies that "a wealth of data has revealed that the average woman who chooses to terminate a pregnancy is more likely to experience various forms of mental illness (e.g., depression, anxiety, substance abuse, suicidal thoughts and behaviors) compared to the average woman who chooses to continue a pregnancy." *Id.* ¶ 13. Dr.

Coleman is the lead author of a landmark 2011 meta-analysis of research on mental-health outcomes of abortion, a study that pooled 22 published studies with over 800,000 participants and over 161,000 women who underwent abortions—the largest study of its kind. *Id.* ¶¶ 108, 109. Dr. Coleman's meta-analysis showed that women with a history of abortion experienced an 81% increased risk for various mental health problems compared with women who had not had an abortion. *Id.* ¶ 109. It also documented a 55% increased risk of mental health problems associated with abortion compared with women who took an unplanned pregnancy to term. *Id.* Dr. Coleman also reports that a major national poll revealed that "56% of women who had an abortion experienced a sense of guilt." *Id.* ¶ 70. In addition, evidence shows that women who have abortions also deal with feelings of loss, shame and phobic responses to infants—effects that can last over a decade. *Id.* ¶ 72. Evidence also shows that "abortion initiates powerful negative feelings and alienation from others." *Id.* ¶ 104. Compared to women who have never had an abortion, women who have obtained an abortion have a 155% increased risk of suicidal behavior. *Id.* ¶ 110.

The stories of several women support these findings. Serena Dyksen struggled with substance abuse from "the trauma from both the sexual abuse [she] experienced as a child and the abortion." Exhibit 21, Declaration of Serena Dyksen in Support of Defendants' Motion for Summary Judgment ¶ 19. Taylor Darnell had thoughts of suicide. Ex. 5 ¶ 12. Elizabeth Gillette "was diagnosed with post-traumatic stress disorder," which "[a] counselor helped [her] trace . . . to the abortion." ECF No. 96 ¶ 13. Leslie Wolbert had "symptoms of post-traumatic stress disorder." ECF No. 96-1 ¶ 16. Tammi Morris "endured eight years of alcoholism, suicidal thoughts, rage-filled outbursts, and debilitating depression." ECF No. 96-2 ¶ 18. Christen Castor was diagnosed with depression. ECF No. 97 ¶ 13. Kristen Rinehart also experienced depression. ECF No. 97-1 ¶ 12.

Dr. Aaron Kheriaty, a board-certified psychiatrist who has evaluated and treated thousands of women who have had abortions and many women who have carried unplanned pregnancies to term, recounts experiences of women he has treated for mental health problems following abortion. Exhibit 14, Expert Report of Aaron Kheriaty, M.D. ¶¶ 11–17. In his clinical experience, "a significant number of women are psychologically harmed by abortion in ways that we can measure and assess," and "many more women may be affected by abortion in ways that will never be captured in studies, because their suffering or symptoms may fall short of the threshold necessary for diagnosis of a specific psychiatric disorder, or because they may never seek clinic attention." *Id.* ¶ 16. He also cites evidence that women diagnosed with fatal prenatal anomalies who carry their pregnancies to term have better psychological outcomes than such women who abort. *Id.* ¶¶ 95–98.

Fortunately for women who may suffer psychological harm following an abortion absent appropriate information and counseling, Dr. Coleman testifies that "[w]hen women are provided adequate information on alternatives to abortion and sufficient time to arrive at well-considered decisions regarding pregnancy resolution, the likelihood of suffering psychologically from decisions to abort is reduced." Ex. 6 ¶ 102.

B. The importance of licensed physicians for all abortions

Having a physician perform the abortion allows the physician to "make decisions and correct problems or complications without having to call other MDs in because they have the background, experience, and training an advance practice provider does not have." Ex. 2 ¶ 64. As Dr. Glazer testified, physical examinations by a physician are often necessary in response to patient complaints or to ensure that there will be no complications during the abortion procedure for a given patient. Exhibit 7, Excerpts from Deposition of Jeffrey D. Glazer, M.D. 56:20–58:25. Furthermore,

the American Board of Medical Specialties authorized establishing fellowship training on "an additional subspecialty of obstetrics/gynecology focusing on abortion practice," which "confirms that within the medical community, surgical abortion procedures are regarded as significant enough to be the subject of specialized training for doctors." Ex. 2 ¶ 68. As Whole Woman's Health's expert Dr. Grossman conceded, considerable evidence shows that non-doctors performing abortions have a higher rate of complications and failure. Exhibit 8, Excerpts from Deposition of Daniel Grossman, M.D. 115:16–23, 122:16–123:4, 132:22–133:7.

Medication abortions do not reduce the need for a physician. Dr. Nancy Goodwine-Wozniak testified that "competent and ethical abortion providers are personally responsible for ensuring that they are prescribing medication abortion . . . within appropriate gestational age limits." Ex. 2 ¶ 56. Simply interviewing the woman about the date of her last menstrual period alone is not sufficient, because "irregular menstrual cycles . . . can lead to a more advanced gestational age" than expected. *Id.* ¶ 53. For this reason, the standard of care requires that physicians perform a physical exam, in conjunction with an ultrasound, to determine the gestational age of the fetus. *Id.* ¶ *54*; *see also* Ex. 3 ¶ 145. A successful medication abortion "leads to the expulsion of the fetus and all products of conception from the uterus when it is successful." Ex. 1 ¶ 37. "Special training" is necessary "in the event of complications," such as managing a hemorrhage or performing a surgical abortion "if the medication does not completely expel the fetus from the uterus, which happens commonly." *Id.*

Furthermore, meeting the patient in-person helps the physician confirm the patient's medical history and rule out ectopic pregnancy and other pregnancy complications that might make a medication abortion unsafe. "[W]ithout a physical, a history could lead to an incomplete—and often misleading—understanding of a patient's individual medical needs." Ex. 2 ¶ 52. According to Dr. Goodwine-Wozniak, "[m]ifepristone use in ectopic pregnancy has been associated with sepsis and

cases of maternal death. *Id.* ¶ 55. Dr. Donna Harrison testified that medication abortion is also contraindicated for women with an "undiagnosed adnexal mass," "chronic adrenal failure," "concurrent long-term corticosteroid therapy," "history of allergy to mifepristone, misoprostol, or other prostaglandins," "hemorrhagic disorders or concurring anticoagulant therapy," "inherited porphyria," or an "intrauterine device." Ex. 4 ¶ 25. Detection of these disorders requires "a physical examination by a physician capable of diagnosing" possible contraindications. *Id.* ¶ 26.

Moreover, requiring a physician to meet with the patient in-person facilitates informed consent. According to Dr. Christopher Stroud, "medical abortion involves decision-making that has unusually grave consequences." Ex. 1 ¶ 47. Dr. Byron C. Calhoun testified that "in-person interactions are superior to remote interactions for decisions of that weight" because they "lead[] to better eye contact, greater ability to read body language, and overall development of a real person-to-person relationship between doctor and patient." Ex. 3 ¶ 143. Dr. Priscilla K. Coleman testified that in-person counseling is "an essential component of the informed consent process." Ex. 6 ¶ 191. And the in-person counseling required by Indiana law is "based on an understanding of the highly personal and complex nature of abortion decisions." *Id.* ¶ 193.

Finally, the in-person examination requirements prevent the diversion of abortion drugs and other drugs prescribed in connection with the abortion. "When a doctor prescribes a medication remotely, there is always a risk that the drug could be abused and diverted to another patient." Ex. 2 ¶ 57. For this reason, Indiana prohibits using telemedicine to prescribe particularly dangerous drugs, such as opioids and abortion-inducing drugs. Ind. Code § 25-1-9.5-8(a)(3)–(4). Both prohibitions are relevant here. "In a medication abortion, the mifepristone and misoprostol could be diverted to another individual for whom it is not indicated." Ex. 2 ¶ 57. Dr. Cowett testifies that she accompanies her medication abortions with a prescription for tramadol, "to fill as needed." Exhibit

43, Rule 26(a)(2)(B) Expert Report of Allison A. Cowett, M.D., M.P.H. ¶ 27. Tramadol is "an opiate that could be resold and abused." Ex. 2 ¶ 57. Says Dr. Calhoun, "in the case of telemedicine it is not possible for the doctor to be sure who takes the prescribed drugs." Ex. 3 ¶ 146.

C. The need for abortion physicians to have hospital admitting privileges

Abortion safety is bolstered if the physician performing the procedure has admitting privileges at a hospital within a reasonable distance from the clinic. Such privileges allow the physician to provide hands-on and in-person care in the event of an emergency resulting from an abortion procedure, and "[i]deally, a doctor would have admitting privileges in place to allow him/her to continue caring for the patient in a seamless manner, minimizing delays of care caused by confusion in the admission process." Ex. 1 ¶ 18.

Dr. Stroud's opinion is consistent with the American College of Surgeons' "Core Principle #4" for patient safety in office-based surgery, which was joined by the American College of Obstetricians and Gynecologists and states: "Physicians performing office-based surgery must have admitting privileges at a nearby hospital, or a transfer agreement with another physician who has admitting privileges at a nearby hospital, or maintain an emergency transfer agreement with a nearby hospital." Exhibit 10, American College of Surgeons, *Patient Safety Principles for Office-Based Surgery* (2003). And a report by the Federation of State Medical Boards concludes that providers should have "written protocols in place for the timely and safe transfer of patients to a pre-specified alternate care facility within a reasonable proximity when extended or emergency services are needed." Exhibit 11, Federation of State Medical Boards, *Report of the Special Committee on Outpatient (Office-Based) Surgery* (2002). These protocols "must include a written transfer agreement with a reasonably convenient hospital(s) or all physicians performing surgery should have admitting privileges at such facility." *Id.*

The physician who performs an abortion procedure has a "much more intimate knowledge of the subtleties of what they've done and what they suspect," and "it's always better that the person who did the procedure is there to at least help take care of the patient." Exhibit 12, Excerpts from Deposition of Nancy Goodwine-Wozniak, M.D. 128:8–10; 128:24–129:1. "The more personal knowledge you have of a patient, the more precise care you can give, the more you're able to basically head off further complications." *Id.* at 125:10–13. Admitting privileges are a critical component of appropriate patient care: To ensure continuity of care after a surgical procedure, "you'd want to have the same … physician doing that or the same person with the same level of care doing that." Exhibit 13, Excerpts from Deposition of Byron Craig Calhoun, M.D. 118:13–15. "[M]ere communication between the clinic and the emergency room is *not* good enough." Ex. 3 ¶ 106. Admitting privileges also "protect[] patients by requiring a peer-review process to maintain competency in the care of patients, particularly those undergoing surgical procedures." *Id.* ¶ 98. Requiring a physician to maintain admitting privileges ensures that they are certified, reviewed for their standard of care, and have access to emergency assistance in the result of complications. *Id.*

D. The need for physicians to report abortions

Abortion complications, including mortality, are likely to be seriously underreported. "[S]tatistics on maternal mortality do not capture all abortion-related deaths" because "the total number of legal abortions in the U.S., and their resulting morbidity and mortality, is unknown." Ex. 3 ¶ 18. The lack of data results from the inconsistency of state-level reporting and the difficulty of connecting abortion-related deaths to the abortion. *Id.* ¶¶ 19–20. Indiana therefore requires reports for each abortion that include basic demographic information along with location of the abortion, identity of the physician, and procedure used, in addition to the patient's maternal history and date of last menses, the age and gender of the fetus, and whether the woman was seeking an abortion as a result of being abused, coerced, harassed, or trafficked. Ind. Code § 16-34-2-5. Additionally, in

cases where the patient was under the age of sixteen years old, the report must state when notice of the minor's abortion was given to the Department of Child Services.

These reporting requirements serve the State's compelling interests in fetal life and women's health and safety. They further the State's interest in fetal life and women's health through the "compilation of relevant maternal life and health factors and data," and by assuring that abortions in Indiana are performed in accordance with the law. Ind. Code § 16-34-2-5(a). "[G]ood epidemiological practice calls for good information regarding abortion demography and practice…" which can be used for many purposes, such as identifying "public health concerns, such as a trend of complications or deaths associated with a particular clinic, or law enforcement issues, such as victims of sex abuse." Ex. 3 ¶ 134. [C]omprehensive data collection is the foundation of good epidemiological study…" and data collection for abortion is woefully lacking in the U.S., which "has significant implications for the healthcare of women." *Id.* ¶ 136.

According to Dr. Christopher Stroud, Indiana's reporting requirements "are reasonable, serve to protect the public health, and are not excessively burdensome for abortion providers." Ex. 1 ¶ 41. In this day and age, "doctors practice medicine in a culture of data and reporting." *Id.* ¶ 42. In his practice, Dr. Stroud is responsible for submitting various kinds of reports to various different authorities: For example, he is responsible for regularly reporting information on sexually acquired infections to the county health department, suspected child abuse to the appropriate agency, every birth to the Indiana State Department of Health including detailed data for the birth certificate, reports on postoperative wound infections, and breast feeding continuation rates. *Id.* He must also report information about patients and procedures to different insurance companies, including Medicaid and Medicare. *Id.* While all this reporting takes time, "physicians understand that it serves various economic and public-health purposes" and that it is part of their professional duty to pursue

quality and safety. *Id.* ¶ 43. Dr. Nancy Goodwine-Wozniak, an OB/GYN who practices at St. Vincent Hospital in Anderson and serves as Department Chair and member of the Medical Ethics board, believes the reporting requirements are reasonable, as they "generate information about medical services, the population served, and potential public health problems." Ex. 2 ¶ 50.

E. The importance of hospitals and ASCs for late-term abortions

Second-trimester abortions are generally accomplished through "dilation & evacuation (D&E), a surgical procedure that uses instruments to dismember a fetus and remove it from the uterus, together with other products of conception." Ex. 2 ¶ 36. The "[u]se of instruments in a D&E introduces additional risks of complications" including uterine perforation, cervical damage, and pain for the patient. *Id.* ¶ 37. Dr. Goodwine-Wozniak, for those reasons, recommends that D&Es "be done [in] a hospital setting or, at the very least, in an ASC." *Id.* ¶ 38. Similarly, Dr. Stroud testifies that "the standard of care requires suction D&C following a pregnancy loss to be performed in a surgery center or hospital." Ex. 1 ¶ 10. Late term abortions in particular require an increased amount of anesthesia to complete the D&C, so a hospital or ASC setting, and the equipment available, is necessary for both the procedure and anesthesia. Exhibit 28, Excerpts from Deposition of Christopher B. Stroud, M.D. 65:5–25. "Most patients undergoing a D&C will require general anesthesia, as without anesthesia these procedures can be extremely uncomfortable." Ex. 2 ¶ 28.

The risk of major complications rises with gestational age, "increasing from about 2 per 1,000 procedures for abortions performed at 7 to 8 weeks' gestation, to 15 per 1,000 after 20 weeks." Exhibit 32, Rule 26(a)(2)(B) Expert Report of James Studnicki, M.P.H., M.B.A., Sc.D. ¶ 49. For abortion mortality rates, the "exponential nature of the risk steepens sharply after 14 weeks, the beginning of the second trimester," from "0.3 deaths per 100,000 procedures performed

at 8 weeks of gestation or less to 6.7 deaths per 100,000 procedures performed at 18 weeks of gestation or greater." *Id.*

F. Abortion clinic licensing

The American College of Obstetricians and Gynecologists sets forth specific requirements that abortion facilities should meet in order to protect the health and safety of pregnant women. *See* Exhibit 15, American College of Obstetricians & Gynecologists, *Report of the Presidential Task Force on Patient Safety in the Office Setting* (2010). The clinic must comply with local building codes and fire codes, as well as rules adopted by the Occupational Safety and Health Administration, the state board of pharmacy, and the Drug Enforcement Administration. *Id.* at 4. It should train and enable personnel to respond quickly to emergency situations and should provide a designated recovery area and space for the treatment of possible complications with resuscitation equipment, including a defibrillator, emergency medication, and an advanced cardiac life-support-certified physician. *Id.* at 4, 6. Finally, the clinic must provide for sterility. *Id.* at 7.

Indiana recognizes the need to ensure patient safety through a licensing process that allows the Indiana State Department of Health to conduct surveys on licensed abortion clinics. ISDH sends two and sometimes three trained surveyors to inspections of abortion clinics. Exhibit 16, Excerpts from Deposition of Matthew Wallace Foster 48:13–17. Abortion clinics are the only facilities that are given advance notice of the ISDH's routine surveys. *Id.* at 45:22–46:1. During a survey by the ISDH a nurse will review medical records, check for adherence to medication protocols, and equipment sterilization and a medical surveyor will check for adherence to policies and safety—such as following equipment protocols. *Id.* at 48:18–49:10. The surveyors follow a packet of questions which are updated each time a law is passed or enjoined. *Id.* at 49:18–50:12. A benefit of the ISDH inspections is that there is a better compliance rate among abortion clinics with fewer deficiencies

cited as a whole: with more frequent inspections there have been "fewer medically oriented citations or deficiencies." *Id.* at 51:1–14. The purpose of licensing is to give ISDH the ability to "deal with problems, to preempt problems, and also be perhaps more timely in dealing with complaints or issues that arise in the course of performing business." Exhibit 17, Excerpts from 30(b)(6) Deposition of Matthew Wallace Foster 102:23–103:3. Licensing also allows the State to monitor the abortion clinics in order to protect the public by affording ISDH the ability to take preemptive steps and get "an advance look at possible problems." *Id.* at 103:4–12.

The importance of limiting abortions to safe, licensed facilities is highlighted by the problems caused by the last abortion clinic in South Bend, run by Ulrich Klopfer. Klopfer's clinic violated many state standards and reporting laws, which resulted in an indefinite suspension of his medical license and criminal charges in multiple counties. ECF No. 93 at 8–17. These violations included the failure to report abortions performed on two 13 year old girls, and the failure to report a 10-year old abortion patient even though her parents told Klopfer that she was pregnant from rape by a family member. *Id.* at 12. These serious violations were discovered through complaint inspections conducted by the State. *Id.* at 8–9. And just this fall, the remains of 2,411 aborted fetuses were discovered in plastic bags and boxes in Klopfer's garage and the trunk of his Mercedes-Benz. Exhibit 18, Chris Sikich, *More Fetal Remains Found in Mercedes-Benz Owned by Indiana Abortion Doctor*, Indianapolis Star (Oct. 10, 2019); Exhibit 19, Lincoln Wright, *Pro-Choice and Anti-Abortion Advocates Express Shock at the Discovery of Fetal Remains at Dr. Ulrich "George" Klopfer's Home*, South Bend Tribune (Sept. 15, 2019). It is believed that these aborted fetuses were from abortions that Klopfer performed between 2000 and 2002 in several different clinics in Indiana, including his South Bend clinic. The State's investigation remains ongoing. Ex. 18; Ex. 19. Serena

Dyksen, one of Dr. Klopfer's former abortion patients, testified that women "deserve better" and that taking these regulations away "would be downright dangerous." Ex. 21 ¶ 22.

II. The Appropriate Content and Procedures of Informed Consent

"[M]edical abortion involves decision-making that has unusually grave consequences." Ex. 1 ¶ 47. It is vital that women considering abortion be able "to consider the risks, benefits, and potential short-term and long-term consequences of each option." Ex. 14 ¶ 17. As even Whole Woman's Health recognizes, the "decision of whether and when to remain pregnant and give birth has significant implications for a person. It affects, among other things, the person's bodily integrity, autonomy, financial and job security, workforce participation, educational attainment, ability to parent existing children, and health." ECF No. 1 ¶ 28. Abortion is also "distinct among all medical procedures because it involves a woman and the demise of her biologically distinct offspring." Ex. 6 ¶ 66. Research indicates that much of the information about abortion available on the Internet is of poor quality, which may cause women to be ill-informed about their options. Ex. 14 ¶ 40. Thus, many women are likely unaware of much of the information covered in the required informed-consent counseling session, and research shows that women prefer to have information on all potential complications, even for risks that are relatively rare. Ex. 6 ¶ 189; Ex. 14 ¶ 22.

Furthermore, "[m]ost women experience an abortion decision as stressful and complex, and decisional ambivalence is common among those consulting for an abortion. Human decision-making under emotionally intense circumstances tends to lack the deep deliberation necessary for thorough examination of options and associated consequences." Ex. 6 ¶ 183. Deciding to terminate a pregnancy "for many women . . . involves complex psychological responses related to loss, related to what might have happened, what could have happened if that pregnancy was carried to term." Exhibit 20, Excerpts from Deposition of Aaron Kheriaty, M.D. 146:19–22. A woman who has

"gone through the process of coming to realize she is pregnant and having that pregnancy end is going to have to contend with that that means for her." *Id.* at 149:6–9. Complicated grief and loss can come with the decision to have an abortion. *Id.* at 144:1–12.

Proper informed consent helps avoid situations like that of Serena Dyksen. At the time of Serena's abortion, she was thirteen years old and "had never even heard the word 'abortion' before." Ex. 21 ¶¶ 2, 4. The counselor at the clinic told her "that the baby was nothing more than a clump of cells" and gave her "no information about resources for new mothers, adoption agencies, or counseling for assault victims." *Id.* ¶ 6. Worst of all, no one at the clinic even "explain[ed] the abortion procedure" to her. *Id.* Similarly, Tammi Morris testified that as a woman "who has had eight abortions spanning 15 years in three different states, I know first-hand that informed consent and full unbiased disclosure was never provided to me." ECF No. 96-2 ¶ 22.

A. The Indiana abortion brochure and required disclosure of information

A general principal of the ethics of informed consent is that "the level of detail of the information provided and the amount of time spent on the informed consent process should be commensurate with what is at stake in the specific medical decision." Ex. 14 ¶ 20. Abortion is "distinct among all medical procedures because it involves a woman and the demise of her biologically distinct offspring." Ex. 6 ¶ 66. Given the gravity of the situation, Indiana law requires that pregnant women seeking abortion be given information about the procedure and alternatives.

To begin, Indiana's informed consent brochure on abortion, required by Indiana Code section 16-34-2-1.5, contains accurate information provided by highly respected federal agencies and non-profit organizations, such as the Mayo Clinic, Medline Plus, the U.S. National Library of Medicine, the National Institute of Child and Human Development, and the United States National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Ex. 6

¶ 190. The brochure contains information on the availability of the fetal ultrasound and fetal heart tone, information on fetal development and viability, accompanied with graphics representing a fetus at different gestational ages, a description of the different types of abortion, risks and complications of abortion, including future infertility and risk of death, risks of pregnancy, and options and assistance available to a woman after an abortion or after giving birth. Exhibit 22, Indiana State Department of Health, *Abortion Informed Consent Brochure* (July 11, 2018).

The use of a brochure is a standard part of the medical informed consent process for many procedures, and research supports the routine use of written handouts in improving the quality of informed consent, especially for women with lower health literacy. Ex. 14 ¶ 53. Even Whole Woman's Health's experts recognize as much, acknowledging that "it is important to give written instructions to people," Exhibit 23, Excerpts from Deposition of Ellyn Stecker, M.D. 88:4–6, and that patients forget the information explained to them. *Id.* at 90:7–9. Indeed, it is Dr. Stecker's standard practice to accompany written instructions with a picture or diagram to help better the patient's understanding. *Id.* at 90:10–25. The brochure "enhances the probability of quality decision-making because many women may not be able to fully absorb orally delivered information under stress." Ex. 6 ¶ 191. And it allows women to review relevant information as many times as needed during the waiting period. *Id.*

Indiana law also seeks to ensure informed consent by requiring a physician or designee to provide specific information to a pregnant woman seeking abortion. Ind. Code § 16-34-2-1.1. Much of this information—including the nature of the procedure, the risks and alternatives, the gestational age and development of the fetus, the emergency contact information, the availability of services, and the recitation of other legal requirements surrounding abortion—is uncontroversial in terms of accuracy. The controversial statements are (1) that "human physical life begins when a human ovum

is fertilized by a human sperm" and (2) that a fetus may be able to feel pain at 20 weeks or before. *Id.* §§ 16-34-2-1.1(a)(1)(E), 16-34-2-1.1(a)(1)(G). Yet even Whole Woman's Health's experts have acknowledged: "I agree that in most cases when the human sperm fertilizes the human ovum that development is beginning towards, you know, creating a person." Exhibit 24, Excerpts from Deposition of William Mudd Martin Haskell, M.D. 95:9–12; *see also* Exhibit 38, Rule 26(a)(2)(B) Expert Report of Lucia D. Wocial, Ph.D., R.N., F.A.A.N. ¶ 11 ("Biological life, the moment when egg and sperm join to make a zygote creates a unique being with potential to become a fully formed human."). Dr. Grossman says that his patients sometimes regard their fetus as a "child" or a "baby," Ex. 8 at 237:3–20, and that he does not "try to assure [those women] that . . . there's no life involved . . . in her fetus," *id.* at 235:23–234:1. At the very least, he believes "people can differ" on whether to consider a fetus a human life. *Id.* at 21:9–15.

Indeed, the phrase "human life begins" can be given either a descriptive interpretation ("when the whole living organism is classified as human") or a normative interpretation ("when this life deserves ethical consideration or legal protections"). Ex. 14 ¶ 59. The descriptive interpretation is not scientifically controversial, while the normative interpretation is. *Id.* That the brochure uses the term descriptively is apparent from the fact that it references human *physical* life. *Id.* ¶ 61. Because this is simply a biological statement, it makes "no philosophical claim regarding the personhood of the embryo or fetus." *Id.* In a recent study by the University of Chicago, 5,502 biologists from 1,058 different academic institutions were polled on statements representing the view that "a human's life begins at fertilization." *Id.* ¶ 60. Overall, 95% of those polled affirmed the view that a human's life begins at fertilization, and the biologists affirming this view fell across the entire spectrum, from "very pro-life" to "very pro-choice." *Id.*

With respect to the capacity of a fetus to feel pain, there is no scientific dispute that "the simplest neural circuitry required to detect and respond to pain is in place by 8–10 weeks of human development." Exhibit 25, Expert Report of Maureen L. Condic, Ph.D. ¶¶ 10, 25. In fact, two commonly cited major reviews of scientific literature on this topic, one published by Royal College of Obstetricians and Gynecologists (RCOG) and one published in the Journal of the American Medical Association (JAMA), agree that "the early arising spinal circuits sufficient for detection and response to pain (i.e. 'nociception') are in place by 8–10 weeks, with more sophisticated thalamic pain circuitry developing between 12–18 weeks…." *Id.* ¶ 26. Indeed, multiple sources of authority suggest that the necessary development for the conscious experience of pain—specifically, connections between the spinal cord and the thalamus—occurs between 12 and 18 weeks. *Id.* ¶¶ 10, 23, 32–42. "[T]he debate over fetal pain is not *whether* a fetus detects pain in some manner during the first trimester of life (all parties agree on this point), but rather *how* pain is experienced." *Id.* ¶ 25.

Furthermore, while both the RCOG and JAMA studies mentioned above assume that additional neurological connections between the thalamus and the cortex are needed for a fetus to be conscious of pain, *id.* ¶ 26–27, those reviews "present *absolutely no data* in support of this critical claim," *id.* ¶ 29. On the contrary, several lines of evidence contradict that assumption. *Id.* ¶¶ 32–47. These assertions are not just unsupported by evidence, but are contradicted by the evidence: "There is an enormous body of scientific data that clearly indicates the cortex is *not* required for either consciousness or suffering—data that RCOG and JAMA simply ignore." *Id.* ¶ 32. For example, studies demonstrate that children who are born without the cortex "are capable of conscious behaviors, including smiling, distinguishing between familiar/unfamiliar people and situations, having preferences for particular kinds of music and having adverse reactions to pain." *Id.* ¶ 35. However, "the largest study conducted to date of human patients with disorders of consciousness

unambiguously concludes that loss of *subcortical*, not *cortical* circuitry is associated with loss of consciousness." *Id.* ¶ 36. In other words, the accumulated body of data clearly indicates that pain perception does not depend on cortical circuitry, but is instead largely mediated by sub-cortical brain networks. And it is universally accepted that sub-cortical circuits capable of pain perception are established between 12–18 weeks gestational age. *Id.* ¶ 42.

B. The 18-hour waiting period

Time to consider and discuss the decision is essential for women to choose "the best outcome for their personal situations, seek counseling, and enhance the probability of preserving their mental health and general sense of well-being." Ex. 6 ¶ 185. Approximately 44% of women have doubts about their decision to abort prior to an appointment for an abortion, with 30% continuing to express doubts on the date of the abortion. *Id.* ¶ 74. Data from Utah, where there is a 72-hour waiting period, reveal that about 8% of women changed their minds about pursuing an abortion between the initial visit and the date of the procedure, *id.* ¶ 81, with some research putting the number as high as 10%, *id.* ¶ 186. This is to be expected, as the length of the waiting period is the strongest predictor of patient comprehension of the procedure. Ex. 14 ¶ 26.

Particularly in light of the many women who are unduly pressured into seeking an abortion in the first place, the waiting period and in-person counseling are essential for ensuring that a woman is free to make the best decision for herself in a particular situation. Ex. 6 ¶ 23; Ex. 14 ¶ 28. Elizabeth Gillette testified that "I think had any one person in that clinic said, 'It's okay not to be sure.' You know, 'Go home and think about it.' Or had there been a requirement for another appointment beforehand or even counseling, I would have had the opportunity to actually make a decision rather than have a decision railed down my throat." Exhibit 26, Excerpts from Deposition of Elizabeth Katherine Gillette 102:1–11. Patients need time to consider the risks, benefits, and

potential short-term and long-term consequences of abortion. Ex. 14 ¶ 17. Waiting periods are the norm in other areas of medicine where some period of time passes between the initial consultation and the planned procedure, which is no less important in the abortion context where the decision has significant implications and is irreversible. *Id.* ¶ 30.

C. The fetal ultrasound

Another critical source of information is a fetal ultrasound, which even Whole Woman's Health's abortion providers provide to their patients. Ex. 7 at 33:20–34:17, 43:4–8, 44:4–11, 47:24–48:3, 51:8–14, 56:6–19, 59:1–60:17, 90:1–8, 96:23–97:10. To begin, ultrasounds are critical for rendering appropriate care, as they increase the likelihood that a provider will catch a maternal or fetal abnormality, Ex. 13 at 157:8–12, and ensure accurate gestational dating of the unborn child. Ex. 3 ¶¶ 144, 159; Ex. 2 ¶¶ 53–54, 58, 63; Ex. 13 at 138:23–139:8, 173:5–21; Ex. 7 at 60:2–17, 96:23–97:10; Ex. 12 at 90:15–91:2; Ex. 20 at 89:12–15. Gestational dating is necessary to determine which procedures may be indicated or contraindicated for a given patient. Ex. 3 ¶ 144; Ex. 2 ¶¶ 63, 72; Ex. 12 at 90:15–91:2. For example, for medication abortions, an ultrasound is the best method for ensuring that the unborn child is the correct gestational age (not more than 10 weeks old) and that the pregnancy is not ectopic, among other restrictions. Ex. 3 ¶ 144. Without an ultrasound, providers would date based on patient menstrual cycle history, a pregnancy dating method that is prone to significant error. Ex. 2 ¶ 53. Incorrect gestational dating is a danger to the patient, as she could be subjected to a contraindicated abortion procedure. *Id.*. ¶ 63; Ex. 12 at 90:15–91:2.

Indeed, the American College of Obstetricians and Gynecologists Committee on Obstetric Practice, the American Institute of Ultrasound in Medicine, and the Society for Maternal-Fetal Medicine (collectively ACOG) agree that a pregnancy dated without use of an ultrasound to confirm or revise the estimated date of delivery does not comport with the standard of care for estimating

due dates and gestational age. *See* Exhibit 27, American College of Obstetricians and Gynecologists, *Committee Opinion: Methods for Estimating the Due Date* (May 2017).

An ultrasound is also an essential source of information as a pregnant woman makes her abortion decision—it allows her to see and hear an actual image of her fetus as she considers whether to terminate the pregnancy. An ultrasound is "critical in verifying fetal gestational age, fetal viability and location of the fetus . . . [t]o hide this important information deprives women of making a knowledgeable, full-informed consent." Ex. 3 ¶ 159. Additionally, treating physicians need an ultrasound to verify the fetal gestational age in order to "adequately counsel[] on which termination procedure is the correct one for her gestational age." Ex. 2 ¶ 72. Moreover, the odds of continuing a pregnancy are 1.86 times higher after a woman views an ultrasound. Exhibit 9, Expert Report of Farr A. Curlin. M.D. ¶ 94. Because of the ease of understanding an ultrasound and its ability to help the woman see "[t]hat the baby is alive, that the baby has a beating heart," ultrasounds ensure that a pregnant woman is able to provide informed consent to the abortion procedure. Ex. 1 ¶ 52. Some of the State's witnesses testified that an ultrasound may have changed their abortion decision. *See* Ex. 5 ¶ 12 ("I think actually seeing my baby would have made me feel like I could be a mother."); ECF No. 97-1 ¶ 5 ("I would like to think I would have made a different decision if I could have seen the baby moving or hear the heartbeat.").

Indeed, one of Whole Woman's Health's experts testified that "I believe patients should be given access to all of the information that is being used as part of their health care; and that, in the interest of transparency around that information, I believe that [patients] should be given that opportunity [to view a fetal ultrasound]. . . . [I]t has become I think generally the standard of care within abortion practice." Ex. 8 at 264:8–15. Several experts have testified that a patient cannot

even *provide* informed consent to abortion at all without viewing an ultrasound of the baby beforehand. Ex. 3 ¶ 159; Ex. 2 ¶ 72; Ex. 1 ¶¶ 52–53. "Visualization of the live fetus by ultrasound allows the patient to understand what the consent to an elective abortion actually means: the ending of the baby's life. To hide this important information deprives women of making a knowledgeable, full-informed consent." Ex. 3 ¶ 159; *see also* Ex. 14 ¶ 45–48; Ex. 20 at 235:16–238:18. Ultrasounds are a safe, noninvasive method by which providers can glean vital health information about their patients for use in determining which procedures are appropriate. Ex. 14 ¶ 42–45; Ex. 13 at 134:9–25; Ex. 12 at 181:15–182:2.

D. In-person counseling

Indiana also requires that the required informed-consent disclosures be made by appropriate medical personnel "in the presence" of the pregnant woman. According to Dr. Kheriaty, "Informed consent conversations require face-to-face time between physician (or his/her appropriate delegate) and patient." Ex. 14 ¶ 21. Dr. Calhoun adds that "in-person interactions are superior to remote interactions for decisions of that weight" because they "lead[] to better eye contact, greater ability to read body language, and overall development of a real person-to-person relationship between doctor and patient." Ex. 3 ¶ 143. According to Dr. Coleman, "[p]rovision of reliable information addressed in Indiana's brochure coupled with the in-person counseling are an essential component of the informed consent process." Ex. 6 ¶ 191.

III. Minors and Abortion

When minors seek abortions, both they and their parents have fundamental rights and interests at stake. It should hardly take expert testimony to establish deficiencies in adolescent decision-making compared with adults, but Dr. Coleman confirms the existence of "compelling evidence that adolescence is a time of risky decision-making." Ex. 6 ¶ 24. "According to research conducted

by Halpern-Felsher and Cauffman (2001), adolescents' and adults' decision-making competence differs, with adults generally outperforming adolescents." *Id.* Indeed, owing to the stage of brain development, "adolescents are apparently prone to making impulsive decisions, which implies that additional time and adult support through the decision-making process are likely to lead minors toward formulating well-reasoned pregnancy decisions." *Id.*

Dr. Stroud testifies that involving parents in the decision-making process can positively affect the conditions of poverty and oppression some women are forced to live in; the notification of parents will allow them to intervene and "give them the opportunity, at least, that might not otherwise have existed, to pause and say we had no idea things were this bad, let's make changes." Ex. 28 at 105:23–106:1. Dr. Stroud, who has experience treating minors who have been abused and neglected by their parents, *id.* at 106:18–23, avers that "more times than not, the parent remains the best source of counsel and information for a minor child" noting that if the opposite is true, the judicial bypass remedy remains available, *id.* at 106:13–17.

Judge Charles F. Pratt and Judge Mary Beth Bonaventura confirm the efficacy of the judicial bypass system. Judge Pratt testified that of eleven judicial bypass cases filed in the Allen Superior Court between 1995 and 2013, nine were granted and only two were denied. Exhibit 35, Expert Report and Declaration of Judge Charles F. Pratt ¶ 9. In each hearing, the minor was represented by a court-funded attorney, the decision was rendered within forty-eight hours of filing the petition, and the hearing was closed and confidential. *Id.* ¶¶ 10–13. Judge Bonaventura testified that the age and maturity levels of the minors vary considerably. Exhibit 29, Expert Report and Declaration of Judge Mary Beth Bonaventura ¶ 8. Younger minors are well-served "by having a neutral judge review their circumstances and make responsible decisions regarding their welfare," *id.* ¶ 10, while the judicial bypass process "ensure[s] that older minors gave serious consideration to the decisions

and had detailed conversations with a doctor and a lawyer," *id.* ¶ 11. During the judicial bypass proceeding, the judge is available to discuss and assess the wishes, mental capacity, maturity level, intelligence and ability of a minor to make the decision. Exhibit 31, Excerpts from Deposition of Mary Beth Bonaventura 89:8–11; 90:14–16. Courts generally make the process more comfortable for minors, such as by sitting at eye level at a table rather than on the bench, foregoing a judicial robe, providing candy and even the companionship of canines in the courtroom. *Id.* at 65:13–67:4.

Judicial bypass is also utilized if a child is in the custody of DCS who wishes to have an abortion and the biological parents are unable, unwilling, or don't have the ability to assist in making the decision. *Id.* at 21:17–22:22. In the case of a minor who is a ward of the State, that minor's legal guardian, the State itself, may not consent to the abortion, meaning that the minor is in precisely the same situation as a minor whose parent refuses to consent to an abortion. Judge Bonaventura testifies that state-appointed "guardians are generally reluctant to make significant medical decisions on their own, even where having the authority to do so, and are eager to involve the Juvenile Division judges in the decision-making process." Ex. 29 ¶ 14.

IV. The Availability of Abortion in Indiana

Uncontroverted evidence shows that Indiana's abortion regulations have not prevented women from accessing abortion in Indiana. Dr. James Studnicki, the State's expert on data analytics, conducted an empirical analysis of Indiana's abortion rates over the last twenty-five years and concluded that "nothing in Indiana's abortion rate over those 25 years suggests any association with any of the challenged laws." Ex. 32 ¶ 8. Dr. Studnicki analyzed the effect of four sets of challenged laws on Indiana's abortion rates. *Id.* ¶ 18. "For decades, Indiana abortion rates . . . have been declining in general concert with national trends." *Id.* ¶ 17. Yet after the enactment of the first three sets of laws, in 1993, 1995, and 2005, Indiana's abortion rate actually increased before resuming

its gradual decline. *Id.* ¶¶ 18–19. After the fourth set of laws was enacted, Indiana's abortion rate continued to decline, but at a *slower* rate than before. *Id.* ¶ 20. Consequently, Dr. Studnicki concluded that there is "no plausible evidence of a link between abortion rates and Indiana's legislative environment regarding abortion." *Id.* ¶ 29.

Whole Woman's Health's experts do not contradict Dr. Studnicki's conclusions. On the contrary, Whole Woman's Health's epidemiology expert, Dr. Heidi S. Moseson, testified that she had *not* established a causal link between Indiana's abortion laws and the Indiana abortion rate. Exhibit 33, Excerpts from Deposition of Heidi S. Moseson Lidow 69:20–25. When asked whether "the disparity . . . between the rate [of abortion] in Indiana and the rate in [Illinois, Ohio, and the United States] is caused by the Indiana laws that are at issue in this case," Dr. Moseson answered that she "ha[d] not done quantitative causal analysis of these data to say that." *Id.* at 66:12–19. She then admitted her report did not even "establish a formal statistical association" between the laws at issue and the difference in abortion rates, *id.* at 68:25–69:5, and that without that association, her report could not "establish that the laws at issue actually cause the difference in abortion rates," *id.* at 69:22–25. She conceded that she had "not done a formal causal analysis of the laws' effect" on Indiana's abortion rates, *id.* at 69:25–70:2, and confirmed that statement at every turn:

- "I have not done quantitative causal analysis of these data to say" that the disparity between Indiana's abortion rate and that of other jurisdictions is caused by the challenged Indiana laws. *Id.* at 66:11–67:2.
- "My report does not use causal language." *Id.* at 67:10–14.
- "[M]y report does not do a formal causal analysis within the State of Indiana." *Id.* at 69:20–21.
- Data from abortion funds "can't be used to establish a causal link" between the challenged laws and the incidences of women seeking abortions. *Id.* at 79:12–25.

Similarly, Dr. Grossman conceded that a number of studies cited in his report find that waiting periods *longer* than Indiana's have *not* been shown to affect abortion rates or to prevent women

from obtaining abortions. Ex. 8 at 167:8–15 (24-hour waiting period), 253:21–255:2 (72-hour waiting period). He also admitted that he has no evidence that Indiana abortion clinics are "capacity limited by lack of providers." *Id.* at 108:19–24.

LEGAL STANDARD

Summary judgment is proper where there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). The "mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986). And where a case involves legislative facts, "those challenging the legislative judgment must convince the court that the legislative facts on which the classification is apparently based could not reasonably be conceived to be true by the governmental decisionmaker." *Vance v. Bradley*, 440 U.S. 93, 111 (1979).

ARGUMENT

I. Plaintiffs Lack (1) Third-Party Standing To Assert Rights of Patients and (2) Injury-in-Fact Standing Against Ultrasound, Physician Exam, and Facility Requirements

Whole Woman's Health has no constitutional rights to perform (or facilitate) abortions or to operate abortion clinics, so third-party-standing doctrine is the only mechanism by which it may litigate undue-burden challenges against state abortion laws. *See, e.g.*, *Harris v. McRae*, 448 U.S. 297, 314 (1980); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 846, 884 (1992). In *Singleton v. Wulff*, 428 U.S. 106 (1976), a plurality of the Court permitted abortion physicians to litigate on behalf of patients the question whether a State could exclude non-therapeutic abortions from Medicaid coverage. Yet in so doing the plurality opinion noted at least two reasons for courts not to resolve cases "on the basis of the rights of third persons not parties to the litigation." *Id.* at 113. "First, . . . the holders of those rights either [may] not wish to assert them, or will be able to

enjoy them regardless . . . . Second, third parties themselves usually will be the best proponents of their own rights." *Id.* at 113–14. Accordingly, the plurality opinion explained, the Court's previous third-party-standing cases—none of which involved abortion—"looked primarily to two factual elements to determine whether the rule should apply in a particular case." *Id.* at 114. In particular: (1) "the relationship between the litigant and the third party . . . [is] such that the former is fully, or very nearly, as effective a proponent of the right as the latter" and (2) "Even where the relationship is close, . . . there is some genuine obstacle to" the right-holder's assertion of the right. *Id.* at 115–16. Those factors require rejection of third-party standing in this case.

Furthermore, a party invoking federal jurisdiction must demonstrate "(1) injury in fact; (2) a causal connection between the injury and the challenged conduct, i.e., traceability; and (3) that it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Plotkin v. Ryan*, 239 F.3d 882, 884 (7th Cir. 2001) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)) (internal citations and quotation marks omitted). Critically, "unadorned speculation will not suffice to invoke the federal judicial power." *Plotkin*, 239 F.3d at 884 (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 44 (1976)) (internal quotation marks omitted).

A. This term the Supreme Court will review whether and when abortion providers may assert the rights of patients, and that decision will affect Whole Woman's Health's standing to litigate much of this case

The State disagrees that Whole Woman's Health has standing to assert challenges to maternal health- and safety-based statutes on behalf of their patients, but recognize that the Seventh Circuit has held that such organizations ordinarily have such third-party standing in the abortion context. *See Planned Parenthood of Wis., Inc. v. Van Hollen*, 738 F.3d 786, 794–95 (7th Cir. 2013). On October 4, 2019, however, the Supreme Court granted certiorari in *June Medical Services, LLC v. Gee*, where it will consider, among other issues, whether abortion providers and facilitators have

standing to challenge health- and safety-based abortion restrictions on behalf of their patients and clients. *June Medical Servs., LLC v. Gee*, No. 18-1323, 2019 WL 4889929 (U.S. Oct. 4, 2019).

In that case, Louisiana argues that, at least where the issue is the validity of abortion regulations designed to protect patient health and safety, physicians and patients lack the unity of interest required to justify third-party standing. In general, a plaintiff "must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties." *Kowalski v. Tesmar*, 543 U.S. 125, 129 (2004). Third-party litigation is disfavored because "courts should not adjudicate" the rights of parties foreign to the litigation "unnecessarily." *Singleton v. Wulff*, 428 U.S. 106, 113–14 (1976). A plaintiff thus may assert the rights of a third party only when (1) it has a "close" relation to the third party; and (2) there is some "hindrance" to the third party's ability to protect his or her own interests. *Kowalski*, 543 U.S. at 130. To satisfy the critical "close relation" element of this test, a plaintiff must at the very least establish a unity of interests with the third party whose rights are invoked. *See Elk Grove Unified Sch. Dist. v. Newdow*, 542 U.S. 1, 14–15 & n.7 (2004) (distinguishing *Singleton* because father and child's interests were "potentially in conflict").

With respect to abortion health-and-safety laws, however, abortion providers are unable to do so vis-à-vis hypothetical future patients. The business interests of the doctors and clinics clearly conflict with the women's interests. It is in their business interests—not any woman's interests—to throw off laws that require them to "[e]mploy[] qualified staff," or to "[e]nsur[e] that sufficient staff [are] present to provide quality patient care" with properly sterilized equipment, ECF No. 1 ¶ 82(b); 410 Ind. Admin. Code §§ 26-5-1, 26-11-2. Similar conflicts arise in abortion providers' challenges to States' informed-consent laws. *Casey* recognized the necessity of informed-consent to "reduc[e] the risk that a woman may elect an abortion, only to discover later, with devastating psychological consequences, that her decision was not fully informed." 505 U.S. at 882. And in

Gonzales v. Carhart, 550 U.S. 124, 159 (2007), the Court noted that some women may come to "regret their choice" leading to "[s]evere depression," "loss of esteem," "grief," and "sorrow." The Court noted that many abortion doctors will "prefer not to disclose precise details" about abortion procedures. *Id.* Whole Woman's Health may also seek third-party standing to challenge laws that ensure abortion providers have been credentialed by their peers. Invalidating these laws may be in the interests of the providers, but it is not in the interests of women seeking abortions.

Whole Woman's Health lacks standing to assert the rights of hypothetical future abortion patients as to all claims. The Supreme Court, in deciding *June Medical*, will clarify the requirements for third-party standing in the abortion context and potentially overrule cases such as *Van Hollen* on this point. If so, the State will be entitled to summary judgment on all claims.

B. Whole Woman's Health lacks Article III standing as to several claims

Whole Woman's Health also cannot demonstrate injury-in-fact regarding challenges to: (1) Indiana Code section 16-34-2-1.1(a)–(c), concerning ultrasound requirements; (2) Indiana Code section 16-34-2-1(a)(1), concerning in-person physical-examination requirements; and (3) Indiana Code section 16-34-2-1(a)(2)(B), concerning facility requirements for surgical abortions.

1. Whole Woman's Health lacks standing to challenge ultrasound requirements because it already performs and will continue to perform ultrasounds

Indiana's ultrasound requirements provide mothers with more information so that they can better consider their pregnancy options and provide informed consent to an abortion provider if abortion is their ultimate choice. Ex. 3 ¶ 159; Ex. 9 ¶ 94; Ex. 2 ¶ 72; Ex. 14 ¶¶ 42–47, Ex. 1 ¶ 52; Ex. 13 at 134:9–25, 157:8–12; Ex. 12 at 10:5–11:20, 56:8–58:19, 181:15–182:2; Ex. 20 at 88:22–89:8, 226:8–20, 232:6–233:9, 235:16–238:18. The ultrasound requirements include, among other rules, that an abortion provider "shall perform, and the pregnant woman shall view, the fetal ultrasound imaging and hear the auscultation of the fetal heart tone if the fetal heart tone is audible

unless the pregnant woman certifies in writing" that she does not wish to view the ultrasound or listen to the fetal heart tone. Ind. Code § 16-34-2-1.1(a)(5). Plaintiffs vaguely challenge this statute as an undue burden on access to abortion. Dr. Glazer, however, has already testified that he performs ultrasounds on his patients before providing abortions. Ex. 7 at 33:20–34:17, 43:4–8, 44:4–11, 47:24–48:3, 51:8–14, 56:6–19, 59:1–60:17, 60:2–17, 90:1–8, 96:23–97:10. He explained that ultrasounds are necessary to date the preborn child properly. *Id.* at 60:2-17, 96:23-97:10. His use of fetal ultrasounds belies the claim that ultrasounds are not medically necessary and demonstrates that ultrasounds are no burden to abortion; an obligation to show the image to the patient or obtain written rejection does not itself impose a burden.

2. Plaintiffs lack standing to challenge physical examination requirements because they already perform them and will continue to do so

The physical examination requirements of Indiana Code section 16-34-2-1(a)(1) ensure the health and physical safety of women and minimize the risk from the abortion procedure. *See supra* Statement of Facts Part I.B. The statute requires only that a physician "examine a pregnant woman in person before prescribing or dispensing an abortion inducing drug." Ind. Code § 16-34-2-1(a)(1). And similar to the fetal ultrasound requirement, Dr. Glazer has already testified that he performs physical examinations of his patients as part of his current abortion practice. Ex. 7 at 56:20–58:25. Dr. Glazer has also stated that such examinations are often necessary in response to patient complaints or to ensure that there will be no complications during the abortion procedure for a given patient. *Id.* Dr. Glazer's practices bely any claim that physical examinations are not medically necessary and demonstrate that Indiana Code section 16-34-2-1(a)(1) is no burden on abortion.

3. Whole Woman's Health lacks standing to challenge facility requirements for surgical abortion clinics because those regulations do not apply to it

The physical plant requirements for abortion clinics (as defined in 410 Indiana Administrative Code section 26-1-3) ensure the health and safety of pregnant women who seek surgical abortions. *See* Ind. Code §§ 16-21-2-2.5(a)(2), 16-18-2-2.5(a)(2); 410 Ind. Admin. Code §§ 26-10-1, 26-11-2, 26-11-3, 26-13-1, 26-13-3, 26-17-2. These physical plant requirements apply only to abortion clinics that provide surgical abortions and do not apply to clinics that provide only medication abortions. 410 Ind. Admin. Code § 26-0.5-1 ("[Article 26] applies to abortion clinics that perform surgical abortion procedures. An abortion clinic that provides an abortion inducing drug for the purpose of inducing an abortion must comply with [Article 26.5]."). And Whole Woman's Health's South Bend clinic does not provide surgical abortions, but instead offers abortions only via an abortion-inducing drug. *See* Ex. 7 at 51:15–17. Thus, Whole Woman's Health is not subject to and will not be burdened by the physical plant requirements applicable to abortion clinics providing surgical abortions. Whole Woman's Health may only challenge statutes or regulations that it alleges directly interfere with abortion access for their patients. Because the physical plant requirements simply do not apply to it, it does not have standing to challenge the applicability of these statutes or assert an undue burden. Whole Woman's Health is not burdened by requirements that do not apply to them.

II. Two of Whole Woman's Health's Witnesses Should Be Disqualified from Testifying as Experts on Core Topics Under Rule 702

This Court should exclude the opinions of Drs. Heidi Moseson and Daniel Grossman on key topics. Rule 702 of the Federal Rules of Evidence governs the admissibility of expert opinion testimony. It requires that would-be expert witnesses be "qualified . . . by knowledge, skill, experience, training, or education" and allows them to testify only if four conditions are all satisfied:

> **(a)** the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the expert has reliably applied the principles and methods to the facts.

Id. In *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 (1993), the Supreme Court recognized the gatekeeping function of federal courts when "[f]aced with a proffer of expert scientific testimony." Courts must determine whether, on each topic, proposed testimony (1) reflects scientific knowledge that will (2) assist the trier of fact to "understand or determine a fact in issue." *Id.*; *Chapman v. Maytag Corp.*, 297 F.3d 682, 686–87 (7th Cir. 2002); *see also Daubert*, 509 U.S. at 592–93 (providing a non-exhaustive list of "general observations" to help determine if testimony reflects scientific knowledge). The proponent of expert testimony bears the burden of proving that it is admissible. *Lewis v. CITGO Petroleum Corp.*, 561 F.3d 698, 706 (7th Cir. 2009).

The expert opinions at issue here should be excluded for different reasons. Dr. Heidi Moseson, despite her background in statistical analysis, failed to conduct any *correlative or causal* analysis of the alleged effects. Her opinion that Indiana's laws cause burdens on abortion thus cannot properly be considered scientific knowledge. Dr. Daniel Grossman, for his part, offers opinions on subjects where he does not have expertise at all. The end result, for both witnesses, is the same: Each should be precluded from testifying as experts on the indicated topics. This matters for summary judgment because it undermines Whole Woman's Health's ability to create material factual disputes on critical issues, as noted in later sections of this memorandum.

A. Dr. Moseson's opinion that the challenged laws impose substantial obstacles is inadmissible

Dr. Moseson, an epidemiologist, asserts in her report that "Indiana's abortion restrictions *create* substantial obstacles to abortion access in the State." Ex. 34 ¶ 48 (emphasis added). Regardless of her academic qualifications and experience, that opinion should be excluded because it fails to reflect scientific knowledge. *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996) ("[A]

district judge asked to admit scientific evidence must determine whether the evidence is genuinely scientific, as distinct from being unscientific speculation offered by a genuine scientist."). Dr. Moseson cannot meet the "high bar" of showing causation in this case, and indeed she conceded that she had "not done a formal causal analysis of the laws' effect" on Indiana's abortion rates. Ex. 33 at 69:25–70:2; *see also id.* at 66:20–67:1–2; 67:10–14; 69:20–21; 79:12–25.

As the Supreme Court has put it, "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). In the absence of a scientifically valid methodology connecting data to a conclusion, *ipse dixit* is all an expert can offer. And it is difficult to imagine a more paradigmatic example of *ipse dixit* than Moseson testifying that Indiana laws cause burdens on abortion without having done the scientific analysis that she agreed would be necessary for such an opinion.

Dr. Moseson, when questioned, did not disagree. In fact she *agreed* that because she did not perform the necessary analysis, her report "cannot itself establish that the laws at issue actually cause the difference in abortion rates" between Indiana and other jurisdictions. Ex. 33 at 69:22–25. She also conceded that she could offer no scientifically supported opinion on (1) any causal relationship between the challenged laws and the closure of clinics, *id.* 162:18–19; or (2) whether the challenged laws cause women to obtain abortions later in their pregnancies, *id.* 74:5–12. Given all of Dr. Moseson's admissions about her methodology and conclusions, she has no basis to offer an opinion that Indiana laws actually cause or correlate with any burdens on abortion.

B. Dr. Grossman may not testify on subjects where he lacks expertise

In addition, Dr. Grossman is unqualified to testify as an expert on several subjects. Critically, "[a] medical degree 'alone does not qualify an expert to give an opinion on every conceivable

medical question.'" *O'Conner v. Commonwealth Edison Co.*, 807 F. Supp. 1376, 1390 (C.D. Ill. 1992) (alteration omitted), *aff'd,* 13 F.3d 1090 (7th Cir. 1994). Rather, a court "must look at each of the conclusions [the expert] draws individually to see if he has the adequate education, skill, and training to reach them." *Gayton v. McCoy*, 593 F.3d 610, 617 (7th Cir. 2010). On at least three topics, Dr. Grossman fails that test.

First, Dr. Grossman has not established his qualifications to testify as an expert on medical ethics. He admits that he does not do research in medical ethics and that medical ethics is not "a main area [he has] written about." Ex. 8 at 50:13–15; *see Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (contrasting experts who testify on "matters growing naturally and directly out of research they have conducted independent of the litigation" versus experts who "have developed their opinions expressly for purposes of testifying"). And while he applies his "training in basic medical ethics" in his medical practice, Ex. 8 at 50:15–17, 50:24–51:3, he concedes that he is unaware of the theoretical underpinnings of medical ethics. A genuine expert in medical ethics would presumably be familiar with differences in ethical theory and be able to situate his assumptions in a broader context. *Cf. Chill v. Calamos Advisors LLC*, No. 15 CIV. 1014 (ER), 2019 WL 5067746, at *30 (S.D.N.Y. Oct. 9, 2019) (excluding testimony of purported expert who "lacked familiarity with several basic … principles and authoritative works" of the field at issue); *Radiance Found., Inc. v. Nat'l Ass'n for the Advancement of Colored People*, 27 F. Supp. 3d 671, 675, 676–77 (E.D. Va. 2013) (excluding testimony of purported expert who was "unfamiliar with basic . . . concepts" of the field). Indiana's expert Dr. Farr Curlin, for example, showed that Whole Woman's Health's witnesses have implicitly adopted assumptions about informed consent that are questioned by other medical ethicists and that do not serve patients' best interests. Ex. 9 at 16–18. But when

obtaining his patients' informed consent, Dr. Grossman admits that he merely uses informed-consent processes he was "trained" to use. Ex. 8 at 222:17–18. He does not even know that other models of informed consent exist. *Id.* at 221:15–222:4. Dr. Grossman concedes that he is not offering any opinions on medical ethics. *See id.* at 51:5–7. But even if he were, his lack of knowledge of the field disqualify him as an expert.

Second, Dr. Grossman is not a neurologist or a neurobiologist and has not shown that he is qualified to testify as an expert on fetal pain. *See* Exhibit 36, Expert Report of Daniel Grossman, M.D. 32; Ex. 8 239:20–23. His knowledge on the subject comes from having read "what I think are considered the most authoritative papers on fetal pain," *id.* at 239:16–18—namely, two literature reviews cited in a fact-sheet published by the American College of Obstetricians and Gynecologists (ACOG), *id.* at 240:3–9; 241:9–21. He appears to have accepted ACOG's view that those literature reviews are the "authoritative texts." *Id.* at 240:3–9. Thus, rather than reach his own opinions through his own expertise and research, Dr. Grossman is merely "parroting the opinion[s]" of *other* individuals who may or may not be experts in the field themselves—and whom Whole Woman's Health has not disclosed. *Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 613 (7th Cir. 2002); *see also Hall v. Flannery*, 840 F.3d 922, 929–30 (7th Cir. 2016).

Dr. Grossman also is not familiar with the limitations of the studies he relies upon. According to him, the literature reviews cited by ACOG conclude that fetal pain depends on the development of connections between the thalamus and the cortex in the fetal brain. Ex. 8 at 240:10–22. But he cannot identify any underlying medical or neurological studies supporting that conclusion. *Id.* at 241:17–242:8. In contrast, Indiana's expert on fetal pain—Dr. Maureen Condic, a neurobiologist—has explained without contradiction why the studies cited by ACOG lack evidentiary support on that subject. Ex. 25 at 16–17. (This Court has previously agreed with Dr. Condic's opinions on a

fetus's capacity for pain. *Planned Parenthood of Indiana, Inc. v. Comm'r of Indiana State Dep't of Health*, 794 F. Supp. 2d 892, 916 & n.9 (S.D. Ind. 2011).) Dr. Grossman is also unaware of animal studies contradicting his view. *Compare* Ex. 8 at 242:9–18, *with* Ex. 25 at 10. These deficiencies mean that Dr. Grossman cannot establish his qualifications as a fetal pain expert.

Third, Dr. Grossman is not a psychiatrist or psychologist and has not otherwise established that he is an expert in mental health. Ex. 8 at 281:14–17. His personal familiarity with the field is limited: On adolescent psychological development, for example, he admitted that he is familiar with the scientific literature in "a very cursory way but not in very—in a lot of depth." *Id.* at 281:21–24. He did not even *write* the section of his report dealing with mental health: two consulting experts did. *Id.* at 62:1–14. With respect to mental health, he has not shown that he would do more than "parrot[] the opinion[s]" of others. *Dura Auto. Sys.*, 285 F.3d at 613.

III. Indiana Is Entitled to Summary Judgment with Respect to Statutes Previously Upheld by the Supreme Court and Seventh Circuit

Whole Woman's Health's complaint challenges nearly the entire Indiana Code on abortion, including statutes that have already been upheld by the Supreme Court and the Seventh Circuit. In its Statement of Claims, ECF No. 203, Whole Woman's Health asks that this Court balance the burdens and benefits of each challenged statute, applying the test from *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2309 (2016). But *Hellerstedt* did not change the applicable test for abortion statutes; it simply applied the undue burden test from *Casey*. *See id.* ("We begin with the standard, as described in *Casey*."). *Hellerstedt*, therefore, does not wipe out the Supreme Court's prior abortion precedents applying the *Casey* standard; rather, it provides guidance for applying that standard to new abortion regulations the constitutionality of which is yet undecided.

The Seventh Circuit confirmed this reading of *Hellerstedt* in its recent decision narrowing this Court's preliminary injunction in this case. This Court had preliminarily enjoined Indiana's

licensing scheme as applied to Whole Woman's Health even though "the Supreme Court has recognized that states may require licenses of abortion care providers." *Whole Woman's Health Alliance v. Hill*, 937 F.3d 864, 874 (7th Cir. 2019). The Seventh Circuit narrowed the injunction, holding "that the district court's broad condemnation of Indiana's licensing scheme runs contrary to Supreme Court precedent." *Id.* at 868.

In sum, precedents upholding licensing are still good law despite *Hellerstedt*, and by implication other controlling precedents upholding abortion regulations remain binding as well. Consequently, the State is entitled to summary judgment on each statute or regulation that has already been upheld by the Supreme Court or the Seventh Circuit.

A. The Seventh Circuit's opinion in this case unmistakably reaffirmed the power of the State to require that abortion clinics have a license

Whole Woman's Health alleges that the facility licensure requirements, Ind. Code §§ 16-18-2-1.5(a), 16-21-1-7, 16-21-2-2(4), 16-21-2-2.5(a), 16-21-2-10 to 16-21-2-11, 16-21-2-14, and 410 Ind. Admin. Code art. 26, "impose an undue burden on access to previability abortion in Indiana in violation of the Due Process Clause of the Fourteenth Amendment." ECF No. 1 ¶¶ 82, 197. Together, these provisions require that any facility providing surgical or medication abortions to five or more patients each year be licensed with the State as an abortion clinic.

In its decision at the preliminary injunction stage of this case, the Seventh Circuit held that Indiana's licensing scheme for abortion clinics is constitutionally valid. It explained that "most of Indiana's licensing statutes appear inoffensive," including "Indiana's requirement that licensees have 'reputable and responsible character.'" *Hill*, 937 F.3d at 875. It then held that "to the extent the district court viewed Indiana's licensing scheme as unconstitutional because licensing provided insufficient benefits to the state as a general matter, that conclusion cannot stand." *Id.* Accordingly,

the facility-licensure requirements neither impose an undue burden facially nor as applied to medication-only abortion clinics.

The Seventh Circuit remanded for factual evaluation of whether the State's treatment of Whole Woman's Health's license application comported with due process. *Id.* at 879. The nature of that claim is unclear, however, as Whole Woman's Health has alleged no "procedural due process" violation, and no "undue burden" doctrine exists to deem denial of a license to a particular *clinic* a violation of a *woman's* right to choose abortion. Regardless, the State plans to seek U.S. Supreme Court review of that issue, and the State is entitled to summary judgment on whatever claim the license-denial issue represents. Consequently, this Court should grant summary judgment to the State on Whole Woman's Health's challenges to the facility-licensure requirements: Ind. Code §§ 16-18-2-1.5(a), 16-21-1-7, 16-21-2-2(4), 16-21-2-2.5(a), 16-21-2-10, 16-21-2-11, 16-21-2-14; 410 Ind. Admin. Code art. 26.

B. Supreme Court precedent makes clear that States may restrict the performance of abortions to licensed physicians

Whole Woman's Health also challenges the physician-only requirements, Ind. Code § 16-34-2-1(a)(1)(A) and 410 Ind. Admin. Code 26-13-2(b), which provide that only a physician may perform an abortion or prescribe an abortion-inducing pill. ECF No. 1 ¶¶ 82, 197. The Supreme Court, however, has already held that such requirements are constitutional.

In *Mazurek v. Armstrong*, a physician-assistant sought a preliminary injunction against a Montana law prohibiting abortions except those provided "by a licensed physician." 520 U.S. 968, 969–70 (1997). The Court held that the physician-only requirement was constitutional because the record was devoid of "any evidence suggesting an unlawful motive on the part of the Montana Legislature" or any evidence "that the requirement posed a substantial obstacle to a woman seeking an abortion." *Id.* at 972 (internal quotation marks omitted). The plaintiffs had argued that "all health

evidence contradicts the claim that there is any health basis," but the Court said that "the Constitution gives the States broad latitude to decide that particular functions may be performed only by licensed professionals, *even if an objective assessment might suggest that those same tasks could be performed by others.*" *Id.* at 973 (quoting *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 885 (1992)) (emphasis in original). The Court also cited its "repeated statements in past cases . . . that the performance of abortions may be restricted to physicians." *Id.* at 974–75 (citing *Roe v. Wade*, 410 U.S. 113, 165 (1973); *Connecticut v. Menillo*, 423 U.S. 9, 11 (1975); *City of Akron v. Akron Ctr. for Reproductive Health*, 462 U.S. 416, 447 (1983)).

The Indiana statute at issue here is materially identical to the Montana statute upheld in *Mazurek*. *Compare* Ind. Code § 16-34-2-1(a) ("Abortion shall in all instances be a criminal act, except when . . . the abortion is performed by the physician.") *with* 1995 Montana Laws ch. 321 (H.B. 442) ("An abortion may not be performed within the state of Montana . . . except by a licensed physician."). Indeed, thirty-eight other States have such restrictions. *See* Ala. Code § 26-23E-4(a); Alaska Stat. § 18.16.010(a)(1); Ariz. Rev. Stat. Ann. § 36-2155(A); Ark. Code Ann. § 20-16-605(a); Del. Code Ann. § 1790(a); Fla. Stat. § 390.0111(2); Ga. Code Ann. § 16-12-141(b)(2); Haw. Rev. Stat. § 453-16(a)(1); Idaho Code Ann. § 18-608; Iowa Code § 707.7(4); Kan. Stat. Ann. § 65-4a10(a); Ky. Rev. Stat. Ann. § 311.723(1); La. Rev. Stat. Ann. § 1061.10(A)(1); Md. Code Ann. Health-Gen. § 20-208; Mass. Gen. Laws ch. 112, § 12L; Mich. Comp. Laws § 750.15; Minn. Stat. § 145.412(1)(1); Miss. Code Ann. § 41-41-107(1); Mo. Rev. Stat. § 188.080; Neb. Rev. Stat. § 28-335(1); Nev. Rev. Stat. § 442.250(1)(a); N.J. Admin. Code § 13:35-4.2(b); N.M. Stat. Ann. § 30-5-1(C); N.C. Gen. Stat. § 14-45.1(a); N.D. Cent. Code § 14-02.1-04(1); Ohio Rev. Code Ann. § 2919.11; Okla. Stat. § 1-731(A); 18 Pa. Cons. Stat. § 3204; 216 R.I. Code R. § 20-10-6.3.4; S.C. Code Ann. § 44-41-20; S.D. Codified Laws § 34-23A-56; Tenn. Code Ann. § 39-15-213(c)(1); Tex.

Health & Safety Code Ann. § 171.063; Utah Code Ann. § 76-7-302(2); Va. Code Ann. § 18.2-72; Wash. Rev. Code § 9.02.110; Wis. Stat. § 940.15(5); Wyo. Stat. Ann. § 35-6-111.

And just as in *Mazurek,* Whole Woman's Health can present no evidence that the Indiana legislature enacted the law for the purpose of imposing an undue burden or that the law does impose such a burden. See Part IV.A, *infra*. Accordingly, the State is entitled to summary judgment as to Ind. Code § 16-34-2-1(a)(1)(A) and 410 Ind. Admin. Code 26-13-2(b)**.**

C. Indiana's requirement that abortions occurring after the first trimester be conducted in an ambulatory surgical center or hospital has already been upheld, and Supreme Court precedent confirms its constitutionality

Whole Woman's Health challenges Indiana's requirement that second trimester abortions be "performed in a hospital or ambulatory outpatient surgical center." Ind. Code § 16-34-2-1(a)(2)(B). But the Supreme Court has also upheld this requirement. *Gary-Northwest Indiana Women's Services, Inc. v. Bowen*, 496 F. Supp. 894 (N.D. Ind. 1980), *aff'd*, 451 U.S. 934 (1981). And it reaffirmed this holding in *Simopoulos v. Virginia*, 462 U.S. 506, 516–17 (1983), upholding a law requiring second trimester abortions to occur in an outpatient surgery center. The State is thus entitled to summary judgment on the ASC/hospital requirement: Ind. Code § 16-34-2-1(a)(2)(B).

D. The Supreme Court has upheld reporting requirements materially identical to Indiana's

Indiana requires health-care providers performing surgical abortions or prescribing abortion-inducing drugs to file a terminated pregnancy report including specified information for each abortion, with additional information for minor patients. *See* Ind. Code §§ 16-34-2-5(a), 16-34-2-5.1, 16-34-2-5(b). The abortion provider must transmit the form to the Department of Health, and, if the woman on whom the abortion was performed is less than sixteen years old, to the Department of Child Services. *Id.* § 16-34-2-5(b). Failure to submit the form is a misdemeanor. *Id.* § 16-34-2-

5(d). ISDH must then summarize the aggregate data and submit it to the Center for Disease Control for inclusion in the annual Vital Statistics Report. *Id.* § 16-34-2-5(f).

The Supreme Court has upheld similar reporting requirements on three separate occasions. *Planned Parenthood of Cent. Mo. v. Danforth*, 428 U.S. 52 (1976); *Planned Parenthood Ass'n of Kan. City, Mo., Inc. v. Aschcroft*, 462 U.S. 476, 489–90 (1983); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 900–01 (1992). In *Casey*, the Court upheld a requirement that physicians report the date; the physician and facility; the referring physician or agency; the type of procedure, the woman's age and her number of prior pregnancies and abortions; gestational age; type of procedure; any pre-existing medical conditions that would complicate pregnancy; medical complications with the abortion; the basis for any determination of medically necessity; and the weight of the aborted fetus. 505 U.S. at 900. In *Danforth*, the Court held that "[r]ecordkeeping and reporting requirements that are reasonably directed to the preservation of maternal health and that properly respect a patient's confidentiality and privacy are permissible." 428 U.S. at 80. In *Ashcroft*, the Court upheld the requirement of a pathology report regarding fetal tissue. 462 U.S. at 489–90.

Much of the information required under Indiana law is materially identical to that required by the Pennsylvania statute at issue in *Casey*. *Compare* Ind. Code § 16-34-2-5(a)(1),(4)–(6), (8), (13)–(18), (20)(A)–(B), (20)(E), (21)–(22), (24)–(26), (29) *with* 505 U.S. at 909–11. And requiring reporting of the results of a pathological examination, Ind. Code § 16-34-2-5(a)(27), was approved in *Ashcroft*. 462 U.S. at 489–90. Other requirements include basic statistical information, Ind. Code § 16-34-2-5(a)(7), (10)–(12), (30), approved in *Danforth*. 428 U.S. at 80. And other reporting requirements aid the State in enforcing its other abortion regulations, including parental consent, Ind. Code § 16-34-2-5(a)(2); prohibitions against abuse, harassment, coercion, and trafficking, *id.* § 16-34-2-5(a)(19); informed consent, *id.* § 16-34-2-5(a)(23); and the requirement that life-sustaining

care be administered to a fetus born alive, *id.* § 16-34-2-5(a)(28). The constitutionality of the reporting requirements follows from the constitutionality of the substantive requirements they help to enforce. *See infra* Part III.E–F (informed consent), Part III.G (parental consent).

Indiana also requires physicians to report "the marital status of a patient." *Id.* § 16-34-2-5(a)(9). While *Casey* invalidated subsection 12 of the Pennsylvania statute which required the reporting of the patient's marital status, it did so only because the subsection also required the reporting of "a married woman's 'reason for failure to provide notice' to her husband." 505 U.S. at 901. Indiana's marital status requirement requires no such unconstitutional spousal notification; Indiana merely seeks to know the marital status of women seeking abortions for statistical purposes. Consequently, this requirement is constitutional under *Casey* and *Danforth*.

Indiana requires that physicians report "[t]he gender of the fetus, if detectable" and "[w]hether the fetus has been diagnosed with or has a potential diagnosis of having Down syndrome or any other disability." Ind. Code § 16-34-2-5(a)(20)(C)–(D). Although the State may not prohibit abortions on the basis of gender or disability, *see Planned Parenthood of Ind. & Ky., Inc. v. Comm'r of Ind. State Dep't of Health*, 888 F.3d 300 (7th Cir. 2018), it still has a statistical interest in knowing the percentage of abortions of males versus females and the percentage of abortions where the fetus has been diagnosed with Down syndrome or another disability. Indeed, the 2020 U.S. census also asks about disability for similar statistical purposes. *See* Exhibit 37, U.S. Census Bureau, *American Community Survey Questionnaire* (2019), at 9.

Finally, the State requires physicians to report "[w]hether a waiver of notification under section 4 of this chapter was obtained." Ind. Code § 16-34-2-5(a)(3). Section 4 is currently enjoined, *see Planned Parenthood of Ind. & Ky., Inc. v. Adams*, 937 F.3d 973 (7th Cir. 2019), so physicians

may simply report that no waiver was obtained. This Court should grant summary judgment to the State on the reporting requirements: Ind. Code §§ 16-34-2-5(a), 16-34-2-5.1, 16-34-2-5(b).

E. Indiana's truthful, non-misleading informed-consent disclosures have been upheld

Whole Woman's Health challenges Indiana's informed-consent requirements. Ind. Code §§ 16-34-2-1.1(a)–(b), 16-34-2-1.5. Under these provisions, at least 18 hours before the abortion the physician or the physician's designee must inform the woman of certain listed information. *Id.* § 16-34-2-1.1(a)(1)–(2). And the pregnant woman must certify in writing that she has received this information. *Id.* § 16-34-2-1.1(a)(3). If the unborn child has been diagnosed with a lethal fetal anomaly, the physician must inform her "of the availability of perinatal hospice services" and provide her with the "perinatal hospice brochure." *Id.* § 16-34-2-1.1(b). All women must be provided the informed consent brochure. *Id.* § 16-34-2-1.5(b).

The Supreme Court has long upheld informed-consent requirements. In *Casey*, the Court upheld requirements that "a physician inform the woman of the nature of the procedure, the health risks of the abortion and of childbirth, . . . the probable gestational age of the unborn child," and "the availability of printed materials published by the State describing the fetus and providing information about medical assistance for childbirth, information about child support from the father, and a list of agencies which provide adoption and other services as alternatives to abortion." 505 U.S. at 881. The Court first explained that "as with any medical procedure, the State may require a woman to give her written informed consent to an abortion." *Id.* But then it went even further, holding that the State may "require doctors to inform a woman seeking an abortion of the availability of materials relating to the consequences to the fetus, even when those consequences have no direct relation to her health." *Id.* at 882. The Court concluded that informed-consent laws violate

neither the Due Process Clause nor the First Amendment, provided that "the information the State requires to be made available to the woman is truthful and not misleading." *Id.*

Much of the informed-consent information required by the Indiana statutes is identical or materially similar to the Pennsylvania statute upheld by the Court in *Casey*. *Compare* Ind. Code §§ 16-34-2-1.1(a)(1)(C)–(D), (F), (H), (2)(A)–(D), (F), 16-34-2-1.5(b)(1)–(6) *with* 505 U.S. at 881.

Statute Upheld in *Casey* *See* 505 U.S. at 902–03	**Similar Indiana Requirement** *See* Ind. Code § 16-34-2-1.1.	**Indiana Brochure** *See* Ind. Code § 16-34-2-1.5.
The nature of the proposed procedure or treatment and of those risks and alternatives to the procedure or treatment that a reasonable patient would consider material to the decision of whether or not to undergo the abortion.	The nature of the proposed procedure or information concerning the abortion inducing drug. Objective scientific information of the risks of and alternatives to the procedure or the use of an abortion inducing drug. That there are physical risks to the pregnant woman in having an abortion, both during the abortion procedure and after.	Objective scientific information concerning the medical risks associated with each abortion procedure or the use of an abortion inducing drug.
The probable gestational age of the unborn child at the time the abortion is to be performed.	The probable gestational age of the fetus at the time the abortion is to be performed.	Objective scientific information concerning the probable anatomical and physiological characteristics of a fetus every two (2) weeks of gestational age.
The medical risks associated with carrying her child to term.	The medical risks associated with carrying the fetus to term.	Information concerning the medical risks associated with carrying the child to term.
The department publishes printed materials which describe the unborn child and list agencies which offer alternatives to abortion and that she has a right to review the printed materials and that a copy will be provided to her free of charge if she chooses to review it.	That adoption alternatives are available and that adoptive parents may legally pay the costs of prenatal care, childbirth, and neonatal care. The: (i) Internet web site address of the state department of health's web site; and (ii) description of the information that will be provided on the web site.	Information regarding telephone 211 dialing code services for accessing human services as described in IC 8-1-19.5, and the types of services that are available through this service.

Medical assistance benefits may be available for prenatal care, childbirth and neonatal care, and that more detailed information on the availability of such assistance is contained in the printed materials published by the department.	That medical assistance benefits may be available for prenatal care, childbirth, and neonatal care from the county office of the division of family resources.	Information that medical assistance benefits may be available for prenatal care, childbirth, and neonatal care.
The father of the unborn child is liable to assist in the support of her child, even in instances where he has offered to pay for the abortion. In the case of rape, this information may be omitted.	That the father of the unborn fetus is legally required to assist in the support of the child. In the case of rape, the information required under this clause may be omitted.	Information that the biological father is liable for assistance in support of the child, regardless of whether the biological father has offered to pay for an abortion.

Other provisions simply provide emergency contact information for the physician and the abortion clinic, Ind. Code § 16-34-2-1.1(a)(1)(A)–(B), (2)(G), information concerning available services, including ultrasound imaging, post-abortion counseling, and perinatal hospice, *id.* § 16-34-2-1.1(a)(1)(I), (2)(J), (b), and information concerning relevant provisions of Indiana law—such as the requirement that pregnancy of a child under age fifteen must be reported to the Department of Child Services, the existence of Indiana's safe haven law, and the right of the pregnant woman to determine the final disposition of the fetus, *id.* §§ 16-34-2-1.1(a)(1)(J), (2)(E), (H)–(I), 16-34-2-1.5(b)(7)–(8). These disclosures all accurately reflect rights and obligations under state law, and Whole Woman's Health cannot present any evidence disputing them.

In its complaint, Whole Woman's Health directly contests the truthfulness of only one provision of Indiana's informed-consent law: "That human physical life begins when a human ovum is fertilized by a human sperm." ECF No. 1 ¶¶ 133–35 (quoting Ind. Code § 16-34-2-1.1(a)(1)(E)). But one of Whole Woman's Health's own witnesses, Dr. Martin Haskell, admitted that this statement is true: "I agree that in most cases when the human sperm fertilizes the human ovum that development is beginning towards, you know, creating a person." Ex. 24 at 95:9–12. Whole

Woman's Health's bioethics expert, Dr. Lucia D. Wocial, also admits in her declaration that "[b]iological life, the moment when egg and sperm join to make a zygote creates a unique being with the potential to become a fully formed human." Ex. 38 ¶ 11. She argues that the provision is misleading because "[b]iological potential is not the same as achieving personhood." *Id.* But the informed-consent provision makes no reference to personhood, only to "human physical life." Ind. Code § 16-34-2-1.1(a)(1)(E). Dr. Grossman offers no opinion on when life begins, Ex. 8 19:9–19, but he admits that his own patients sometimes regard their fetus as a "child" or a "baby," *id.* 237:3–13, and that he does not "try to assure [those women] that . . . there's no life involved . . . in her fetus[.]" *Id.* 235:23–234:1. At the very least, he agreed that "people can differ" on whether to consider a fetus to be human life. *Id.* 21:9–15. Hence, there is no contested issue of fact on whether that provision is truthful.

Some of Whole Woman's Health's witnesses also contest the truthfulness of the requirement that the physician inform the woman "[t]hat objective scientific information shows that a fetus can feel pain at or before twenty (20) weeks of postfertilization age." Ind. Code § 16-34-2-1.1(a)(1)(G); *see, e.g.*, Ex. 38 ¶ 17; Ex. 36 ¶ 100. The *only* fetal pain expert in this case, however, is Dr. Maureen L. Condic, who has opined that fetal pain responses are possible in the first trimester, and that a fetus can be conscious of pain by early in the second trimester. As her declaration explains in detail, there is no scientific dispute that "the simplest neural circuitry required to detect and respond to pain is in place by 8–10 weeks of human development." Ex. 25 ¶ 25; *id.* ¶ 10. Multiple authorities suggest that the necessary development for the conscious experience of pain—specifically, connections between the spinal cord and the thalamus—develop between 12 and 18 weeks. *See id.* ¶¶ 10, 23, 32–42; Statement of Facts Part II.A.

The testimony of Drs. Grossman and Wocial is not enough to create a material issue of fact on this point. As argued above, *see supra* Part II, Dr. Grossman lacks expertise in fetal pain, and the Court should exclude his testimony on this point. Neither Dr. Grossman nor Dr. Wocial is a neurologist or neurobiologist, and neither appears otherwise qualified to offer expert opinions on fetal pain. And in any event, both Dr. Wocial and Dr. Grossmam cite only a single one-page statement from the American College of Obstetricians and Gynecologists. *See* Ex. 38 ¶ 17 & n.1; Ex. 36 ¶ 100 & n.109; Exhibit 39, American College of Obstetricians & Gynecologists, Facts Are Important: Fetal Pain (July 2013). That statement cites two literature reviews on fetal pain, but they agree with Dr. Condic on the neurological facts. Ex. 25 ¶ 26. Those reviews nonetheless *assume* that more advanced neurological development (specifically, additional neurological connections between the thalamus and the cortex) are necessary for a fetus to be conscious of pain. *Id.* ¶ 26–27. But the literature reviews "present *absolutely no data* in support of this critical claim," *id.* ¶ 29, and several lines of evidence contradict it. *Id.* ¶¶ 32–47.

Given the evidence presented by Dr. Condic, Whole Woman's Health cannot prove the fetal pain disclosure is false. The State is therefore entitled to summary judgment. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986) ("[The] mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact.").

F. The Supreme Court and Seventh Circuit both have already upheld waiting period and in-person counseling requirements

Indiana requires that the physician (or qualified designee) provide informed consent "[a]t least eighteen (18) hours before the abortion and in the private, not group, presence of the pregnant woman." Ind. Code § 16-34-2-1.1(a)(1); *see also id.* § 16-34-2-1.1(a)(2), (a)(4), (b)–(c). Whole Woman's Health challenges the waiting period and in-person counseling requirements, ECF No. 1

¶¶ 130, 197, but both the Supreme Court and the Seventh Circuit have already upheld such requirements. In *Casey*, the court upheld Pennsylvania's 24-hour waiting period, which it understood to require two trips to the abortion clinic (meaning first for in-person counseling and second for the abortion itself). 505 U.S. at 886. And in *A Woman's Choice—East Side Women's Clinic v. Newman* the Seventh Circuit upheld the same Indiana requirements at issue here. 305 F.3d 684 (2002). There plaintiffs argued that the 18-hour "in the presence" requirement "obliges the woman to make two trips to the clinic or hospital[,] . . . rais[ing] the cost (both financial and mental) of an abortion." *Id.* at 685. The court noted that "the text of this law is materially identical to the one held constitutional in [*Casey*]," *id.* at 684, and rejected the plaintiffs' evidence of declining abortion rates in Mississippi and Utah after similar statutes went into effect as "leav[ing] open both the extent to which other states would experience the same effect and the reason *why* the effect occurs," *id.* at 692.

Whole Woman's Health cannot fill that gap here. While its experts claim the 18-hour waiting period might make abortion more difficult for women in abusive relationships, it has no evidence that the waiting period/in-person combination has prevented women from having an abortion. Dr. Moseson testified that she could establish no causal or correlative link between Indiana's abortion laws and the ability of women to seek abortions in Indiana, Ex. 33 69:20–70:2, so her testimony attributing burdens to Indiana's laws should be excluded. Dr. Grossman, moreover, has conceded that a number of studies cited in his report find that waiting periods *longer* than Indiana's have *not* been shown to affect abortion rates or prevent women from obtaining abortions. Ex. 8 at 167:8–15 (24-hour waiting period), 253:21–255:2 (72-hour waiting period).

A vague idea that the waiting period and in-person counseling requirements might make it more difficult for some women to obtain abortions is not sufficient to part with *Casey* and *A Woman's Choice*. *See Casey*, 505 U.S. at 874 ("The fact that a law which serves a valid purpose,

one not designed to strike at the right itself, has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it."). Therefore, summary judgment in favor of the State is appropriate for the in-person counseling and waiting period requirements: Ind. Code §§ 16-34-2-1.1(a)(1), 16-34-2-1.1(a)(2), (a)(4), (b)–(c).

G. Indiana's parental consent and judicial bypass requirements follow *Bellotti*

Whole Woman's Health challenges Indiana's parental consent and judicial bypass requirements, Ind. Code §§ 16-34-2-1(a)(1)(C), 16-34-2-4(a), but Indiana follows the exact model approved in *Bellotti v. Baird*, 443 U.S. 622, 625–26 (1979). Under that standard, a parental consent statute must provide a judicial bypass procedure that (1) allows the minor to have an abortion without parental consent if she is sufficiently mature to make the decision on her own; (2) allows the minor to have an abortion without parental consent if it is in her best interests; (3) ensures the anonymity of the minor throughout the judicial proceeding; and (4) may be conducted expeditiously. *Id.* at 643–44. The Indiana statute meets this standard, as it requires judicial waiver of parental consent "if the court finds that the minor is mature enough to make the abortion decision independently," or "that an abortion would be in the minor's best interests." Ind. Code § 16-34-2-4(e). The statute also requires that "[a]ll records of the juvenile court and of the supreme court or the court of appeals that are made as a result of proceedings conducted under this section are confidential," § 16-34-2-4(h) and that "[t]he juvenile court must rule on a petition filed by a pregnant minor . . . within forty-eight (48) hours of the filing of the petition." *id.* § 16-34-2-4(e). It also provides that the minor "is entitled to an expedited appeal," *id.* § 16-34-2-4(g).

The testimony of Judge Charles F. Pratt and Judge Mary Beth Bonaventura establishes the efficacy of this system. Judge Pratt testified that of eleven judicial bypass cases filed in the Allen Superior Court between 1995 and 2013, nine were granted and only two were denied. Ex. 35 ¶ 9.

In each hearing, the minor was represented by a court-funded attorney, the decision was rendered within forty-eight hours of filing the petition, and the hearing was closed and confidential. *Id.* ¶¶ 10–13. Judge Bonaventura testified that the age and maturity levels of the minors vary considerably. Ex. 29 ¶ 8. Younger minors are well-served "by having a neutral judge review their circumstances and make responsible decisions regarding their welfare," *id.* ¶ 10, while the judicial bypass process "ensure[s] that older minors gave serious consideration to the decisions and had detailed conversations with a doctor and a lawyer," *id.* ¶ 11. Regardless of age, courts generally take steps to make the process more comfortable for minors. *Id.* ¶¶ 15–16.

The State's abortion ban for minors who are wards of the State, Ind. Code § 16-34-1-10, is valid because they, too, may avail themselves of the judicial bypass process. *Id.* § 16-34-2-4(b)(2). Wards are in precisely the same situation as minors whose parents refuse consent. In any event, "guardians are generally reluctant to make significant medical decisions on their own, even where having the authority to do so, and are eager to involve the Juvenile Division judges in the decision-making process." Ex. 29 ¶ 14. Summary judgment is appropriate for the State on the parental consent and judicial bypass requirements: Ind. Code §§ 16-34-2-1(a)(1)(C), 16-34-2-4(a).

H. The constitutionality of the criminal penalties for violating Indiana's abortion restrictions follow the constitutionality of the substantive provisions they enforce

Whole Woman's Health specifically challenges Indiana's criminal penalties for violating its substantive abortion regulations. ECF No. 1 ¶ 155 (challenging Ind. Code §§ 16-34-2-7(a)–(b), 16-21-2-2.5(b), 16-34-2-5(d)). But these challenges do not constitute a unique constitutional issue; the criminal prohibitions are valid if the substantive restrictions they enforce are valid. For example, the federal partial-birth abortion ban, 18 U.S.C. § 1531, imposes criminal penalties on doctors who violate its prohibitions punishable by up to two years in prison, and the Supreme Court upheld that regime in *Gonzales v. Carhart*, 550 U.S. 124, 150 (2007). Similarly, in *Casey*, the Court upheld

Pennsylvania's criminalization of informed-consent failures. 505 U.S. at 904. The analysis for Indiana's abortion regulations does not differ, so the constitutionality of Indiana's criminal penalties follows that of the substantive provisions that they enforce.

IV. Whole Woman's Health Cannot Prove That Any Challenged Statute Imposes an Undue Burden

Even apart from whether controlling precedents have already approved of Indiana's abortion statutes, Whole Woman's Health cannot supply evidence creating a genuine dispute of material fact that any statute it challenges imposes an undue burden on a woman's right to choose abortion. In this respect, a proper understanding of the decisional methodology of *Casey* and *Hellerstedt* is critical. *Casey* requires those challenging an abortion statute to prove that it creates a substantial obstacle to abortion for a "large fraction" of women. *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 874 (1992). *Hellerstedt* is properly limited to cases where a new abortion law will necessarily cause major disruption to the status quo of the abortion-provider market—a circumstance that does not describe any statute challenged in this case. But in all events it merely elaborates on *Casey* with a three-part analytical method: First, the challengers must show that a challenged regulation imposes a "substantial obstacle" on the right to choose abortion; second, if the challengers satisfy that burden, the State must demonstrate that the law serves some legitimate governmental purpose; third, "courts consider the burdens a law imposes on abortion access together with the benefits those laws confer." *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2309 (2016). Critically, the State is required to prove the benefits of the law *if and only if* the challengers can show that it imposes a substantial burden on a woman's abortion decision.

Furthermore, while the Court in *Hellerstedt* revisited the question whether admitting privileges and ASC requirements for first-trimester abortions were justified by any notion of medical necessity, it did not negate the authority of legislatures to choose one side in a reasonable dispute

over medical science. In general, courts assessing the benefits and the burdens of challenged statutes must defer to the government on questions of legislative fact, *i.e.*, facts about the state of the world, unless "the legislative facts . . . could not reasonably be conceived to be true by the governmental decisionmaker." *Vance v. Bradley*, 440 U.S. 93, 111 (1979). In the abortion context, the Supreme Court in *Gonzales v. Carhart* held that courts should defer to legislative decisionmaking when it comes to taking sides in a medical dispute. *See* 550 U.S. 124, 163 (2007) ("The Court has given state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty."). To be sure, in *Hellerstedt* the Court refused to defer to Texas regarding whether health and safety concerns justified the State's admitting privileges and ASC requirements, but only because Texas had presented *no* evidence that the requirements furthered its interests. *See* 136 S. Ct. at 2311 ("We have found nothing in Texas' record evidence that shows that, compared to prior law . . . the new [admitting privileges] law advanced Texas' legitimate interest in protecting women's health."); *id.* at 2316 ("The upshot is that this record evidence [regarding the surgical center requirement's lack of health benefits], along with the absence of any evidence to the contrary, provides ample support for the District Court's conclusion [that the law was unjustified].").

The way to reconcile *Gonzales* and *Hellerstedt* is to say that, where the plaintiff demonstrates that an abortion law imposes a substantial burden on the right to choose abortion, the State may be required to present at least *some* evidence that a challenged statute furthers its legitimate interests, but that courts must defer to legislative judgments when the medical benefits or burdens of the statute at issue are genuinely disputed. *See Gonzales v. Carhart*, 550 U.S. 124, 166–67 (2007). Here, Whole Woman's Health cannot carry its burden of demonstrating that any of the challenged statutes imposes a substantial burden on the right to choose abortion, so the Court need not even attempt to reconcile *Hellerstedt* and *Gonzales* on this point.

Regardless, the State supplies evidence that the law advances legitimate (indeed, compelling) government interests, and even if Whole Woman's Health supplies evidence suggesting that reasonable people could differ over those interests or the degree to which the law advances them, such evidence does not create a genuine dispute of material fact precluding summary judgment for the State. With reasonably disputed medical science, legislatures may decide which side is more likely correct without being second-guessed via trial in federal court.

A. Whole Woman's Health has failed to establish that any of the challenged statutes imposes a substantial obstacle on women seeking abortions

This case may be resolved under the first step of the test: Whole Woman's Health has no evidence that the challenged statutes impose a substantial obstacle on women considering abortion. In a case where questions of causation are complex and not "obvious to laymen," expert testimony is necessary to show causation. *Myers v. Illinois Cent. R. Co.*, 629 F.3d 639, 643 (7th Cir. 2010). And Dr. Moseson, Whole Woman's Health's epidemiology expert, *agreed* that "nationally there is no consistent association between 'restrictive' abortion laws and the variation in abortion rates or the decline in the number of abortions." Ex. 33 at 152:18–153:5, 160:15–18. Plaintiffs must therefore provide expert testimony sufficient to establish how the challenged laws burden abortion.

But, once again, Dr. Moseson testified that she had *not* established a causal link between Indiana's abortion laws and the Indiana abortion rate. *Id.* at 69:20–25. When asked whether "the disparity . . . between the rate [of abortion] in Indiana and the rate in [Illinois, Ohio, and the United States] is caused by the Indiana laws that are at issue in this case," Dr. Moseson answered that she "ha[d] not done quantitative causal analysis of these data to say that." *Id.* at 66:12–19. She then admitted that her report did not even "establish a formal statistical association" between the laws at issue and the difference in abortion rates, *id.* at 68:25–69:5, and that without that association, her report could not "establish that the laws at issue actually cause the difference in abortion rates," *id.*

at 69:22–25. And because her expert report should be excluded in its entirety, Plaintiffs have no evidence whatsoever of substantial burden. The State is therefore entitled to summary judgment on all claims.

B. The benefits of the challenged statutes outweigh any plausible burdens they impose

The targeted statutes serve government interests much weightier than any burdens even remotely attributable to them.

1. Licensing and inspections promote safety, fetal life, and the medical profession

Indiana law requires abortion facilities to have a license and undergo regular inspections. *See* Ind. Code §§ 16-18-2-1.5(a), 16-21-1-7, 16-21-2-2(4), 16-21-2-2.5(a), 16-21-2-10 to 16-21-2-11, 16-21-2-14; 410 Ind. Admin. Code art. 26. Indiana's licensing and inspection rules—"well within the realm of accepted regulations of medical practices," *Whole Woman's Health All. v. Hill*, 937 F.3d 864, 875 (7th Cir. 2019)—serve compelling interests in protecting women's health, promoting fetal life, and safeguarding the integrity of the medical profession. Abortion carries the risk of short-term and long-term complications, so licensing and inspections are necessary to ensure that abortion providers are qualified, competent, law-abiding, and trustworthy to perform abortions safely and consistent with Indiana's informed-consent and reporting requirements. Ex. 1 ¶ 12; Ex. 3 ¶ 13, 49. Through regular surveys, ISDH reviews medical records, checks adherence to equipment, medication and general safety protocols, and inspects equipment sterilization. Ex. 16 at 48:18–50:12. One result is better compliance and fewer "medically oriented citations or deficiencies." *Id.* at 51:1–14. Licensing allows ISDH to "deal with problems, to preempt problems, and also be . . . more timely in dealing with complaints or issues that arise." Ex. 17 at 102:23–103:3. The still-unfolding Klopfer saga powerfully dramatizes the need for licensing and inspections. *See supra*, Statement of Facts Part I.F.

Accordingly, the interests furthered by Indiana's licensing and inspection rules easily outweigh any burden these rules could plausibly impose, particularly in light of the six abortion providers operating in Indiana who have encountered no trouble in obtaining and maintaining their licenses or complying with state inspections. Ex. 16 at 68:6–14; *see also* Exhibit 40, Indiana State Department of Health, *Abortion Center Directory* (Oct. 24, 2019).

2. The physician-only requirement promotes safety

Only a physician may perform an abortion or prescribe an abortion-inducing pill, Ind. Code § 16-34-2-1(a)(1)(A), 410 Ind. Admin. Code 26-13-2(b), a requirement that advances the State's interest in ensuring patient safety. *See Mazurek v. Armstrong*, 520 U.S. 968, 974–75 (1997) ("[T]o ensure the safety of the abortion procedure, the States may mandate that only physicians perform abortions."). As the State's experts establish, allowing only physicians to perform abortions ensures a patient's safety because it reduces the risk of complications and ensures better care if complications do occur. Ex. 1 ¶ 34. Dr. Glazer even testified at his deposition of the necessity for physician care for abortion procedures. *See supra*, Statement of Facts Part I.B.

On the burden side, Whole Woman's Health cannot prove that limiting abortion practice in this way poses a substantial obstacle to abortion. Indeed, Dr. Grossman admits that he has no evidence that Indiana abortion clinics are "capacity limited by lack of providers." Ex. 8 at 108:19–24. And Whole Woman's Health's epidemiology expert disclaimed any causal or associational relationship between the challenged Indiana statutes and the State's abortion rate. Ex. 33 at 69:20–25. Therefore, this Court should grant summary judgment to the State on the physician-only requirement: Ind. Code § 16-34-2-1(a)(1)(A); 410 Ind. Admin. Code 26-13-2(b).

3. The ASC/hospital requirement ensures safety of late-term abortions

Second trimester abortions may only be "performed in a hospital or ambulatory outpatient surgical center," Ind. Code § 16-34-2-1(a)(2)(B), which ensures the health and safety of women undergoing more complex and risky procedures associated with second-trimester abortion—such as dilation and evacuation, which is a surgical procedure that requires anesthesia. *See supra,* Statement of Facts Part I.E. Such treatment must occur in a hospital or outpatient surgical setting both to provide pain management and to provide resources to manage complications such as retained placenta, uterine perforation and cervical damage. Ex. 2 ¶ 28, 37. Despite these restrictions on second-trimester abortions, such abortions remain available in Indiana, *see* Exhibit 41, Excerpts from Deposition of Caitlin Bernard 10:25–11:5, 13:5–14:1, and in all events the restrictions advance weighty government interests in patient safety that justify any burden on access to abortion.

4. The benefits of reporting requirements outweigh any burdens

Indiana law requires abortion providers to file terminated pregnancy reports containing specified information for each abortion with ISDH. *See* Ind. Code §§ 16-34-2-5(a), 16-34-2-5.1, 16-34-2-5, 16-34-2-5.1. If the patient is less than sixteen years old, the report must be separately sent to the Department of Child Services within three days of the abortion. *Id.* § 16-34-2-5(b). These requirements serve the State's compelling interests in developing and maintaining public health records, encouraging compliance with abortion regulations, and promoting both fetal life and women's health and safety. Doctors who practice medicine and care for patients on a daily basis in Indiana are used to completing reports, including birth certificate forms, which require the same information as a termination report. Ex. 28 at 86:12–90:13. *See also supra,* Statement of Facts Part I.D. Data collection for abortion generally is "woefully lacking in the U.S.," which is a problem because "comprehensive data collection is the foundation of good epidemiological study," and the

lack of it has "significant implications for the health of women." Ex. 3 ¶ 136. Reporting requirements also help protect minors from sexual predators. Ind. Code § 16-34-2-5(a)(19).

Indiana's reporting requirements are not excessively burdensome and are a normal part of medical practice. Their benefits clearly outweigh any burdens.

5. By promoting better decisions, the informed-consent requirements promote medical ethics, maternal psychological health, and fetal life

Indiana law requires abortion providers to obtain informed consent before performing an abortion. Ind. Code §§ 16-34-2-1.1(a)–(b), 16-34-2-1.5. In order to ensure the consent is truly informed, Indiana requires qualified medical personnel to provide a pregnant woman with an informed-consent brochure supplied by ISDH and other specified information at least 18 hours before the abortion—and requires the pregnant woman to certify that she received the information. *Id.* §§ 16-34-2-1.1(a)(1)–(3), 16-34-2-1.5(b); Exhibit 22. If the woman's unborn child has been diagnosed with a lethal fetal anomaly, the physician must inform her "of the availability of perinatal hospice services" and provide her with the "perinatal hospice brochure," Ind. Code § 16-34-2-1.1(b).

Indiana's informed-consent statute protects women's psychological health by ensuring that they are provided enough information to make a fully informed and well-thought-out decision. A general principal accepted in the ethics of informed consent is that "the level of detail of the information provided and the amount of time spent on the informed-consent process should be commensurate with what is at stake in the specific medical decision." Ex. 14 ¶ 20. As even Whole Woman's Health recognizes, the "decision of whether and when to remain pregnant and give birth has significant implications for a person. It affects, among other things, the person's bodily integrity, autonomy, financial and job security, workforce participation, educational attainment, ability to parent existing children, and health." ECF No. 1 ¶ 28.

The informational brochure enhances the probability of quality decision-making, because it can be difficult to fully absorb orally delivered information under stress. This brochure gives the women the opportunity to review the information as many times as needed during the mandated waiting period. Ex. 6 ¶ 191. It provides illustrations of a fetus and fetal viability information at different weeks of gestation, which provide a more complete understanding of the gravity of the abortion decision. And the perinatal hospice information helps a pregnant woman bearing a baby with a lethal fetal anomaly understand that an alternative to abortion exists—namely, an opportunity for dignified and loving care for the child, no matter how short the life.

Informed consent is standard practice in any medical setting, and even Dr. Stecker admits that she regularly provides written material to aid patients. Ex. 23 at 90:4–25. *See also supra,* Statement of Facts, Part II.A. Ample evidence demonstrates that women seeking an abortion benefit from more information and more time to make the decision. And Whole Woman's Health can provide no evidence that the informed consent requirements pose a substantial obstacle to abortion. These requirements must therefore be upheld.

6. The waiting period and in-person counseling requirements allow a critical period of reflection

Indiana law requires that a physician providing an abortion or the physician's designee provide informed consent "[a]t least eighteen (18) hours before the abortion and in the private, not group, presence of the pregnant woman." Ind. Code § 16-34-2-1.1(a)(1); *see also id.* § 16-34-2-1.1(a)(2), (a)(4), (b)–(c). It is the norm in other areas of medicine that some period of time pass between the initial consultation and the planned procedure, and it is no less important in the abortion context, where the decision has significant implications and is irreversible. Ex. 14 ¶ 30.

The waiting period and in-person consultation requirements protect fetal life and maternal mental health by giving women time to weigh the gravity of the abortion decision. *See supra*, Statement of Facts, Part II.B. These requirements ensure that "ambivalent women and those pressured will have sufficient opportunity to consider options and secure feedback and assistance from trusted others" and "help[] women who are highly susceptible to negative post-abortion consequences . . . arrive at healthy pregnancy decisions." Ex. 6 ¶ 184. This includes women "in abusive relationships, sexually exploited youth, women confronting a significant fetal-anomaly, and those who have pre-existing mental illnesses." *Id.*

The in-person counseling requirement is important since "[i]n-person interactions are superior to remote interactions for decisions of that weight" because they "lead[] to better eye contact, greater ability to read body language, and overall development of a real person-to-person relationship between doctor and patient." Ex. 3 ¶ 143. Indeed, it may very well be that "presenting the information in person is critical to its persuasive effect." *A Woman's Choice-East Side Women's Clinic v. Newman*, 305 F.3d 684, 690 (7th Cir. 2002). Regardless, Plaintiffs lack evidence that waiting period and in-person counseling rules pose substantial obstacles to abortion.

7. Requiring parental consent, subject to judicial bypass, reasonably safeguards the rights and interests of parents and minor children

Indiana law generally requires the consent of an unemancipated minor's parents before she may undergo an abortion, but the law provides for judicial bypass of this requirement where "the minor is mature enough to make the abortion decision independently or [where] an abortion would be in the minor's best interests." Ind. Code § 16-34-2-4(e). *See generally See id.* §§ 16-34-2-4, 16-34-2-1(a)(1)(C). The parental consent statute serves "the special interest of the State in encouraging an unmarried pregnant minor to seek the advice of her parents in making the important decision whether or not to bear a child." *Bellotti v. Baird*, 443 U.S. 622, 639 (1979); *see also* Statement of

Uncontested Facts, Part III, *supra* (testimony of Dr. Stroud as to benefits of parent-child interaction with respect to the abortion decision). Yet the statute also affords expedited consideration by a juvenile court and expedited appeal—a process that is highly efficient and effective in safeguarding minors' rights. Ex. 35 ¶¶ 10–15; Ex. 29 ¶¶ 10–11. Accordingly, the benefits of the parental consent requirement to all concerned outweigh burdens on minors, as effective and expeditious judicial bypass procedures provide an alternative path to abortion in appropriate cases.

8. Indiana requires that abortion-inducing drugs be provided consistent with FDA approval, which is plainly reasonable and justified

Indiana law requires that "an abortion inducing drug may not be dispensed, prescribed, administered, or otherwise given to a pregnant woman after nine (9) weeks of postfertilization age unless the Food and Drug Administration has approved the abortion inducing drug to be used for abortions later than nine (9) weeks of postfertilization age." It also requires, "in accordance with FDA guidelines, the physician shall provide the pregnant woman with a copy of the manufacturer's instruction sheets and require that the pregnant woman sign the manufacturer's patient agreement form. The physician shall retain a copy of the signed patient agreement form, and the signed physician's agreement form required by the manufacturer, in the patient's file." Ind. Code § 16-34-2-1(a)(1). The Indiana statute permits "both regimes for administration of Mifeprex now approved by the FDA." Ex. 4 ¶ 7. The Sixth Circuit has already upheld a similar Ohio law. *Planned Parenthood of Sw. Ohio Region v. Dewine*, 696 F.3d 490, 517 (6th Cir. 2012) (upholding statute permitting only the FDA-approved protocol of mifepristone).

Critically, while Whole Woman's Health vaguely challenges this provision by arguing that the statute prevents "abortion providers from incorporating scientific advancements in the provision of medication abortion," ECF No. 1 at ¶ 101, they do not "disclose an intention to employ any regimen for administration of Mifeprex other than the regimens already approved." Ex. 4 ¶ 7. In

any event, the challenged statute allows for any scientific advancements in abortion inducing drugs approved by the FDA to be incorporated. "The FDA considers the off-label use of Mifeprex prohibited due to serious concerns about safety," and using regimens "other than those approved by the FDA. . . would risk the health and safety of women in Indiana." *Id.* at ¶ 23.

Given the safety benefits of requiring compliance with FDA approvals and Whole Woman's Health's lack of any alternative protocol, this requirement's benefits plainly outweigh any burdens.

9. The ultrasound requirement is critical for informed consent, patient physical and mental health, and even fetal life

Consistent with professional standards—and Whole Woman's Health's own practices—Indiana requires abortion providers to perform an ultrasound before performing an abortion. Ind. Code § 16-34-2-1.1(a)(5). The ultrasound requirement has many benefits, including requiring providers to obtain informed consent, accurately identifying the gestational age of the baby, requiring providers to adhere to the appropriate standard of care in the prenatal context, and assisting providers in identifying which procedures (abortion or otherwise) may be indicated or contraindicated for a given patient. Ex. 2 ¶¶ 53–55; Ex. 13 134:9–25; Ex. 3 ¶¶ 144–145; Ex. 14 ¶¶ 42–45.

Whole Woman's Health alleges that "the ultrasound requirement codified at Ind. Code § 16-34-2-1.1(a)(5) [is a substantial obstacle][] to the extent it requires providers to perform, and patients to undergo, often redundant and medically unnecessary ultrasound examinations." ECF No. ¶ 130(c). Yet, Dr. Glazer himself has stated multiple times that he performs ultrasounds as part of his own abortion practice. Ex. 7 at 33:20–34:17, 43:4–8, 44:4–11, 47:24–48:3, 51:8–14, 56:6–19, 59:1–60:17, 90:1–8, 96:23–97:10. Ultrasounds cannot be both medically unnecessary and standard practice for Whole Woman's Health. If it is already performing fetal ultrasounds and will continue to do so, it is not burdened by Indiana Code § 16-34-2-1.1(a)(5). Regardless, requiring a pregnant woman to have and view (or not) an ultrasound does not even implicate abortion access.

Ultrasound requirements have been almost universally upheld against undue burden challenges. *See Planned Parenthood of Wis., Inc. v. Van Hollen*, 738 F.3d 786, 803–04 (7th Cir. 2013); *EMW Women's Surgical Ctr., P.S.C. v. Beshear*, 920 F.3d 421, 446 (6th Cir. 2019); *Tex. Med. Providers Performing Abortion Servs. v. Lakey*, 667 F.3d 570, 580 (5th Cir. 2012); *Falla Church Medical Ctr., LLC v. M. Norman Oliver*, No. 3:18-cv-428, 2019 WL 4794529 (E.D. Va. Sept. 30, 2019); *Summit Med. Ctr. Of Ala. v. Siegelman*, 227 F.Supp. 2d 1194 (M.D. Ala. 2002). This Court should uphold Indiana's as well.

10. The facility requirements ensure patient safety and burden neither Whole Woman's Health nor other Indiana abortion providers

Indiana law requires abortion clinics providing surgical abortions to meet minimum safety requirements. Ind. Code 16-21-2-2.5(a)(2) (ISDH's authority to promulgate rules), 16-18-2-1.5(a)(2) (definition of abortion clinic); 410 Ind. Admin. Code, art. 26, including 410 Ind. Admin. Code §§ 26-10-1(b)(5) (observance of patient during recovery), 26-11-2(a) (sterilization of equipment), 26-11-3 (laundry), 26-13-1 (anesthesia), 26-13-3(b)–(c) (equipment), 26-17-2(c)(3)–(4) (access to certain facilities or equipment), 26-17-2(d)(1)–(4) (clinical facilities requirements), (d)(6) (drug distribution station), 26-17-2(e)(1) (housekeeping), (8) (antiscalding requirements). Again, these facility requirements are not applicable to clinics offering only medication abortions, so Whole Woman's Health is not burdened by them and lack standing to challenge them.

In any event, the facility requirements advance the health and safety of pregnant women seeking surgical abortions and closely track facility recommendations made by ACOG itself:

ACOG Recommendation	ISDH Regulation
The clinic should "[a]rrange for transfer agreement with local hospital."	"The clinic shall develop, implement, and maintain . . . [w]ritten procedures for . . . [t]ransfer." 410 I.A.C. 26-5-2(a)

The clinic should provide resuscitation equipment including defibrillator, emergency medication, and an advanced cardiac life support, pediatric advanced life support, or basic life support certified physician or other certified health care professional immediately available to provide emergency resuscitation.	"The clinic shall provide immediate lifesaving measures . . . to all persons in the clinic, to include . . . [t]imely assessment [and b]asic life support." 410 I.A.C. 26-5-2(b)
The clinic should train and enable personnel to quickly respond to emergency situations and provide a reliable oxygen source and resuscitation equipment including defibrillator.	"The following equipment and supplies must be available to the procedure and recovery areas: (1) Emergency call system. (2) Oxygen. (3) Resuscitation equipment." 410 I.A.C. 26-13-3(b)
The clinic must comply with state board of pharmacy and Drug Enforcement Administration.	"The clinic must provide drugs and biologicals in a safe and effective manner in accordance with accepted professional practice." 410 I.A.C. 26-16-1
The clinic must comply with local building codes, fire codes, and the Occupational Safety and Health Administration.	"The clinic must provide a physical plant and equipment that meets the statutory requirements and regulatory provisions of the fire prevention and building safety commission, Indiana fire prevention codes, and Indiana building codes." 410 I.A.C. 26-17-1(a)(2) (internal citations omitted)
The clinic should provide sufficient space for the treatment of possible complications including vasovagal episode, local anesthetic complication, cardiac event, allergic reaction, uterine hemorrhage, respiratory arrest, and excessive sedation.	"Procedure rooms shall be segregated and removed from general traffic flow and be a minimum of . . . one hundred twenty (120) square feet . . . for procedures requiring only local analgesia or nitrous oxide [and] two hundred fifty (250) square feet . . . for procedures that require conscious sedation." 410 I.A.C. 26-17-2(d)(1)
The clinic should provide for sterility.	"A hand washing station shall be included within each procedure room. . . . Scrub facilities . . . shall be provided near the entrance of procedure rooms . . . . A toilet room containing a lavatory for hand washing shall be accessible from all examination and procedure rooms." 410 I.A.C. 26-17-2(d)(3), (4), (7); *see also* 410 I.A.C. 26-11-2 (sterility requirements)
The clinic should provide a "designated recovery area adequately staffed and equipped to assure that the patient has the level of monitoring appropriate for the procedure and anesthesia."	"A separate recovery room or area shall be included . . . ." 410 I.A.C. 26-17-2(d)(4)

See Ex. 15.

Indiana has five surgical abortion clinics, each of which complies with these requirements. Exhibit 42, Expert Report and Declaration of Matthew Foster ¶ 9. Whole Woman's Health cannot demonstrate an excessive burden.

11. The in-person physician examination and telemedicine rules ensure patient safety and medication control

Indiana law requires a physician to examine a pregnant woman in person—which necessarily excludes "examination" via telemedicine services—before prescribing or dispensing an abortion-inducing drug. Ind. Code §§ 16-34-2-1(a)(1), 25-1-9.5-8(a)(4). The in-person physician examination requirement and telemedicine ban advance the State's interests in health and safety. An in-person examination is critical for determining the gestational age of the fetus—patient reporting of last menstrual period is an unreliable alternative method. *See supra* Statement of Facts Part I.B. Meeting the patient in-person also helps physicians confirm the patient's medical history and rule out ectopic pregnancy and other complications that might make medication abortion unsafe. *Id.* An in-person examination (and telemedicine ban) also helps facilitate informed consent by providing "better eye contact, greater ability to read body language, and overall development of a real person-to-person relationship between doctor and patient. Ex. 3 ¶ 143. It also enables the physician "to immediately perform a physical examination if the conversation reveals cause for one." *Id.*

Finally, these requirements prevent the diversion of mifepristone, misoprostol and other drugs prescribed in connection with the abortion, including opioids. Indiana prohibits the prescription of particularly dangerous drugs, including both opioids and abortion-inducing drugs, through telemedicine. Ind. Code § 25-1-9.5-8(a)(3)–(4). Fundamentally, "in the case of telemedicine it is not possible for the doctor to be sure who takes the prescribed drugs." Ex. 3 ¶ 146. For these reasons, the benefits of the telemedicine ban and in-person examination requirement outweigh its burdens, and this Court should grant summary judgment to the State.

12. The admitting-privileges requirement promotes continuity of care and deters patient dumping

Indiana requires physicians who provide abortions to have admitting privileges "in writing at a hospital located in the county where abortions are provided or in a contiguous county." Ind. Code § 16-34-2-4.5(a)(1). This requirement advances the State's interest in women's health and safety by ensuring patient safety and continuity of care. A physician with admitting privileges at a reasonably proximate hospital (no further than the next county) is in a position to provide hands-on care in the event of an emergency; "[i]deally, a doctor would have admitting privileges in place to allow him/her to continue caring for the patient in a seamless manner, minimizing delays of care caused by confusion in the admission process." Ex. 1 ¶ 18. An absence of admitting privileges could lead to patient dumping, where patients are left in the care of physicians who were not present when a serious complication arose. "No other group of doctors performing significant medical procedures away from hospitals conduct themselves that way: it is simply not done." Ex. 3 ¶ 107. *See also supra,* Statement of Facts Part I.C.

Additionally, the admitting-privileges requirement "protects patients by requiring a peer-review process to maintain competency in the care of patients, particularly those undergoing surgical procedures." Ex. 3 ¶ 98. A physician who provides outpatient surgery but does not regularly admit patients to a hospital may be permitted to join the hospital's courtesy staff, and on that basis, have admitting privileges. Courtesy privileges are a way to ensure admitting doctors are able to "take responsibility for their own complications" and provide continuing, hands-on care for their patients. *Id.* ¶ 109.

Indiana's admitting-privileges requirement differs in at least three significant ways from the Texas law invalidated in *Hellerstedt*: (1) Indiana permits privileges at hospitals at a distance of greater than 30 miles from an abortion clinic; (2) Indiana, unlike Texas, permits satisfaction of this

requirement via backup physician; and (3) Indiana's admitting privileges law does not threaten to shut down any existing clinics. Indeed, for Whole Woman's Health, ISDH already determined that the admitting privileges held by a back-up physician satisfied the statutory requirements. ECF No. 92-2 ¶ 44. Given the ease with which Indiana abortion clinics have been able to comply with the admitting privileges requirement, there is no case to be made that its burdens outweigh its benefits.

V. Whole Woman's Health's "Cumulative Burdens" Claim Is Not Valid

In addition to its separate undue burden challenges against each law, Whole Woman's Health argues that even if each challenged statute does not impose an undue burden individually, Indiana's abortion laws "collectively[] impose an undue burden on access to previability abortion in Indiana." ECF No. 1 ¶ 197. This is not a valid theory under *Casey* or *Hellerstedt*.

First, the Seventh Circuit already rejected the cumulative burdens theory in this case. In its preliminary injunction opinion, this Court had concluded that a "confluence of factors"—including Indiana's 18-hour pre-abortion in-person counseling requirement, "high monetary costs undefrayed by state aid," a "reportedly hostile" "social environment," and "the high opportunity costs" of obtaining an abortion—made Indiana's licensing requirement for a clinic in South Bend unduly burdensome. 388 F. Supp. 3d at 1047–48. The Seventh Circuit repudiated such reasoning, rejecting a "wholesale exemption from licensing" in South Bend notwithstanding the district court's "cumulative burden" finding. 2019 WL 3949690 at *11. *But see Planned Parenthood of Ind. & Ky. v. Adams*, 937 F.3d 973, 986 (7th Cir. 2019) ("Cumulative effects are relevant.").

Moreover, the Supreme Court has long evaluated undue burden challenges by considering one statute or regulation at a time, rather than looking at all the statutes cumulatively. For instance, in *Casey*, the Court examined one-at-a-time multiple provisions of Pennsylvania's abortion statute, invalidating the spousal notification requirement, but not the remaining regulatory scheme. *See* 505

U.S. at 879 ("We now consider the separate statutory sections at issue."). The Court has taken the same approach in numerous cases. *See Doe v. Bolton*, 410 U.S. at 193–202 (evaluating the constitutionality of multiple statutes individually); *Webster v. Reproductive Health Servs.*, 492 U.S. 490, 504 (1989) (analyzing five provisions of Missouri abortion law "seriatim"); *Planned Parenthood of Cent. Mo. v. Danforth*, 428 U.S. 52, 62–63 (1976) ("Our primary task . . . is to consider *each of the challenged provisions* of the new Missouri abortion [statute] in the particular light of . . . Roe and . . . Doe.") (emphasis added). *Contra Ohio v. Akron Ctr. for Reproductive Health*, 497 U.S. 502, 527 (1990) (Blackmun, J., dissenting) (criticizing the majority for "consider[ing] each provision in a piecemeal fashion, never acknowledging or assessing the 'degree of burden that the entire regime of abortion regulations' places' on the minor [seeking an abortion].").

The Fifth Circuit has also cast doubt on the "cumulative burdens" theory. In *In re Gee*, that court, while expressly reserving ultimate judgment on the "cumulative burdens" theory, criticized the theory as "unprecedented" and "not blessed" by the Supreme Court. No. 19-30353, 2019 WL 5274960, at *14 (5th Cir. Oct. 18, 2019). It explained that "the Court has analyzed abortion provisions separately rather than cumulatively" and that *Hellerstedt* does not endorse such a theory. *Id.* at *14–*15. Rather, *Hellerstedt* found "one constitutional violation: a single sentence in the Texas Health and Safety Code." *Id.* at *15.

The "cumulative burdens" theory raises a host of remedial problems. How does the court determine which statutes to invalidate? Does it invalidate the entire regulatory scheme wholesale even though each statute would have been upheld if challenged individually? Does it invalidate the most recently enacted statute? Does the answer change if the most recently enacted statute is the least burdensome? When have enough statutes been invalidated to alleviate the cumulative burden? This Court should avoid these insoluble problems and reject the "cumulative burdens" claim.

VI. Equal Protection Doctrine Does Not Supply a Separate Theory for Invalidating Abortion Statutes Otherwise Upheld Using the Undue Burden Standard

Whole Woman's Health alleges that Indiana's laws "single out abortion, impinge on women's bodily integrity, limit women's opportunities, and reflect and reinforce sex stereotypes in violation of the Equal Protection Clause of the Fourteenth Amendment." ECF No. 203 ¶¶ 1–14. They say the challenged laws "restrict and demean women in ways that the State does not restrict and demean men, and they perpetuate women's subordination." ECF No. 1 ¶¶ 87, 121, 140, 158. The Supreme Court, however, has soundly rejected the idea that opposition to abortion is equivalent to "animus against women" or that to disfavor abortion "is ipso facto to discriminate invidiously against women as a class." *Bray v. Alexandria Women's Health Clinic*, 506 U.S. 263, 268–274 (1993). In *Geduldig v. Aiello*, 417 U.S. 484 (1974), the Court rejected the proposition that heightened scrutiny applies to abortion regulations because they affect only women. "While it is true that only women can become pregnant, it does not follow that every legislative classification concerning pregnancy is a sex-based classification." *Id.* at 496 n.20; *see also Kazimer v. Widman,* 225 F.3d 519, 527 (5th Cir. 2000) ("discrimination on the basis of pregnancy . . . is not . . . discrimination on the basis of sex").

A. Because the abortion right derives from components of both the Due Process and Equal Protection Clauses, standard equal protection doctrine does not apply here

The *Casey* "undue burden" standard combines elements of both the Due Process Clause and "constitutional guarantees of gender equality." *Id.* at 928. It therefore leaves no room for a separate inquiry into whether abortion regulations violate equal protection principles simply because they affect procedures that only women undergo. Since *Casey*, the Supreme Court has "abandoned both traditional equal protection scrutiny analysis and the accompanying trimester framework of *Roe* for determining when state regulation of abortion to promote these two important interests is justified

and when it is not." *Tucson Woman's Clinic v. Eden*, 379 F.3d 531, 539 (9th Cir. 2004). "*Casey* replaces the intermediate scrutiny such a law would normally receive under the equal protection clause with the undue burden standard." *Id.* at 549.

If intermediate scrutiny and an equal protection analysis applied in challenges against abortion laws, those challenging abortion laws could unilaterally elevate the level of scrutiny courts apply, contrary to generally applicable doctrine. *See Birth Control Ctrs., Inc. v. Reizen,* 743 F.2d 352, 358 (6th Cir. 1984) ("[W]e are not aware of any authority that allows plaintiffs to use their patients' due process rights as a means of elevating the standard of review for their own equal protection rights."); *see also Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 172–73 (4th Cir. 2000) ("The *Casey* decision does not refer to the abortion-decision right as fundamental and does not apply the traditional strict-scrutiny standard which protects fundamental rights. Rather, the Court adopted an 'undue burden' standard"); *A Woman's Choice-East Side Women's Clinic v. Newman*, 132 F. Supp. 2d 1150, 1181 (S.D. Ind. 2001), *rev'd on other grounds*, 305 F.3d 684 (7th Cir. 2002) ("In light of all the attention devoted to litigating abortion rights under the Due Process Clause, the court does not see a basis for applying any different standard by invoking the Equal Protection Clause. The court therefore concludes that the Equal Protection theory adds nothing to plaintiffs' case."). This Court should thus reject the equal protection claim out of hand.

B. Even if the Equal Protection Clause protects abortion procedures or providers separately, Indiana's abortion regulations are constitutional

Even if abortion laws were subject to traditional equal protection analysis, rational-basis applies because abortion providers are not a suspect class and abortion providers do not have "a fundamental liberty interest in performing abortions free from governmental regulation." *Greenville Women's Clinic,* 222 F.3d at 173 (applying rational-basis to a South Carolina law regulating abortion providers because it neither impinged on a fundamental right nor addressed a suspect

class). "For the same reasons that abortion providers are not a suspect class, we hold that those who provide larger numbers of abortions are not a suspect class. . . . Thus, this classification is subject only to rational basis review." *Tucson Woman's Clinic v. Eden*, 379 F.3d 531, 547 (9th Cir. 2004).

To the extent Indiana's abortion regulations "single out abortion," they do so for permissible and justifiable reasons distinguishing abortion from other medical procedures. The Supreme Court and Seventh Circuit have repeatedly confirmed the legitimacy of regulating abortion differently from other medical procedures. *Planned Parenthood of Cent. Mo. v. Danforth*, 428 U.S. 52, 80–81 (1976) (recognizing that abortion providers can be treated different from those providing "other, and comparable, medical or surgical procedures."); *Planned Parenthood of Ind., Inc. v. Comm'r of Ind. State Dep't of Health,* 699 F.3d 962, 988 (7th Cir. 2012) ("[T]he government need not be neutral between abortion providers and other medical providers . . . . [T]he government is free to treat abortion providers differently."). More fundamentally, "[a]bortion is inherently different from other medical procedures, because no other procedure involves the purposeful termination of a potential life." *Harris v. McRae,* 448 U.S. 297, 325 (1980).

Here, as demonstrated in the Statement of Undisputed Material Fact and in Part IV.B., *supra*, each of the challenged laws advances at least one of three legitimate state interests: the preservation of fetal life, the protection of maternal health, and the integrity of the medical profession. *See Gonzales v. Carhart,* 550 U.S. 124, 127 (2007) (acknowledging States may enact abortion regulations that "'protect[] the integrity and ethics of the medical profession'" and that "promote respect for life"); *Casey,* 505 U.S. at 846 (acknowledging the State's legitimate interest "from the outset of pregnancy in protecting . . . the health of the woman . . . [and] the life of the fetus that may become a child"). Whole Woman's Health's claims must fail even under traditional equal protection analysis.

VII. The State Is Entitled to Summary Judgment Against Vagueness Claims

Whole Woman's Health argues that three Indiana statutes are void for vagueness: (1) the requirement that an abortion provider must be of "reputable and responsible character" (Ind. Code § 16-21-2-11(a)(1); 410 Ind. Admin. Code 26-2-5(1)); (2) the requirement that an applicant disclose whether an abortion clinic closed "as a direct result of patient health and safety concerns" (Ind. Code § 16-21-2-11(d)(1)) or if a principal or clinic staff member was ever "employed by a facility owned or operated by the applicant that closed as a result of administrative or legal action" (Ind. Code § 16-21-2-11(d)(3)); and (3) the restrictions on dosage and administration of chemical abortion medication (Ind. Code § 16-34-2-1(a)(1)). ECF No. 1, ¶¶ 88–89; ECF No. 203, ¶ 7.

Laws can be void as applied only if they fail to provide explicit standards to prevent arbitrary and discriminatory enforcement. *Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498 (1982). "[A]n abortion statute that imposes liability on a physician for erroneous medical determinations is void for vagueness only if it leaves physicians uncertain as to the relevant legal standard under which their medical determinations will be judged." *Karlin v. Foust*, 188 F.3d 446, 463 (7th Cir. 1999) (citing *Smith v. Goguen*, 415 U.S. 566, 578 (1974)).

A. This Court has already upheld the "reputable and responsible character" standard

Indiana Code section 16-21-2-11(a)(1) requires a hospital license applicant to "submit an application for a license on a form prepared by the state department showing that: the applicant is of reputable and responsible character." Whole Woman's Health challenged this provision earlier, ECF No. 77 at 30–32, but this Court upheld it because "subjective judgments do not equal vagueness when these are appropriate and even necessary to accomplish permissible regulatory goals," ECF No. 116 at 47. The Seventh Circuit affirmed because requiring licensees to have reputable and

responsible character is "nothing unusual or suspect" and mirrors the "character and fitness requirement administered by every state bar in the country." *See Whole Woman's Health All. v. Hill*, 937 F.3d 864, 875 (7th Cir. 2019). The State is entitled to summary judgment on this claim.

B. There is nothing vague about requiring an applicant to disclose if the applicant, an applicant's owner, or an applicant's affiliate operated an abortion clinic that closed under specific, enumerated circumstances

Whole Woman's Health challenges the requirements that an applicant to disclose whether "the applicant, or an owner or affiliate of the applicant, operated an abortion clinic that was closed as a direct result of patient health and safety concerns" (Ind. Code § 16-21-2-11(d)(1)) and whether "a principal or clinic staff member was ever employed by a facility owned or operated by the applicant that closed as a result of administrative or legal action" (Ind. Code § 16-21-2-11(d)(3)). What Whole Woman's Health finds vague about these requirements is not clear. Each reasonably describes the information being requested. Whole Woman's Health has previously alleged that the term "affiliate" is vague, but that issue has already been resolved. *Whole Woman's Health All. v. Hill*, 937 F.3d 864, 872 (7th Cir. 2019); Ind. Code § 16-18-2-9.4. The provisions provide fair warning about what is expected, in clearly ascertainable terms, and leaves no room for interpretation by the licensing agency such that the provision could be applied arbitrarily.

In any event, regulatory statutes are less susceptible than criminal prohibitions to vagueness challenges "because the consequences of imprecision are qualitatively less severe." *Hoffman Estates*, 455 U.S. at 499. While the void-for-vagueness doctrine may apply to licensing, *City of Mesquite v. Aladdin's Castle*, 455 U.S. 283, 290 (1982), agencies may enforce licensing standards that would be susceptible to vagueness challenges if used to prohibit conduct generally, *see Hegwood v. City of Eau Claire*, 676 F.3d 600, 603–04 (7th Cir. 2012) (upholding law permitting revocation or suspension of liquor license if the licensee "keeps or maintains a disorderly or riotous, indecent

or improper house" without defining those terms). And laws governing *issuance*, rather than revocation, of licenses are reviewed under an even less stringent standard. *Baer v. Wauwatosa*, 716 F.2d 1117, 1124 (7th Cir. 1983); *see also* ECF No. 116 at 43. With this low standard and the high interest in protecting women's health and safety, the vagueness claim must fail.

C. Restrictions on administering mifepristone provide clearly ascertainable standards

Whole Woman's Health takes issue with what it describes as "dosage and administration restrictions on medication abortion," arguing that the restrictions in Indiana Code section 16-34-2-1(a)(1) are unconstitutionally vague. ECF No. 1 ¶ 101. This statute, which does not set forth any requirement for *dosage amounts* of abortion-inducing drugs, provides, in relevant part: "[A]n abortion inducing drug may not be dispensed, prescribed, administered or otherwise given to a pregnant woman after nine weeks of postfertilization age unless the Food and Drug Administration has approved the abortion inducing drug to be used for abortions later than nine (9) weeks of postfertilization age." Indiana Code section 16-34-2-1(a)(1). No portion eludes understanding by a reasonable person. The prohibition on using an abortion-inducing drug not approved by the FDA for use in abortions later than nine weeks of postfertilization is clear as to what it prohibits and provides fair warning to abortion providers. An abortion-inducing drug either has been approved by the FDA for use beyond nine weeks postfertilization age, or it has not; there is no ambiguity or room for interpretation here. Moreover, nothing in this statute leaves room for interpretation in enforcement such that the interpretation would be left to a jury or a judge. *See Grayned v. City of Rockford*, 408 U.S. 104, 108-110 (1972). The standards for conduct are laid out explicitly and are clearly ascertainable what conduct is prohibited by this statute. The State is entitled to summary judgment on this claim.

CONCLUSION

The State respectfully request this Court to grant its Motion for Summary Judgment.

Respectfully submitted,

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