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 OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

More than nine months after it filed this lawsuit—and more than fourteen months after the Indiana State Department of Health first denied its application for a license to operate an abortion clinic—Whole Woman's Health has now moved for a preliminary injunction that amounts to a unique and effectively comprehensive exception from Indiana's abortion laws. Its failure to bring this motion earlier belies its assertion that an "Abortion Access Crisis," Pl.'s Mem. 2, necessitates the "extraordinary and drastic remedy" of a preliminary injunction, *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997). Whole Woman's Health acknowledges that it brought this motion simply because it is dissatisfied with the status of its ongoing state administrative proceedings, Pl.'s Mem. 39; Exhibit 1, Miller Dep. 90:3-16—which are stalled because it has refused to provide the Department information, about other "Whole Woman's Health"-branded clinics controlled by its CEO, the Department needs in order to determine whether Whole Woman's Health has the "reputable and responsible character" necessary for a license.

Rather than provide this information—or even seek judicial review of the Department's decision in Indiana courts—Whole Woman's Health has asked this Court for a preliminary injunction authorizing it to operate an abortion clinic without a license. This would effectively exempt Whole Woman's Health—and only Whole Woman's Health—from many of the State's abortion regulations and would make it practically impossible for the State to monitor its compliance with virtually *all* of Indiana's abortion laws. Not only does the requested preliminary injunction go far beyond any relief ever granted in any abortion case, but it is also entirely unsupported by Whole Woman's Health's claims, which are nothing more than repackaged arguments it could and should have made during the administrative proceedings. The preliminary injunction it seeks is untimely, unnecessary, and unprecedentedly broad. It should be denied.

STATEMENT OF FACTS

1. Whole Woman's Health has been seeking a license to open an abortion clinic in South Bend, Indiana for several years. On August 11, 2017, it sent the Department a license application, and after reviewing the application, the Department asked Whole Woman's Health to revise its application and correct informational discrepancies. Exhibit 2, Foster Decl. ¶¶ 5, 15.

In late September 2017, while the Department waited for the revised application, the Department's Chief of Staff, Trent Fox, began reviewing Whole Woman's Health's original application; he did so because the Department had never received an application for an abortion-clinic license from a previously unknown entity. *Id.* ¶ 17. His involvement was not unusual. He has been involved with license applications from several types of healthcare facilities, particularly where they have raised especially complex policy or interpretive issues. Exhibit 3, Fox Decl. ¶ 4.

On October 6, 2017, Whole Woman's Health submitted its revised application. Ex. 2 ¶ 19. Fox had immediate concerns, for the application listed Liam Morley as the clinic's administrator, and Morley had a connection with Dr. Ulrich Klopfer—who recently lost his abortion clinic and medical licenses for serious violations, including failing to exercise reasonable care with patients, failing timely to report abortions on two girls under the age of 14, failing to follow proper sedation practices, failing to keep a log of cleaning procedure rooms, and failing to dispose of expired medications. Ex. 3 ¶ 11. In addition, shortly after receiving the revised application, the Department received several surveys raising concerns regarding abortion clinics in other States controlled by Amy Hagstrom Miller, President and CEO of Whole Woman's Health. Ex. 2 ¶ 20. Miller founded Whole Woman's Health in 2014 under the name "Whole Woman's Advocacy Alliance." *Id.* ¶ 45. She alone appointed its initial board of directors, served as president, and chaired the board during its entire existence under that name. *Id.* It changed its name to Whole Woman's Health Alliance in 2015, and since the name change, Miller has without interruption chaired the organization's

board of directors and served as its President and Chief Executive; this gives her unlimited power to control Whole Woman's Health unilaterally. *Id.* ¶¶ 48, 51.

In addition to Whole Woman's Health, Miller controls several separately incorporated abortion clinics, which several surveys indicate have violated numerous health codes. These other clinics are owned and controlled by a company called Booyah Group, Inc., Ex. 1 at 30:21–25, which in turn owns Whole Woman's Health, LLC, a company Miller claims is a "management company . . . [that] doesn't own any clinics." *Id.* at 16:21–25. She claims that the Whole Woman's Health, LLC clinics are "each their own limited liability corporation, and I am the president of each of those corporations." *Id.* at 31:13–15. All of these clinics are listed together with the Whole Woman's Health clinics on wholewomanshealth.com. Ex. 2 ¶¶ 52–57.

The particular violations at issue involved Texas clinics that Miller controlled and that used the name "Whole Woman's Health" and included: (1) failing to account for medications, (2) failing to ensure proper sterilization of instruments, (3) failing to provide hospital contact information, (4) failing to schedule required follow-up appointments, (5) failing to evaluate employee performance, (6) failing to properly store hazardous cleaning solutions, (7) failing to provide a sanitary environment, (8) failing to train staff in sterilizing instruments, (9) failing to staff clinics with registered or licensed nurses, (10) failing to follow policy for fire and disaster drills, (11) failing to keep current emergency medication, and (12) failing to train staff in CPR. *Id.* ¶ 21.

Beyond the surveys listing these violations, Indiana State Senators expressed concerns to the Department about the potential South Bend clinic. *Id.* ¶ 22. For example, Senator Erin Houchin pointed out that in other States Whole Woman's Health "inspection records have uncovered numerous cases which demonstrate a pattern of negligence regarding basic health and safety standards, from rusty equipment, to open syringes, and more." *Id.* ¶ 25.

The Department emailed a list of supplemental questions to Whole Woman's Health asking it to "[p]rovide a complete ownership structure or description" and "[p]rovide a list of all the abortion and health care facilities currently operated by applicant, including its parent, affiliate or subsidiary organizations." *Id.* ¶¶ 28–30. Whole Woman's Health disclosed only two other clinics: Austin and Charlottesville. *Id.* ¶ 31. But that response conflicted with listings on wholewomanshealth.com and public statements Miller made that there were eight Whole Woman's Health clinics in five different States. *Id.* ¶ 32. Whole Woman's Health's responses were also incomplete and inaccurate because (1) they did not address Miller's "common control" of the various for-profit "Booyah" clinics that used the "Whole Woman's Health" name, and (2) they mentioned board members that were "affiliated" with other Whole Woman's Health entities but did not name those individuals as the Department had requested. *Id.* ¶ 33.

On January 3, 2018, the State Health Commissioner formally denied Whole Woman's Health's license application because it "failed to disclose, concealed, or omitted information related to additional clinics," and "failed to meet the requirement that the Applicant is of reputable and responsible character and the supporting documentation provided inaccurate statements or information." *Id.* ¶¶ 34–35. The administrative Appeals Panel, the agency's ultimate decision-making body, affirmed because Whole Woman's Health's license application failed to disclose numerous affiliate entities that "are under the common control of Amy Hagstrom Miller." *Id.* ¶ 37.

Whole Woman's Health did not seek judicial review of that decision. *Id.* ¶ 38. Instead, it submitted a new application on January 19, 2019. *Id.* ¶ 39. The Department again requested documents regarding Whole Woman's Health's previously undisclosed affiliates and further requested that Whole Woman's Health fix other deficiencies in its new application, such as providing expired Emergency Services Agreements. *Id.* ¶ 40; Exhibit 4, Letter from ISDH to Ms. Rupali Sharma

(Feb. 25, 2019). Whole Woman's Health refused to provide the requested documents and thus has not received a license. Ex. 2 ¶ 41.

2. The as-yet-unlicensed facility that Whole Woman's Health seeks to operate would provide chemical, also known as "medication," abortions. Dkt. 76 at 1. Whole Woman's Health intends to hire Dr. Jeffrey Glazer, a resident of Louisville, KY, to serve as Medical Director of the clinic. Exhibit 5, Glazer Dep. 27:10–12. Dr. Glazer claims to "regularly review the medical literature relevant to [his] practice areas and . . . keep up to date on professional association guidelines and recommendations, including those published by the American College of Obstetricians and Gynecologists ("ACOG"), and the National Abortion Federation ("NAF")." Dkt. 76-4, Glazer Decl. ¶ 7. When asked about these publications at his deposition, however, he said he would have to "review [the NAF guidelines] to make sure he was following [them]," Ex. 5 at 28:24–29:9; admitted he was not sure whether the NAF guidelines conflicted with the ACOG guidelines, *id.* at 29:10–12; and, when asked if he disagreed with any guidelines in the ACOG manual admitted "I haven't reviewed it, so I don't know," *id.* at 29:13–15. Finally, when asked if he thinks it is important that practitioners follow the ACOG guidelines he admitted: "I haven't reviewed this recently, so I don't have an opinion on that." *Id.* at 30:19–24. He was not even sure if he was certified as required by the FDA to prescribe Mifeprex (a drug necessary for chemical abortions). *Id.* at 24:18–20.

Chemical abortions may be performed up to ten weeks gestation and involve two medications subject to FDA regulations: mifepristone and misoprostol. Mifepristone kills the fetus by blocking the effects of the mother's progesterone, *id.* at 6:12–7:5, and misoprostol induces uterine contractions, which cause the uterus to empty its contents, including the fetus, *id.* at 7:11–16. A woman who has a chemical abortion is likely to have "bleeding much heavier than menses (and

potentially with severe cramping) and is best described to patients as comparable to a miscarriage." Exhibit 8, American College of Obstetricians and Gynecologists, Practice Bulletin: Medical Management of First Trimester Abortion 3 (2014). Misoprostol will also cause the woman either to pass an intact fetus or to pass several clumps of fetal tissue, after which a doctor should confirm that the pregnancy has been terminated and that no part of the fetus remains within the woman's uterus. *Id.* at 5. A doctor should also ensure that the woman is coping with the usual side effects, such as severe cramping, nausea, vomiting, diarrhea, dizziness, exhaustion, and mild fever. *Id.* at 3.

In addition to these ordinary side effects, chemical abortions sometimes have serious complications, such as infection, hemorrhaging, failure to terminate the pregnancy, incomplete abortion, and psychological disorders such as depression. *Id.* at 3; Exhibit 9, Ralph P. Miech, *Pathophysiology of Mifepristone-Induced Septic Shock Due to Clostridium Sordellii*, 39 Annals Pharmacotherapy (2005); Exhibit 10, Ralph P. Miech, *Pathopharmacology of Excessive Hemorrhage in Mifepristone Abortions*, 41 Annals Pharmacotherapy (2007); Exhibit 7, Priscilla K. Coleman, *Abortion and Mental Health: Quantitative Synthesis and Analysis of Research Published 1995–2009*, 199 Brit. J. Psychiatry 180 (2011). When an incomplete abortion (the most common complication) occurs, the standard of care requires a suction dilation and curettage (D&C) to remove the remaining tissue from the uterus, which are most commonly done in a surgical facility. Ex. 8 at 3. The complication rate for chemical abortion is four times greater than that of surgical abortion. Exhibit 6, Maarit Niinimaki et al., *Immediate Complications After Medical Compared with Surgical Termination of Pregnancy*, 114 Obstetrics & Gynecology 795, 795 (2009). Yet Dr. Glazer is not even aware of studies showing higher complication rates for chemical abortions. Ex. 5 at 25:4–19.

The stories of five women who have undergone chemical abortions help illustrate the need for state licensing of pill-only abortion clinics.

Elizabeth Gillette: In 2011, Elizabeth Gillette found out she was pregnant at 24 years old. Exhibit 11, Gillette Decl. ¶ 3. Out of fear and pressure from her boyfriend, she scheduled an appointment for a chemical abortion. *Id.* ¶ 4. While at the abortion facility, she received no information about how the chemical abortion worked, no information regarding other options or help that she could receive for her pregnancy, and no information on how to dispose of the fetus. *Id.* ¶ 8. During the ultrasound, she asked to see the baby but was told office policy prohibited showing her the sonogram. *Id.* ¶ 6. When she insisted, the doctor showed her a still shot and claimed the baby was not viable, which Gillette knew to be a lie. *Id.* ¶¶ 6–7. After almost an hour of crying and uncertainty, she finally swallowed the mifepristone when the doctor said she could not get a refund. *Id.* ¶¶ 8–9. The next day, after she had taken the misoprostol, she began to bleed heavily: "There was so much pain and blood I thought I might die." *Id.* ¶ 10. Finally, she passed the gestational sac: "It was transparent yellow, about the size and shape of a tennis ball. When I picked it up, I could see the baby inside. He looked like a little gummy bear. I sat and held him and cried. Then I flushed my baby down the toilet." *Id.* ¶ 11.

No one from the clinic ever called to check on Ms. Gillette's well-being, and she was never scheduled for a follow-up visit. *Id.* ¶ 12. She later suffered from anorexia, abusive relationships, and post-traumatic stress disorder, which a counselor traced directly to her abortion. *Id.* ¶ 13. Because of the complications she suffered from her abortion, Ms. Gillette believes that "[r]equiring licenses for clinics that dispense the chemical abortion medication is an important step towards protecting women in their most vulnerable moments." *Id.* ¶ 15. "With a chemical abortion," she says, "women leave the clinic and pass the fetus alone, without the care of a doctor or nurse to help

them if they have complications. My heart breaks for the women who would experience this from a clinic with no license. Pill only abortions are touted as safe and easy, completed in the comfort of your own home. Tragically, this was the opposite of what I experienced." *Id.*

Leslie Wolbert: At twenty-one years old, Leslie Wolbert believed she was pregnant for the first time and went to a Planned Parenthood to take a pregnancy test. Exhibit 12, Wolbert Decl. ¶ 3. When the test came back positive, the Planned Parenthood worker, unprompted, began scheduling an abortion appointment; at no point did anyone at the clinic inform Ms. Wolbert of other options besides abortion. *Id.* ¶ 4. She was scheduled for a chemical abortion at the clinic a short time later, and at the clinic the day of the abortion, she "told the doctor that I was scared, but he didn't acknowledge my fear or even look me in the eye. . . . The experience was dehumanizing, isolating, and terrifying. I felt like a sheep led to slaughter, but I took the pill anyway." *Id.* ¶ 9.

She took the misoprostol the next day and suffered severe pains and screamed for hours with no one to help her: "My experience was incredibly scary and nothing like a normal period. The pain I felt was much more similar to labor contractions than normal cramps. I remember sitting on the toilet discharging blood while also vomiting and shaking all over." *Id.* ¶¶ 10, 12. Even worse: "I got in the shower to wash away the blood. Suddenly, I passed a large mass that clogged the drain. Even though it looked like a blood clot, I realized immediately that it must be the baby. Not knowing what else to do, I bent down, scooped it out of the drain with my bare hands and, sobbing, flushed it down the toilet." *Id.* at ¶ 13.

For years to come, Ms. Wolbert suffered severe psychological trauma, such as panic attacks and post-traumatic stress disorder, all attributable to her chemical abortion. *Id.* ¶ 16. She says that "Chemical abortion is an abortion. And it is an incredibly terrifying, isolating, painful experience. It should not be downplayed as similar to a heavy period or an early miscarriage. I've had both

heavy periods and an early miscarriage and the pain of the chemical abortion was a violent, unnatural pain. The fear, worry and confusion of what was happening during my chemical abortion made me scared that I was going to die." *Id.* ¶ 19. She is concerned that Whole Woman's Health seeks to perform chemical abortions without a license: "If an abortion clinic doesn't have to be labeled as such, then the chemical abortion can be handed out like cold medicine. Yet they are sending women back to their own homes to partake in the death of their own child." *Id.* at ¶ 22.

Tami Morris: Ms. Morris had her first chemical abortion when she was twenty-five. Exhibit 13, Morris Decl. ¶ 8. She had previously obtained two surgical abortions, but she hoped a chemical abortion would involve less pain and trouble. *Id.* ¶ 9. When she arrived at the abortion clinic to inquire about obtaining a chemical abortion, she says "was told that I would experience light cramping and bleeding and pass some blood clots, but no more than a normal menstrual cycle. They did not offer to show me an ultrasound image of my baby. I was not given any pregnancy resources or told about adoption." *Id.* ¶ 12. After taking the second of the two abortion pills at her home, Ms. Morris experienced extreme cramping, similarly severe to what she felt when delivering her daughter—"It was nothing like they had told me." *Id.* ¶ 13.

After several hours, "the pain and the urge to push were so intense" that she sat on the toilet. "I pushed until I felt something come out and I heard a sound. I looked down and screamed. It was not just a blob of tissue. I had given birth to what looked like a fully-formed, intact 14-week old fetus covered in blood." *Id.* ¶ 14. Then, "I scooped my baby out of the toilet. I sat on the floor and held him and cried. I cannot remember what I did with my baby afterwards." *Id.* at ¶ 15.

Morris continued to bleed so profusely "for weeks" that she feared she might die. *Id.* ¶ 16. She called her abortion clinic, "but they told me it was normal," and offered neither help nor a follow-up appointment, instead telling her to go to the ER or her family doctor. *Id.* After the trauma

of seeing her baby in a toilet, Ms. Morris endured eight years of alcoholism, divorce, suicidal thoughts, rage-filled outbursts, and debilitating depression. *Id.* ¶ 18.

Morris remains concerned about what other women might experience with chemical abortions. "As a women 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." *Id.* ¶ 22. With chemical abortion, furthermore, "the risks are much greater to the woman who is self-administering her own chemical abortion, medical procedure. In what other circumstance would the healthcare industry encourage and support an untrained patient to self-administer a medical procedure that could result in fatal blood loss, with no means to have professional medical intervention available?" *Id.* In her view, "abortion clinics around the country should be highly regulated and mandated to follow medically sound protocols to ensure the safety of the patient regardless of the method they use to terminate a woman's child in the womb." *Id.* ¶ 23.

Christen Castor: Ms. Castor had a similar experience with severe bleeding and cramping after she underwent a chemical abortion in her early twenties. Exhibit 14, Castor Decl. ¶¶ 3–4. The nurse at the abortion clinic told her she was only three weeks along and that a chemical abortion would cause her to experience "something like a heavy period." *Id.* ¶ 7. The nurse did not inform Castor of any other options aside from a passing reference to adoption, and gave Castor no warning about the possibilities of infection, infertility, or psychological trauma she may face. *Id.* ¶¶ 6–7. There was no waiting period, so Castor took the mifepristone that day at the clinic. *Id.* ¶ 8. A day later, she inserted the mifepristone vaginally and "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." *Id.*

She was unprepared for the emotional and psychological pain that would follow. She has long suffered from depression, but believes it has been intensified by the abortion. *Id.* ¶ 13. "I feel

like I lost a part of my soul with that baby," she says. *Id.* ¶ 12. She explained: "The pill is so easy it doesn't give the mother time to truly reflect on what her actions will be doing and the lifelong consequences it can cause. The ease of the pill and the lack of positive counseling on creating a child (for me, it would have been the knowledge of finding out my child's DNA would never exist again) is appalling to me. To me it seems a very easy way for the business to make a quick buck by feeding on the fear of the scared and naive mother, who will be the one that is forced to live with the consequences while the business profits and moves on to the next mother." *Id.* ¶ 13.

Kristen Rinehart: Ms. Rinehart also underwent a chemical abortion after becoming unexpectedly pregnant in her early twenties. Exhibit 15, Rinehart Decl. ¶¶ 3–4. The abortion clinic confirmed Ms. Rinehart's pregnancy and blood type; the clinic also provided an ultrasound, but "the screen was turned away from me so that I could not see the baby." *Id.* ¶ 5. She eventually saw a still shot, "but I had never seen an ultrasound image before, and I couldn't tell what was what. The nurse told me nothing about the image or the fetal heartbeat and gave me no description of the stage of development that my baby was at." *Id.* She says "I would like to think I would have made a different decision if I could have seen the baby moving or heard the heartbeat." *Id.*

Without any waiting period, she underwent a chemical abortion: "The nurse told me that because I was only 6 ½ weeks along, I could have a chemical abortion. I was told that I would have experience some bleeding, like a heavy period, and would pass some blood clots. They made it sound like it was really not a big deal. They told me nothing about the psychological and emotional side effects of abortion." *Id.* ¶ 6. She took the first pill alone—the nurse said she could not be accompanied in the room—and she later inserted the misoprostol vaginally; she experienced such severe bleeding that a friend insisted on taking her to the hospital, which she refused in order to keep her abortion secret. *Id.* ¶¶ 8–9. "At some point," she says, "I passed a very large blood clot

about the size of a softball. I realized even then that it must be the baby and felt sick to my stomach. I flushed it down the toilet." *Id.* ¶ 10. She continued to bleed for weeks. *Id.* ¶ 11.

Rinehart also suffered depression after her abortion. *Id.* ¶ 12. Her abortion was in 2008, but "it was not until I began attending a post-abortive women's group in 2018, that I finally began to recover from the emotional and psychological side effects of my abortion." *Id.* at ¶ 13. She also worries about unlicensed pill-only clinics: "I am worried that the clinic would not have to follow the informed consent laws for the state and that safety procedures and protocols would not be in place. As you can see through my story, a chemical abortion is a real abortion, and I feel it would be unsafe for an abortion clinic to operate without a license." *Id.* ¶ 14.

ARGUMENT

To determine whether a preliminary injunction should be granted, the Court weighs several factors: (1) whether the plaintiff has demonstrated at least a reasonable likelihood of prevailing on the merits; (2) whether the plaintiff has no adequate remedy at law, thus causing irreparable harm; (3) whether plaintiff's threatened injury outweighs the threatened harm the grant of the injunction will inflict on the defendant; and (4) whether granting the preliminary injunction would harm the public interest. *See, e.g., HH-Indianapolis, LLC v. Consol. City of Indianapolis & Cty. of Marion*, 889 F.3d 432, 437 (7th Cir. 2018). Whole Woman's Health's preliminary injunction motion raises as-applied challenges to Indiana's Licensing Law, but it neither demonstrates a likelihood of success on any claim nor satisfies the remaining preliminary injunction factors.[1]

[1] Whole Woman's Health also argues that Indiana's admitting-privileges requirement was unconstitutional as applied to it "to the extent" that requirement would prevent Whole Woman's Health "from providing medication abortions." Pl.'s Mem. 1. But because the Department has deemed acceptable the relationship Whole Woman's Health has demonstrated with Dr. Poe, Ex. 3 ¶¶ 42–43, those arguments are no longer relevant.

WHOLE WOMAN'S HEALTH CANNOT DEMONSTRATE A LIKELIHOOD OF SUCCESS ON THE MERITS

I. The "Reputable and Responsible Character" Standard Is Not Unconstitutionally Vague

An applicant for an abortion-clinic license must show that it "is of reputable and responsible character." Ind. Code § 16-21-2-11(a)(1). This provision's implementing regulations authorize the Department to "request additional information," "conduct a further investigation," or "deny the application" if the Department finds that an applicant has failed to comply with this requirement. 410 Ind. Admin. Code §§ 26-2-4(b), 26-2-5(1). Whole Woman's Health argues that this requirement is unconstitutionally vague. *See* Pl.'s Mem. 21–23. It is not, but as a threshold matter, Whole Woman's Health never makes clear what statutory terminology gives it trouble. It disputes the meaning of "affiliate" but does not challenge that term as vague (for obvious reasons). And to the extent it seeks to revisit the Department's application of state law in the pending state proceeding, such a claim would violate sovereign immunity doctrine, which precludes federal courts from applying state law to bind state officials. *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 106 (1984).

A. A law that prohibits conduct may be unconstitutionally vague if "it fails to provide 'fair warning' as to what conduct will subject a person to liability" or fails to "contain an explicit and ascertainable standard" in order to prevent "arbitrary and discriminatory" enforcement. *Karlin v. Foust*, 188 F.3d 446, 458–59 (7th Cir. 1999). Yet, as the Seventh Circuit recently observed, even a *criminal* prohibition is constitutional so long as it has "a core of understandable meaning." *Trs. of Ind. Univ. v. Curry*, 918 F.3d 537, 540 (7th Cir. 2019). "Some uncertainty at the margins does not condemn a statute," as long as it uses words "which people use and understand in normal life." *Id.* The "reputable and responsible character" requirement challenged here is not even a criminal law; it merely sets out a requirement to obtain a license. Particularly in the licensing-qualifications

context, this requirement is a common-sense standard with "a core of understandable meaning"—which is why so many jurisdictions use it for so many licensing purposes.

Indeed, the Supreme Court has already rejected a similar vagueness challenge to the materially identical "character and fitness" qualification standard, *see Law Students Civil Rights Research Council, Inc. v. Wadmond*, 401 U.S. 154, 159 (1971), which is used by every bar in the country, *see* National Conference of Bar Examiners, Comprehensive Guide to Bar Admission Requirements 2019, http://www.ncbex.org/assets/BarAdmissionGuide/NCBE-CompGuide-2019.pdf. Both the "reputable and responsible character" requirement and the "character and fitness" standard authorize regulators to assess the reliability and trustworthiness of those seeking a license to provide services that have the potential not only to help others, but also inflict great harm. If the latter standard is constitutional, the former assuredly is as well.

Furthermore, in *Indiana University*, the Seventh Circuit explained that the vagueness doctrine does not justify federal court intervention every time a regulated entity raises questions about the meaning of a state statute: The court rejected a vagueness challenge to a statute that prohibited, on pain of criminal prosecution (and not merely denial of a license), "transfer" of aborted fetal tissue. 918 F.3d at 540–541 (construing Ind. Code § 35-46-5-1.5(d)). Notably, Indiana University could obtain state-court clarification of the challenged statutory language only by way of a declaratory judgment action. But that was enough for the Seventh Circuit: "Instead of using a readily available state-law remedy for unwelcome risk, they asked a federal court to blot the law from the books. That's not how uncertainty should be addressed." *Id.* at 541. Whole Woman's Health could have sought clarity regarding the meaning of Indiana law in a multi-level administrative proceeding, and it could have pursued its case further with judicial review—which it chose not to do.

The lesson from *Indiana University* thus applies here with even greater force. As the Supreme Court has explained in a related context, "[p]rinciples of comity . . . require that the state courts be afforded the opportunity to perform their duty, which includes responding to attacks on state authority based on the federal law," a requirement which "permits the state courts to exercise their authority, which federal courts . . . do not have at least to the same extent, to construe state statutes so as to avoid or obviate federal constitutional challenges such as vagueness and overbreadth." *Webb v. Webb*, 451 U.S. 493, 499–500 (1981).

B. As Whole Woman's Health appears to acknowledge, Pl.'s Mem. 21–22, the objective of the void-for-vagueness doctrine is to ensure that "penal statute[s] define the criminal offense with sufficient definiteness that ordinary people can understand what conduct is prohibited and in a manner that does not encourage arbitrary and discriminatory enforcement." *Kolender v. Lawson*, 461 U.S. 352, 357 (1983). In other words, the purpose of the doctrine is to protect people from being thrown in jail for conduct they had no reason to believe was unlawful.

That is why Whole Woman's Health only cites cases involving statutes prohibiting *conduct*, and why it fails to cite any cases invalidating *licensing qualifications* on vagueness grounds. In *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, the Court addressed a definition of conduct that was prohibited absent a license (on pain of quasi-criminal sanctions); the plaintiffs alleged that someone could be punished for failing to obtain a license they had no reason to believe they needed. 455 U.S. 489, 498 (1982). Even there the Court upheld the definition, in part because (as here) the government offered guidance. *Id.* at 500–501. Similarly, in *Women's Medical Center of Northwest Houston v. Bell*, the Fifth Circuit invalidated a requirement that physicians provide care matching each patient's subjective expectations, based on the patient's sense of "individuality," "self-esteem" and "self worth." 248 F.3d 411, 422 (5th Cir. 2001). Again, these standards

regulated conduct, not qualifications, and would have "subject[ed] physicians to sanctions" based on "the subjective expectations or requirements of an individual patient as to the enhancement of her dignity or self-esteem." *Id.* And in *Colautti v. Franklin*, the Court invalidated a requirement that abortion providers take certain actions if "the fetus may be viable," because guessing wrong about potential viability could result in criminal prosecution. 439 U.S. 379, 390–93 (1979).

Here, uncertainty over the meaning of the "reputable and responsible character" requirement will not lead to criminal or quasi-criminal sanctions. As illustrated by Whole Woman's Health's own experience, Indiana law clearly requires Whole Woman's Health to obtain a license before performing abortions, and any uncertainty Whole Woman's Health might have about Indiana's licensing requirements can be resolved through back-and-forth discussions with the Department, perhaps followed by administrative appeal and judicial review of the agency's interpretation. Ind. Code § 4-21.5-5-1. The administrative process thus affords a readily accessible means of resolving any vagueness or ambiguity in the meaning of the "reputable and responsible character" requirement. *See Vill. of Hoffman Estates*, 455 U.S. at 498 ("[T]he regulated enterprise may have the ability to clarify the meaning of the regulation by its own inquiry, or by resort to an administrative process."); *Trs. of Ind. Univ.*, 918 F.3d at 541 (state court system can resolve "the uncertainties that lurk at every statute's periphery").

Moreover, Whole Woman's Health cannot credibly claim ignorance over what the "reputable and responsible character" standard requires, for the Department has expressly set forth what it needs time and time again, including express demands for Whole Woman's Health to identify its affiliates and ownership structure. The appeals panel confirmed that all of the clinics Miller owns are affiliates. Exhibit I to Ex. 2, Order of the Appeals Panel 9 ¶ 17. And if that were not enough, when the Department received Whole Woman's Health's second application, it invoked

the appeals panel's understanding of the term "affiliate" and demanded "documents that concern . . . any investigation, inspection, or survey of the affiliate[s]," "documents that concern . . . any application by the affiliate[s] for licensure," "documents that concern . . . any regulatory or administrative enforcement action . . . involving the affiliate[s]," and the "legal name and current address of each . . . officer of the affiliate[s]." Ex. 4. Yet Whole Woman's Health still refuses to provide these documents. Ex. 2 at 57:12–58:10.

Beyond that, Whole Woman's Health cites no case striking down any "reputable and responsible character" or similar requirement—perhaps because these standards are so commonly used and understood, both by ordinary citizens and by licensing agencies. The precise phrase "reputable and responsible character" is used in a variety of licensing contexts here and across the country.[2] Thus, if the "reputable and responsible character" requirement is unconstitutionally vague, "then big chunks of the legal system are invalid, because those words are ubiquitous in statutes, regulations, and judicial opinions." *Trs. of Indiana Univ.*, 918 F.3d at 539.

[2] *See, e.g.*, Ind. Code § 12-25-1-4 (mental health facilities); Ind. Code § 16-28-2-2 (health facilities generally); Ind. Code § 16-21-2-11 (hospitals); Ala. Code § 22-21-23 (hospitals, nursing homes, and other health facilities); Cal. Health & Safety Code § 1596.95 (daycare centers); Cal. Health & Safety Code § 1569.15 (nursing homes); Cal. Health & Safety Code § 1265.3 (health facilities generally); Cal. Health & Safety Code § 1796.19 (home care aides); Cal. Health & Safety Code § 1575.2 (adult daycare homes); Cal. Health & Safety Code § 1416.22 (nursing homes); Cal. Health & Safety Code § 1597.54 (family daycare homes); Cal. Health & Safety Code § 1212 (medical clinics); Ga. Code Ann. § 43-27-6 (nursing homes); Haw. Rev. Stat. Ann. § 346-154 (childcare facilities); Md. Code Ann., Health-Gen. § 19-319 (hospitals); Md. Code Ann., Health-Gen. § 19-906 (hospice care facilities); Minn. Stat. Ann. § 144.51 (hospitals and other health facilities); Nev. Rev. Stat. Ann. § 449.4311 (intermediary service organizations); Nev. Rev. Stat. Ann. § 449.040 (medical facilities generally); N.D. Cent. Code Ann. § 23-17-02 (chiropractic hospitals); Okla. Stat. Ann. tit. 63, § 1-703 (hospitals); Okla. Stat. Ann. tit. 10, § 1430.14 (homes for the disabled); Okla. Stat. Ann. tit. 63, § 330.53 (long-term care facilities); Okla. Stat. Ann. tit. 63, § 1-1904 (nursing homes); S.C. Code Ann. § 40-35-40 (health care administrators); Tenn. Code Ann. § 33-2-406 (mental health and substance abuse facilities); Tenn. Code Ann. § 71-2-404 (adult day care); Tenn. Code Ann. § 68-11-206 (traumatic brain injury residential homes); W. Va. Code Ann. § 16-5B-2 (hospitals, ambulatory surgical centers, and extended care facilities).

If Whole Woman's Health disagrees that Indiana statutes authorize the Department to make such demands, it could have challenged the Department's interpretation of Indiana law in administrative and judicial review proceedings. Those proceedings, not collateral attacks in federal court, provide the opportunity to cure any uncertainty regarding the "reputable and responsible character" requirement. *See Trs. of Ind. Univ.*, 918 F.3d at 541. And again, any attempt to now challenge the Department's interpretation is barred by sovereign immunity under *Pennhurst*.

C. Finally, Whole Woman's Health supplies no evidence that the Department has enforced the "reputable and responsible character" requirement in a discriminatory or arbitrary manner. Trent Fox is the Chief of Staff at the Department, and part of his job is to supervise licensing (and many other) decisions, so he frequently becomes involved in them. Ex. 4 ¶ 8–9. Whole Woman's Health makes no assertion that Fox imposed some secret, extra-legal standard to its application. And it cross-examined Fox regarding his involvement with its application as part of its administrative review process. Dkt. 76-10, at 17, Tr. Proceedings, August 22, 2018. Critically, while Whole Woman's Health now contends that Fox's involvement rendered the Department's rejection of its license "arbitrary," it abandoned the very state judicial review process specifically designed to air such claims. Ind. Code § 4-21.5-5-14 (permitting courts to overturn administrative licensing decisions that are "arbitrary").

Regardless, Whole Woman's Health knows exactly what the licensing standard and the Department require of it. It merely wishes not to comply. It is not likely to succeed on the merits of its claim that the "reputable and responsible character" requirement is unconstitutionally vague.

II. The Licensing Law Does Not Impose an Undue Burden on Abortion Rights

Supreme Court doctrine safeguards to a pregnant woman who does not want to bear a child a right to decide, without undue interference from the State, to have a pre-viability abortion. But

that doctrine neither safeguards a right of clinics and physicians to provide abortions nor precludes States from regulating pre-viability abortions. Before viability, the State may regulate abortion to "preserv[e] and protect[] the health of the pregnant woman [and] . . . the potentiality of human life." *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 875–76 (1992). It may also regulate to "protect[] the integrity and ethics of the medical profession." *Gonzales v. Carhart*, 550 U.S. 124, 157 (2007). A law furthering those objectives is unconstitutional "[o]nly where state regulation imposes an undue burden on a woman's ability to make th[e abortion] decision." *Casey*, 505 U.S. at 874; *see also Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2309 (2016).

Whole Woman's Health has challenged Indiana's Licensing Law, Ind. Code §§ 16-18-2-1.5, 16-21-1-9, 16-21-2-2.5, 16-21-2-10, 16-21-2-11, even though the Supreme Court and federal appellate courts have repeatedly recognized that licensing requirements do not impose an undue burden on a woman's right to abortion. The plaintiffs in *Casey* did not even bother challenging Pennsylvania's licensing laws, perhaps because two circuits had already upheld similar laws. *Baird v. Dep't of Pub. Health of Mass.*, 599 F.2d 1098 (1st Cir. 1979); *Birth Control Ctrs., Inc. v. Reizen*, 743 F.2d 352 (6th Cir. 1984). And in *Mazurek v. Armstrong*, the Court upheld a law prohibiting anyone but a licensed physician from performing an abortion. 520 U.S. 968 (1997). Two more circuits later upheld licensing requirements. *See, e.g.*, *Greenville Women's Clinic v. Bryant*, 222 F.3d 157 (4th Cir. 2000); *Greenville Women's Clinic v. Comm'r, S.C. Dep't of Health & Envtl. Control*, 317 F.3d 357 (4th Cir. 2002); *Women's Med. Ctr. of Nw. Houston v. Bell*, 248 F.3d 411 (5th Cir. 2001). And at least one circuit has upheld specific licensing regulations for chemical abortions. *See Planned Parenthood of Sw. Ohio Region v. DeWine*, 696 F.3d 490 (6th Cir. 2012).

These precedents squarely foreclose Whole Woman's Health's undue-burden challenge. *Hellerstedt*, which plaintiffs characterize as merely applying the *Casey* standard, Pl.'s Mem. 24–

25, did not purport to disturb any of the precedents approving of abortion regulations—including those that permit state licensing laws—so it does not prompt a more skeptical view of clinic-licensing laws. In any event, the benefits of licensing chemical-only abortion clinics far outweigh the burdens on the abortion right. *Hellerstedt*, 136 S. Ct. at 2309.

A. The Licensing Law benefits the State's interests in protecting women's health, fetal life, and the integrity of the medical profession

The Licensing Law serves the State's interests in protecting women's health, fetal life, and the integrity of the medical profession by ensuring that abortion providers dispense chemical abortions safely and follow the State's informed-consent and reporting requirements. It allows the Department to confirm that only qualified professionals prescribe chemical abortions, Ind. Code § 16-34-2-1(a)(1)(A), that those professionals inform women of the medical and moral consequences of abortion, *id.* § 16-34-2-1.1, and that they report any complications resulting from abortions, *id.* § 16-34-2-4.7. It also authorizes the Department to inspect clinics annually to ensure that chemical abortions are provided in a safe and legal manner, *id.* § 16-21-2-2.6. Dr. Glazer confirmed the importance of an ultrasound to determine the gestational age of the fetus and informing women of the risks of chemical abortion. Ex. 5 at 21:7–25. Without the Licensing Law, the Department would have no way to enforce these requirements against non-compliant abortion clinics.

1. Indiana's licensing requirement is justified by its interest in protecting fetal life, which is furthered by ensuring that clinics follow proper informed-consent procedures. Indiana requires physicians and clinical designees to provide women with specific information in person at least eighteen hours before the abortion, including information regarding the potential medical risks and alternatives to abortion. Ind. Code § 16-34-2-1.1. Notably, the need to follow these informed-consent protocols does not extend to the miscarriage context, where the fetus is already dead and there is no need to discuss other options or persuade the woman to change her mind.

"Abortion 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).

State law also requires abortion clinics to gather each patient's signature confirming that she has received the state-mandated information and to place that signed form into her file. Ind. Code § 16-34-2-1(a). The law authorizes the Department to inspect patient files to determine whether clinics are complying with these mandates. *Id.* § 16-21-2-2.6. If Whole Woman's Health were to prevail on its motion, the Department would have no systematic means of monitoring compliance. Ex. 2 ¶ 10. And as the testimonies of five women in this case attest, adequate informed consent can be especially critical for the proper care of women seeking chemical abortions. Exs. 11–15.

2. The licensing law is justified by the State's public-health interests in gathering information about abortion and responding to complaints about health clinics. Again, the Department has the authority to inspect licensed abortion clinics annually. Ind. Code § 16-21-2-2.6. During these inspections, the Department can check to make sure the clinics are filing terminated pregnancy reports for each abortion, 410 Ind. Admin. Code 26-7-2, and potentially (though the complication-reporting statute is currently enjoined) are reporting any abortion complications to the State. Ind. Code § 16-34-2-4.7. The Department can also inspect a licensed clinic in response to a complaint and can revoke a clinic's license if it discovers that the clinic is not complying with reporting laws and substantive abortion regulations. *Id.* § 16-21-2-10, -13.

The FDA requires that Mifeprex be administered in accordance with its Risk Evaluation and Mitigation Strategy (REMS) program. *See* Exhibit 16, U.S. Food & Drug Administration, *Mifeprex (mifepristone) Information*. Only a healthcare provider that meets certain qualifications

and has completed a Prescriber Agreement Form may dispense Mifeprex. *Id.* That healthcare provider must require each patient who receives Mifeprex to fill out and sign a Patient Agreement Form. *Id.*

3. Licensing pill-only abortion clinics is also justified by the need to ensure patient safety. Dr. Glazer's testimony demonstrates the need for regulatory supervision. He initially claimed that failure to terminate the pregnancy and incomplete abortion were the only possible complications of chemical abortion, but then admitted that infection is also possible. Ex. 5 at 11:11–25. He also testified that, even in his present clinic work, he does not follow up with patients to see whether they have complications and is not usually present for follow-up appointments at the clinic. *Id.* at 15:6–8, 17–20. (As he lives about 250 miles from South Bend in Louisville, *id.* at 27:10–12, that practice seems unlikely to change.) When a woman has retained tissue (where a D&C or a second dose of misoprostol is the medically recommended course of treatment) Dr. Glazer sometimes manages by "do[ing] nothing and just hav[ing] them follow up in an appropriate amount of time." *Id.* at 16:15–17. Without licensing and inspections, the safety of Whole Woman's Health's proposed clinic would be entirely in the hands of Dr. Glazer, who has no opinion on whether practitioners should follow the ACOG guidelines because he "ha[s]n't reviewed [them] recently," *id.* at 30:19–24; who, when asked if he is certified by the FDA to prescribe Mifeprex said "I'm not sure. I don't know," *id.* at 24:18–20; and who admits that the "state medical license board" would be the way to ensure women receive adequate abortion care, *id.* at 31:15–25. Because the purported safety of chemical abortion has only been studied when FDA and ACOG guidelines are followed, it is reasonable to assume that these abortions would have even higher complication rates if these guidelines were not followed.

Whole Woman's Health's CEO gives no greater comfort that patient safety would be ensured: She prefers medical licensing boards to stop bad actors—but only after women get sick. When asked about a scenario where a clinic has tools that are not properly sanitized, she said: "there would likely be patients who have infections and who have complications, and there would probably be some sort of incident that would trigger the doctor or the nurse to have disciplinary practices." Ex. 1 at 83:19-84:9. The point of licensing and inspections by the Department, of course, is to monitor clinics and correct unsafe practices *before* women get sick.

The State's compelling concern for patient safety applies to surgical abortions *and* chemical abortions with equal force. Chemical abortions can lead to serious complications, including infection, hemorrhaging, failure to terminate the pregnancy, incomplete abortion (retained tissue), missed ectopic pregnancy, and psychological disorders such as depression. Ex. 8 at 3; Ex. 9; Ex. 10; Ex. 7. Indeed, chemical abortions have *greater* complication rates than surgical abortions. Ex. 6 at 795.

Moreover, the State has presented the Court with declarations from five women testifying about their personal experiences with chemical abortion that illustrate just some of the risks and shocks of chemical abortions. All five women experienced significantly more bleeding and cramping than they were told to expect. Ex. 13 ¶ 13; Ex. 15 ¶ 9; Ex. 12 ¶ 12; Ex. 11 ¶ 10; Ex. 14 ¶ 8. Indeed, Ms. Rinehart and Ms. Morris continued to bleed for weeks after their abortions. Ex. 15 ¶ 11; Ex. 13 ¶ 16. Ms. Morris and Ms. Gillette both passed an intact fetus. Ex. 13 ¶ 14; Ex. 11 ¶ 11. Ms. Gillette also had an adverse reaction to the antibiotics she was given. Ex. 11 ¶ 12.

Mifepristone and misoprostol are not benign, risk-free medications. These powerful drugs must be taken properly, and patients who take them must be monitored properly by the medical offices that treat them, which requires some adherence to the principle of "continuity of care." *See*

Exhibit 17, American College of Obstetricians and Gynecologists, Committee Opinion: Communication Strategies for Patient Handoffs 1 (2012) (explaining that proper patient handoff requires communication between the two physicians, so that the physician assuming care is fully aware of prior events and all potential complicating factors). Such concern is one reason the State requires abortion clinic physicians to have admitting privileges at local hospitals, or at the very least an agreement with a local physician who does. Yet Dr. Glazer said that he did not understand the meaning of "continuity of care" and that women experiencing complications should merely be instructed to go to the emergency room rather than calling him. Ex. 5 at 23:5–6, 24:2–3. State licensing and regulation play an important role when it comes to ensuring patient safety.

The licensing law is also justified by the State's interest in protecting and promoting the integrity of the medical profession. *Gonzales v. Carhart*, 550 U.S. 124, 157 (2007) ("There can be no doubt the government 'has an interest in protecting the integrity and ethics of the medical profession.'" (quoting *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997)). That is why the Licensing Law requires that applicants be of "reputable and responsible character." Ind. Code § 16-21-2-11(a)(1). The integrity of the profession is undermined when clinics go unsupervised and patients are harmed as a result, which appears to be the preferred regulatory model of the CEO of Whole Woman's Health. Ex. 2 at 83:19-84:14.

The necessity of licensing abortion clinics is aptly illustrated by the problems caused by the last abortion clinic in South Bend, which was run by Ulrich Klopfer. This clinic violated many state standards and reporting laws. These violations resulted in an indefinite suspension of Klopfer's medical license and criminal charges in multiple counties. Exhibit A to Ex. 3, Final Order of the Medical Licensing Board. Klopfer's violations were discovered through the Department's surveys, the very surveys the Plaintiffs are seeking to eliminate. The Department found that

Klopfer's clinic filed thousands of incomplete and inaccurate termination of pregnancy reports, failed to submit reports for abortions performed on two 13 year old girls within three days as required by law, *id.* at 21-23, failed to ensure informed and voluntary consent, failed to have qualified staff monitor anesthesia, failed to keep up with proper medical and competency standards, and failed to report a 10-year old abortion patient to authorities even though her parents told Klopfer she was pregnant from rape by a family member, *id.* at 30. In this instance, the Department's licensing and inspections were critical to ferreting out violations of the same reporting laws with which Whole Woman's Health must comply.

And there is reason to be concerned about Whole Woman's Health in particular, for Dr. Glazer apparently does not always report the abortions he performs—or else cannot recall where he performs abortions. Dr. Glazer said that he provides abortions at the Indianapolis Clinic for Women and at Planned Parenthood's clinics in Bloomington, Indianapolis, and Merrillville. Dkt. 76-4, Glazer Decl. ¶ 5. But when questioned during his deposition, he admitted to also performing abortions at another clinic in Indianapolis, *although he was unsure of the clinic's name*. Ex. 5 at 13:8–16. (When asked if the declaration was otherwise accurate, Dr. Glazer responded: "I do not know if there are any other inaccuracies.") Ex. 5 at 31:20–22. Terminated pregnancy reports on file at the Department confirm that Dr. Glazer performs abortions at the Women's Med Center in Indianapolis. Ex. 3 ¶ 62. However, the Department has *no* terminated pregnancy reports signed by Dr. Glazer for the Indianapolis Clinic for Women, *id.*, even though Dr. Glazer testified that he performed around a thousand abortions there in the past year. Ex. 5 at 13:23–14:7.

For his part, Dr. Glazer claims that he files terminated pregnancy reports for each abortion, although he admits that he does not keep copies of those reports. Ex. 5 at 14:8–14. Either Dr. Glazer is performing abortions at Clinic for Women without filing the reports required by state

law, or he simply does not remember where he performs abortions and cannot even be bothered to check before signing a federal court declaration under oath. Both possibilities are concerning (to say the least) and further justify the State's licensing and oversight requirements.

B. All of these interests apply to Whole Woman's Health's proposed clinic

In the face of these overwhelming state interests, Whole Woman's Health explicitly disclaims that its preliminary injunction motion does *not* seek "facial invalidation" of Indiana's Licensing Law. Pl.'s Mem. 1. Instead, it argues that the Indiana licensing requirements are unconstitutional *as applied to it*. Its argument boils down to the contention that requiring *Whole Woman's Health* to have a license will not advance the State's interests because, so Whole Woman's Health maintains, it "and Dr. Glazer are qualified abortion providers who would be able to safely provide medication abortion at the South Bend Clinic." Pl.'s Mem. 27. Whole Woman's Health is thus attempting to use this as-applied undue-burden challenge to re-litigate matters from the Department's previous and ongoing licensing proceedings.

Whole Woman's Health has not established that as-applied challenges to licensing regimes are even cognizable in the first place. It cites only one case, *Planned Parenthood of Kansas v. Drummond*, No. 07-4164-CV-C-ODS, 2007 WL 2463208 (W.D. Mo. Aug. 27, 2007), that involved any "as applied" undue-burden challenge. *Drummond* did not involve a challenge to a requirement that abortion clinics be licensed; the challenged regulation applied physical-plant specifications for surgical clinics to pill-only clinics. Indeed, notwithstanding *Drummond*, to this day Missouri requires pill-only clinics to be licensed. *See* Mo. Stat. § 197.205 (requiring abortion clinics to obtain licenses); Mo. Stat. § 188.015 (defining abortion clinics to include chemical-abortion clinics). *Drummond* provides no rationale for exempting particular clinics from such a basic regulatory requirement as licensing and inspection. Whole Woman's Health has asked the Department

to grant it a waiver from several regulatory requirements once it is licensed, and provides no evidence that the Department will categorically deny that request were it to grant the license. Indeed, the Department has granted multiple waivers to Planned Parenthood's pill-only clinic in Lafayette, but it still licenses and inspects that clinic.

Regardless, Whole Woman's Health's contention that there is no need to subject *it* to licensing or other regulations because the Supreme Court has already declared that "its clinics are safe," Pl.'s Mem. 29, is both factually unsupported and irrelevant. First, it is noteworthy that, while Whole Woman's Health seeks generally to distance itself from non-alliance clinics for purposes of making disclosures to the Department, it has no trouble embracing that relationship when it thinks doing so will redound to its benefit—which only reinforces the Department's need to get to the bottom of that relationship, whatever it might be. Second, *Hellerstedt* did not declare that Whole Woman's Health's clinics were safe; it said that "abortion *in Texas* was extremely safe." 136 S. Ct. at 2311 (emphasis added). Plainly, that observation does not pertain to Indiana, nor does it even absolve any abortion clinics, in Texas or elsewhere, from ongoing licensing and oversight.

Moreover, the evidence raises substantial questions as to whether Whole Woman's Health and its doctors can be trusted to operate scrupulously. Dr. Glazer testified during his deposition that he: was "not sure" whether he was certified by the FDA to prescribe Mifeprex, Ex. 5 at 24:18–20; does not recall completing the required provider agreement forms, *id.* at 25:2–3; was not aware of studies regarding the possible complications of chemical abortion, *id.* at 25:10–13; has not reviewed the ACOG guidelines in "many years," *id.* at 26:25, and is not sure if he follows the guidelines set by the National Abortion Federation, *id.* at 29:7–9. Yet Whole Woman's Health asks this Court to create a special exception to allow it to open an unlicensed clinic led by Dr. Glazer. Ex. 2 at 87:8-21.

Beyond the concerns with Dr. Glazer, the State has identified specific evidence that other Whole Woman's Health clinics have failed to operate safely. A survey from Whole Woman's Health's Austin clinic showed discrepancies in the count of Schedule II pain medications, improper sterilization of surgical instruments, failure to provide pregnant women with contact information for the nearest hospital, and failure to schedule follow-up appointments within 14 days. Ex. 3 ¶ 21. A survey from its San Antonio clinic showed failure to properly evaluate employee performance and improper storage of hazardous cleaning solutions. *Id.* And a survey from its Beaumont clinic showed thirteen violations, including failure to provide a clean and sanitary environment and failure to have emergency medication. *Id.*

In response to this evidence, Whole Woman's Health alleges that only the Austin and Charlottesville clinics are affiliated with it. *Id.* ¶ 31. But Whole Woman's Health also lists these other clinics under "our clinics" on its website. *Id.* ¶ 32. And in any case Miller is ultimately responsible for all of these clinics. Ex. 2 at 29:20–23; 30:21–25; 31:10–15. And even if these other clinics were entirely disconnected from Whole Woman's Health, if the Court were to grant Whole Woman's Health's request to be entirely exempted from Indiana's Licensing Law, the Department would have no way of preventing or addressing similar health code violations in Indiana.

Most importantly, the seriousness of these clinics' violations—and the degree to which Whole Woman's Health is connected to these clinics—are not questions that should be resolved with this preliminary injunction motion. These disputes should be left to the state administrative proceeding—and, if necessary, state judicial review.

C. The Licensing Law imposes little, if any, burden on Indiana women

When a plaintiff seeks a preliminary injunction against an abortion regulation, the regulation usually is a new requirement that threatens to upend the abortion-access status quo. *Cf. Whole*

Woman's Health v. Hellerstedt, 136 S. Ct. 2292, 2297 (2016); *Planned Parenthood of Ind. & Ky., Inc. v. Comm'r of Ind. State Dep't of Health*, 896 F.3d 809, 819 (7th Cir. 2018); *Planned Parenthood of Ind. & Ky., Inc. v. Comm'r, Ind. State Dep't of Health*, 258 F. Supp. 3d 929, 947 (S.D. Ind. 2017). Here, however, Indiana's licensing scheme has been around since 2015. 2015 Ind. Legis. Serv. 92-2015. And Whole Woman's Health does not even identify anyone who wants an abortion but cannot obtain one.

Instead, it essentially argues that, although Indiana has six abortion clinics from Merrillville to Bloomington, an insufficient number of abortions occur each year, and that it needs to operate a chemical abortion clinic in South Bend to achieve some minimally acceptable quantum of abortion access in that area. It is not the responsibility of the State, however, to ensure that every woman who wants an abortion can obtain one, and indeed "not every law which makes a right more difficult to exercise is, *ipso facto*, an infringement of that right." *Casey*, 505 U.S. at 873.

The argument Whole Woman's Health makes in its preliminary injunction motion is a variation of its broader claim that the cumulative burdens of Indiana's abortion laws constitutes an undue burden on the right to abortion. Compl. ¶ 197. Without a specific new burden on the abortion right to attack, its theory appears to be that *Hellerstedt* requires the court to weigh the cumulative benefits against the cumulative burdens of the entire state regulatory regime. *Hellerstedt* authorized no such wholesale-impact review, particularly given that the Court's concern regarding burden in that case was that the *marginal effect* of a *new* Texas law that would require many abortion clinics to shut down. *Hellerstedt*, 136 S. Ct. at 2296–97. And the Supreme Court has always evaluated the burdens of challenged abortion laws one at a time, in spite of the objection of dissenting members of the Court. *See 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 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 cumulative burdens theory is also fundamentally unsound. Regulations that are constitutional when enacted separately do not become unconstitutional when combined. Such a theory would require articulating an arbitrary "appropriate" number of abortions and would effectively give abortion clinics a right to override any regulations that frustrate their business models. Quite telling in this regard, neither Miller, nor Dr. Glazer, nor Guerrero think enjoining the Licensing Law—or any other abortion regulation—would achieve adequate access to abortion. Ex. 5 at 17:12–18:16; Exhibit 18, Guerrero Dep. 46:5–47:6; Ex. 1 at 70:21–71:6. This theory would require the Court to lift regulation after regulation until there is a sufficient number of abortions. But plaintiffs' own testimony demonstrates that they have no concrete goal in mind, only complete deregulation of abortion. And Miller realizes that even then socioeconomic circumstances may impede access to abortion for some women. Ex. 1 at 70:21–71:6; 72:22–24. This theory thus posits an idealized standard that can never exist and that cannot be used to measure this or any other abortion regulation.

Finally, whether or not Whole Woman's Health's burden theory is cognizable at all, the Supreme Court's abortion doctrine makes clear that an abortion regulation cannot be declared invalid unless it imposes a substantial obstacle for a large fraction of women who seek an abortion. *Casey*, 505 U.S. at 895. Whole Woman's Health does not even attempt to meet this test. It supplies no data, for example, as to the number of women who are seeking an abortion but cannot obtain one because of Indiana's Licensing Law. It hypothesizes that some women in South Bend may have a harder time getting an abortion than in other places; but even if that were true, that demonstrates, at most, a market demand for an abortion clinic in South Bend, not a constitutional right to

one. Tellingly, Whole Woman's Health has not found a single Indiana woman who needs a chemical abortion and cannot obtain one. *See Planned Parenthood of Sw. Ohio Region v. DeWine*, 696 F.3d 490, 516 (6th Cir. 2012) (holding that restrictions on chemical abortion did not impose an undue burden in part because "all of the affected women who gave statements proceeded to obtain a surgical abortion regardless of their preference for a medical procedure").

The only potential patient supporting Whole Woman's Health alleges that she was inconvenienced by her inability to obtain an abortion in South Bend; but she does not allege that this inconvenience was so great as to prevent her from obtaining an abortion. To the contrary, she successfully obtained an abortion at a clinic in Chicago, even though that clinic was farther than Indiana's Merrillville clinic, which is licensed to dispense chemical abortions. Dkt. 76-2, Doe Decl. ¶ 8. It is not an undue burden that she may have preferred to have an abortion in South Bend but could not do so. *See DeWine*, 696 F.3d at 515–16 (explaining that the fact that "some women prefer a medical abortion" does not mean that "the unavailability of a medical abortion would create a *substantial obstacle* for a large fraction of women in deciding whether to have an abortion").

Calling this an "as applied" challenge makes it even weaker. Whole Woman's Health seems to be suggesting that the Indiana licensing law is imposing an undue burden only on women in South Bend, such that even if the licensing law is otherwise valid, it must give way so that South Bend may have the clinic to which it is entitled. Presumably, once Whole Woman's Health opens its unlicensed doors, the undue burden will be lifted, and the next pill-only abortion clinic seeking to open in South Bend (*i.e.*, Whole Woman's Health's competitors) will not similarly be entitled to a business-protection injunction by a Federal Court. The constitutional law of abortion is not designed to provide advantages to certain abortion clinics at the expense of others, but Whole

Woman's Health's "as applied" theory would do just that, which is a strong indication that it is wrong. Whole Woman's Health cites no precedent for declaring an abortion clinic licensing requirement invalid only in one particular region of a State, and this court should not be the first.

In any event, in an as-applied challenge, the court must "examine the facts of the case . . . exclusively . . . not any set of hypothetical facts under which the statute might be unconstitutional." *Hegwood v. City of Eau Claire*, 676 F.3d 600, 603 (7th Cir. 2012). Whole Woman's Health has not shown that *any* women are actually burdened by the Licensing Law, much less a substantial burden for a large fraction of them. It cannot prevail on its newfangled as-applied theory.

D. The benefits of the Licensing Law outweigh its burdens

Even if the Licensing Law burdens the abortion right, its safety benefits are weightier. Whether abortion can be provided safely in an unlicensed facility is a determination for the legislature to make, and other courts have upheld such determinations. *See Baird v. Dep't of Pub. Health of Mass.*, 599 F.2d 1098 (1st Cir. 1979); *Birth Control Ctrs., Inc. v. Reizen*, 743 F.2d 352 (6th Cir. 1984); *Greenville Women's Clinic v. Bryant*, 222 F.3d 157 (4th Cir. 2000); *Greenville Women's Clinic v. Comm'r, S.C. Dep't of Health & Envtl. Control*, 317 F.3d 357 (4th Cir. 2002); *Women's Med. Ctr. of Nw. Houston v. Bell*, 248 F.3d 411 (5th Cir. 2001). And, again, at least one circuit has upheld specific regulations for chemical abortions. *See DeWine*, 696 F.3d at 490.

Planned Parenthood of Kansas v. Drummond, No. 07-4164-CV-C-ODS, 2007 WL 2463208 (W.D. Mo. Aug. 27, 2007), is the only case Whole Woman's Health cites that invalidates a statute even somewhat related to the licensing of abortion clinics. But, as explained above, the statute at issue in *Drummond* would have required abortion clinics, including chemical-abortion clinics, to meet the facility requirements for ambulatory surgical centers and would have shut down the only two abortion clinics in the State of Missouri outside the St. Louis area. *Id.* at *4–5. Whole

Woman's Health cannot show any such dire consequences here. The benefits of the Licensing Law outweigh its burdens, and plaintiffs cannot show likely success on their undue burden claim.

III. The Licensing Law Does Not Violate Equal Protection

A. Heightened scrutiny does not apply in the abortion context

Whole Woman's Health argues that the Licensing Law merits "intermediate scrutiny" under the Equal Protection Clause, which requires the State to "show at least that the [challenged] classification serves 'important governmental objectives and that the discriminatory means employed' are 'substantially related to the achievement of those objectives." *United States v. Virginia*, 518 U.S. 515, 533 (1996), because the law "burdens the fundamental right to abortion." Pl.'s Mem. 35. Whether the Licensing Law "burdens the fundamental right to abortion," however, is a matter to be decided using the undue burden standard. *See Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2309 (2016); *Gonzales v. Carhart*, 550 U.S. 124, 146 (2007); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 874 (1992). Merely because a law regulates abortion does not justify even *higher* scrutiny via the Equal Protection Clause. If it did, courts would never need the undue burden standard because plaintiffs challenging abortion laws could always cast their claims in equal protection terms and thereby invoke an even more difficult standard for the government to meet. *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.").

Furthermore, nowhere in *Hellerstedt* did the Court equate the undue burden standard to heightened scrutiny or suggest heightened scrutiny as an alternative test. If such a higher standard had applied, the district court and Fifth Circuit in *Hellerstedt* could simply have disposed of the

case on equal protection grounds and saved everyone the onus of litigating the undue burden standard in the Supreme Court. *Whole Woman's Health v. Lakey*, 46 F. Supp. 3d 673, 687–88 (W.D. Tex. 2014) (rejecting equal protection claim but holding that the challenged laws "create an undue burden on a woman seeking a previability abortion"); *Whole Woman's Health v. Cole*, 790 F.3d 563, 590 (5th Cir.) (affirming dismissal of equal protection claim and also holding "Plaintiffs failed to prove that the ASC requirement imposes an undue burden on a large fraction of women").

Nor does Whole Woman's Health cite any case applying a different standard under the Equal Protection Clause than would be applicable under the Due Process Clause. *See* Pl.'s Mem. 34–35. In *Obergefell v. Hodges*, 135 S. Ct. 2584, 2604 (2015), the Court applied strict scrutiny under both the Equal Protection and Due Process Clauses. And in *City of Cleburne v. Cleburne Living Center*, 473 U.S. 432, 440 (1985) and *Vision Church v. Village of Long Grove*, 468 F.3d 975, 1000 (7th Cir. 2006), the courts merely acknowledged that heightened scrutiny applies when either a fundamental right or suspect class is involved.

Plaintiffs' invocation of "intermediate scrutiny" is thus wholly unsupported. No court has established a connection between that "quasi-suspect" class standard and abortion regulations. With no doctrine supporting review of differential treatment of abortion clinics and other medical offices under "heightened scrutiny," the Court must affirm Indiana's line-drawing so long as it is rationally advances legitimate objectives—which it does, as explained below.

B. If the Licensing Law draws classifications, it passes even heightened scrutiny

Whole Woman's Health argues that the Licensing Law draws three classifications subject to equal protection scrutiny: (1) "it subjects [Whole Woman's Health] to greater scrutiny than other abortion clinic license applicants;" (2) it "treats the South Bend Clinic's first four chemical abortion patents each year differently than its subsequent patients;" (3) it "treats patients seeking

chemical abortions differently than patients seeking medical management of a miscarriage using the exact same medication regimen." Pl.'s Mem. 35–36. Of these, only the third even plausibly describes a classification, albeit one amply supported by compelling government interests.

1. First, the Licensing Law does not subject Whole Woman's Health to greater scrutiny than other applicants. On its face, it applies to Whole Woman's Health on exactly the same terms as other license applicants. Whole Woman's Health argues only that the Department subjected it to "greater" scrutiny in applying the Licensing Law when a senior official at the Department—Trent Fox—took part in reviewing Whole Woman's Health's application. But if Whole Woman's Health's is attempting to prove a "class of one" claim, it falls woefully short. It neither cites governing "class of one" cases nor attempts to grapple with the Seventh Circuit's divided decisions as to the proof necessary to bring a "class of one claim." *Cf. D. Del Marcelle v. Brown Cty. Corp.*, 680 F.3d 887 (7th Cir. 2012) (en banc).

In any case, the State's evidence demonstrates that Fox is *frequently* involved in licensing decisions, and Whole Woman's Health has provided no evidence that the Department targeted it with a unique licensing standard or that it denied the application out of "animus." The most Whole Woman's Health asserts is that the Department involved a "political" appointee (Fox) in the licensing review process, but it provides no evidence either that Fox holds his job based solely on political patronage (or argues why that might matter) or that he employed "political" standards (whatever that might mean) to Whole Woman's Health's application. As this Court recently observed, while the Seventh Circuit's "class of one" standard is unsettled at the margins, it requires at the very least that the plaintiff demonstrate the lack of any rational basis for the government's decision. *Hinterberger v. City of Indianapolis*, No. 1:16-cv-01341-SEB-MJD, 2019 WL 1439159 (S.D. Ind. Mar. 30, 2019) ("As for animus, not even the *Del Marcelle* dissent held that it can

complete an equal-protection violation where the government's conduct is rational.").

Here, Fox's involvement in Whole Woman's Health's application was wholly justified by legitimate government concerns and does not represent greater substantive "scrutiny" of Whole Woman's Health's application. As Chief of Staff, Fox sits in a hierarchically superior position to the staff who first examine license applications, and he frequently reviews, according to the standards set forth by law, license applications for medical facilities. Ex. 4 ¶¶ 8–9. He became involved in this case for the same reasons he has become involved in other license applications—the application involved an organization previously unknown in the State seeking a license that only one other clinic (Planned Parenthood's Lafayette clinic) has thus far obtained. *Id.* ¶ 7. And despite having deposed Fox as part of the administrative review of its first license applications, Whole Woman's Health does not claim that Fox ordered the use of a non-statutory standard applicable only to Whole Woman's Health.

In short, the Department has been transparent about the statutory reasons for denying Whole Woman's Health's license application (insufficient information to make a "reputable and responsible character" finding), and Fox's participation does not denote substantively more rigorous review. Nothing about this process was extraordinary—the Department regularly denies licenses to applicants who do not provide it with the proper documentation. Ex. 2 ¶¶ 12–13.

Even under heightened scrutiny, the Department and Fox's enforcement of the Licensing Law in response to Whole Woman's Health's application is substantially related to the State's "important and legitimate interest in preserving and protecting the health of the pregnant woman." *Roe v. Wade*, 410 U.S. 113, 162 (1973). The State need not license a clinic that may have affiliates in other States with a history of safety violations, or a clinic that refuses to comply with statutory

requirements to provide information about itself and its affiliates. And involving Fox was important to ensure that the licensing staff employed the little-used standards for licensing pill-only clinics in accord with the Commissioner's understanding of those standards.

2. Second, Whole Woman's Health claims that the Licensing Law somehow draws a line between its first four patients of the year and the remainder of its patients each year. Nonsense. The statute merely exempts from abortion-clinic licensing those medical offices that perform fewer than five abortions each year. Whole Woman's Health's challenge to that modest regulatory safe-harbor is premised on the unserious idea that each year it would be *unlicensed* for the first four patients but then *licensed* for the remainder. Plainly, that is not Whole Woman's Health's plan. Obviously each year it will be licensed to serve all its patients or it will not serve any.

In any event, the law's distinction between clinics that perform fewer than five abortions per year and clinics that perform five or more abortions per year is substantially related to the State's important interests in fetal life and women's health. The legislature made a logical judgment call in determining that its interests would be better served by devoting resources to licensing, inspecting, and monitoring clinics that perform abortions on a regular basis, rather than on rare occasions. Notably, the legislature originally supplied a small-practice safe harbor by exempting "physicians' offices" entirely from the licensing requirement. *See Planned Parenthood of Ind. & Ky., Inc. v. Comm'r, Ind. State Dep't of Health*, 984 F. Supp. 2d 912, 922 (S.D. Ind. 2013). In a challenge to that original safe harbor, Judge Magnus-Stinson—using the rational-basis standard—struck down that distinction on equal protection grounds because, while creating a de minimis safe harbor is a legitimate government interest, there is nothing special about "physicians' offices" that advances that interest. *Id.* at 924–25. Instead of appealing, the State asked the legislature to fix the statute so that it created a safe harbor exemption based on the number of abortions performed

rather than the type of office where the abortions were performed. The legislature amended the law, deciding that five abortions would be the licensing threshold. 2015 Ind. Legis. Serv. 92-2015.

Whole Woman's Health now apparently thinks the State should not be permitted to create a de minimis safe harbor at all. The Constitution does not preclude the State from exercising such regulatory flexibility, for it advances important government interests in both regulating frequent practitioners who attract many abortion patients that need to be protected from unsafe conditions and not overwhelming practitioners who may encounter only occasional patients in need of abortion services. At least three circuits have upheld similar distinctions based on the number of abortions performed. *See Women's Med. Ctr. of Nw. Houston v. Bell*, 248 F.3d 411, 419 (5th Cir. 2001) (upholding a Texas licensing law that exempted clinics performing fewer than 300 abortions per year); *Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 174 (4th Cir. 2000) (upholding a South Carolina licensing statute exempting clinics that perform fewer than five first-trimester abortions per month); *Birth Control Ctrs., Inc. v. Reizen*, 743 F.2d 352, 359 (6th Cir. 1984) (upholding licensing law regulating freestanding facilities where abortions were performed but not physicians' private offices where abortions were performed). This Court should do so as well.

3. Plaintiffs complain the Licensing Law leaves out clinics that supply mifepristone and misoprostol only to complete miscarriages. But abortion and miscarriage implicate profoundly different interests. At the very least, because abortion, not miscarriage, implicates the State's interest in protecting fetal life, the State has a legitimate interest in ensuring informed-consent procedures are followed so that the woman fully contemplates her decision to end her baby's life. The State also does not require reporting miscarriages or miscarriage complications the way it does with abortion, which means it does not have the same need to ensure proper reporting.

Whole Woman's Health has not shown likely success on its equal protection claim.

PLAINTIFFS HAVE NOT DEMONSTRATED IRREPARABLE HARM

Whole Woman's Health must establish that the denial of an injunction will result in irreparable harm. Again, this is not a case where a new abortion regulation is threatening to shut down an existing clinic. Licensing is a standard feature of American business life, and the mere denial of a license does not justify an immediate injunction by a federal court. The Licensing Law has been in place for many years; Whole Woman's Health first applied for a license in 2017 and filed this lawsuit last June. It was apparently content to let both play out in the ordinary course, and it does not explain why its situation is now so urgent to warrant immediate relief, particularly when judicial review of its original license denial would by now be moving through state court.

Furthermore, women seeking abortion in Indiana are not at risk of irreparable harm absent an injunction. Indiana already has six *licensed* abortion clinics where women may legally have chemical (and surgical) abortions. Whole Woman's Health has failed to show that even a single woman has been prevented from having an abortion by the Licensing Law. Plaintiffs offer no data proving Indiana suffers from an abortion access "crisis." Pl.'s Mem. 2.

PUBLIC POLICY AND THE BALANCE OF EQUITIES FAVOR THE STATE

Here, the need for judicial restraint is particularly high, as "the court must consider that all judicial interference with a public program has the cost of diminishing the scope of democratic governance." *Ill. Bell Tel. Co. v. WorldCom Techs., Inc.*, 157 F.3d 500, 503 (7th Cir. 1998). Indiana has a strong interest in implementing laws passed by its duly elected representatives. *See United States v. Rural Elec. Convenience Coop. Co.*, 922 F.2d 429, 440 (7th Cir. 1991) ("[T]he government's interest is in large part presumed to be the public's interest . . . ."). Its interests are even greater here because Whole Woman's Health is asking for special judicial permission to dispense powerful hormone-curbing, abortion-inducing, uterus-contracting prescription drugs without any

state regulatory oversight whatever. The State has many substantive restrictions, informed consent requirements, and recordkeeping laws that Whole Woman's Health does not challenge in its preliminary injunction motion. The Licensing Law serves the public interest by ensuring that Whole Woman's Health provides chemical abortions in compliance with these unchallenged (for present purposes) laws. The harm to women by allowing unlicensed clinics to dispense chemical abortions outweighs any speculative burdens Whole Woman's Health or its nonexistent patients may incur in the near term. Accordingly, the State's interests in enforcement outweigh the harms Whole Woman's Health might suffer pending a final decision on the merits.

CONCLUSION

The Court should deny the Motion for Preliminary Injunction.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 15, 2019, a copy of the foregoing was electronically filed with the Clerk of the Court using the CM/ECF system, which sent notification of such filing to the following:

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