

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

PLANNED PARENTHOOD OF)	
INDIANA AND KENTUCKY, INC.,)	
)	
Plaintiff,)	
)	
v.)	Case No. 1:18-cv-1219-RLY-DLP
)	
COMMISSIONER, INDIANA STATE)	
DEPARTMENT OF HEALTH, <i>et al.</i> ,)	
)	
Defendants.)	

**DEFENDANTS' MEMORANDUM
IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT
AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT**

Curtis T. Hill
Attorney General of Indiana

Thomas M. Fisher
Solicitor General

Julia C. Payne
Deputy Attorney General

Office of the Attorney General
IGC-South, Fifth Floor
Indianapolis, Indiana 46204
Tel: (317) 232-6255
Fax: (317) 232-7979
Email: Tom.Fisher@atg.in.gov

Counsel for Defendants

TABLE OF CONTENTS

TABLE OF AUTHORITIES.....iii

DEFENDANTS’ MEMORANDUM IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS’ MOTION FOR SUMMARY JUDGMENT..... 1

INTRODUCTION..... 1

STATEMENT OF MATERIAL FACTS NOT IN DISPUTE 2

I. Abortion and its Complications..... 2

II. Inspections of Abortion Clinics..... 4

III. Procedural History..... 6

STATEMENT OF FACTS ASSERTED BY PLANNED PARENTHOOD AND DISPUTED BY THE STATE, BUT ULTIMATELY IMMATERIAL TO THE CLAIMS..... 8

LEGAL STANDARD 11

ARGUMENT 11

I. Under Evidence Rule 702 and Controlling Precedents, Planned Parenthood’s Experts Are Not Qualified To Offer Some Opinions that They Tender 11

II. The Reporting Requirement Is Not Unconstitutionally Vague 14

A. The Reporting Requirement is properly read to include a *mens rea* requirement 14

B. The phrase “arising from the induction or performance of an abortion” is not unconstitutionally vague..... 15

C. The specific listed complications are not vague..... 19

1. The term “psychological complications” is not vague 19

2. “Any other adverse event” as defined by the FDA is not vague 21

D. Specific complications are severable 23

III. The Reporting Requirement Does Not Violate Due Process 24

IV. Neither the Reporting Requirement nor the Inspection Requirement Violates Equal Protection..... 28

 A. The Reporting Requirement does not violate equal protection because there is no evidence that it singles out abortion providers for disfavored treatment 28

 B. The Inspection Requirement does not violate equal protection 32

CONCLUSION 35

TABLE OF AUTHORITIES

CASES

Hayden ex rel. A.H. v. Greensburg Cmty. Sch. Corp.,
743 F.3d 569 (7th Cir. 2014)24

Adarand Constructors, Inc. v. Pena,
515 U.S. 200 (1995)29

Anderson v. Liberty Lobby, Inc.,
477 U.S. 242 (1986)8, 11

Beecham v. United States,
511 U.S. 368 (1994)19

Bell’s Gap R. Co. v. Pennsylvania,
134 U.S. 232 (1890)29

Box v. Planned Parenthood of Ind. & Ky., Inc.,
139 S. Ct. 1780 (2019)24, 27

CF&I Steel Corp. v. United Mine Workers of Am.,
507 F.2d 170 (10th Cir. 1974)16

Columbus Bd. of Educ. v. Penick,
443 U.S. 449 (1979)30

Coplen v. Omni Rests., Inc.,
636 N.E.2d 1285 (Ind. Ct. App. 1994)16

Ctr. for Individual Freedom v. Madigan,
697 F.3d 464 (7th Cir. 2012)19

Dandridge v. Williams,
397 U.S. 471 (1970)31, 32, 34

Exxon Corp. v. Eagerton,
462 U.S. 176 (1983)23

FCC v. Beach Commc’ns, Inc.,
508 U.S. 307 (1993)30

Franklin v. City of Evanston,
384 F.3d 838 (7th Cir. 2004)30

Gambino v. Music Television, Inc.,
932 F. Supp. 1399 (M.D. Fla. 1996)16

CASES [CONT'D]

Gonzales v. Carhart,
550 U.S. 124 (2007)31

Harris v. McRae,
448 U.S. 297 (1980)25, 31, 33

Heller v. Doe by Doe,
509 U.S. 312 (1993)30

Karlin v. Foust,
188 F.3d 446 (7th Cir. 1999).....14, 17

D.B. ex rel. Kurtis B. v. Kopp,
725 F.3d 681 (7th Cir. 2013).....25

Lees v. Carthage Coll.,
714 F.3d 516 (7th Cir. 2013).....12

Leigh v. Olson,
497 F. Supp. 1340 (D.N.D. 1980)28

Lewis v. CITGO Petroleum Corp.,
561 F.3d 698 (7th Cir. 2009).....12

Planned Parenthood of Cent. Mo. v. Danforth,
428 U.S. 52 (1976)30

Planned Parenthood of Ind. & Ky., Inc. v. Comm’r, Ind. State Dep’t of Health,
64 F. Supp. 3d 1235 (S.D. Ind. 2014)34

Planned Parenthood of Ind., Inc. v. Comm’r of Ind. State Dep’t of Health,
699 F.3d 962 (7th Cir. 2012).....30, 31

Planned Parenthood of Se. Pa. v. Casey,
505 U.S. 833 (1992)25

Planned Parenthood of Se. Pa. v. Casey,
686 F. Supp. 1089 (E.D. Penn. 1988).....28

Planned Parenthood of Se. Pa. v. Casey,
744 F. Supp. 1323 (E.D. Penn. 1990).....28

Planned Parenthood of Wisc., Inc. v. Van Hollen,
738 F.3d 786 (7th Cir. 2013).....32

Roe v. Wade,
410 U.S. 113 (1973)24

CASES [CONT'D]

Simopoulos v. Virginia,
462 U.S. 506 (1983)24

Smith v. California,
361 U.S. 147 (1959)15

Sprunger v. Egli,
44 N.E.3d 690 (Ind. Ct. App. 2015)15

State v. Keihn,
542 N.E.2d 963 (Ind. 1989).....15

United States v. Collins,
272 F.3d 984 (7th Cir. 2001)18

United States v. Cook,
914 F.3d 545 (7th Cir. 2019).....17, 18

United States v. Johnson,
875 F.3d 360 (7th Cir. 2017).....19, 20

United States v. Lim,
444 F.3d 910 (7th Cir. 2006)18

United States v. Williams,
553 U.S. 285 (2008)19

Vance v. Bradley,
440 U.S. 93 (1979)10, 11, 26

Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.,
455 U.S. 489 (1982)14

Washington v. Glucksberg,
521 U.S. 702 (1997)24

Williamson v. Lee Optical of Okla., Inc.,
348 U.S. 483 (1955)11, 25, 33

CONSTITUTIONAL PROVISIONS

U.S. Const. Amendment XIV, § 129

STATUTES

18 Pa. Cons. Stat. § 3214(h)28

STATUTES [CONT'D]

18 U.S.C. § 1531(a).....15

Ariz. Rev. Stat. Ann. § 36-216228

Ind. Code § 1-1-1-8(b).....23

Ind. Code § 16-21-2-24

Ind. Code § 16-21-2-2.64, 5, 6

Ind. Code § 16-21-2-13(b)(2).....4, 34

Ind. Code § 16-21-2-13(g).....4

Ind. Code § 16-34-2-4.76

Ind. Code § 16-34-2-4.7(a).....8, 15, 26

Ind. Code § 16-34-2-4.7(a)(4)27

Ind. Code § 16-34-2-4.7(a)(23)14, 19, 20

Ind. Code § 16-34-2-4.7(a)(25) *passim*

Ind. Code § 16-34-2-4.7(b)..... *passim*

Ind. Code § 16-34-2-4.7(g).....6

Ind. Code § 16-34-2-4.7(h).....6

Ind. Code § 16-34-2-4.7(j)6

Ind. Code § 31-33-5-115

Ind. Code § 35-47-7-115

Mich. Comp. Laws § 333.283728

Minn. Stat. § 145.413228

Miss. Code Ann. § 41-41-7728

N.D. Cent. Code § 14-02.1-07.....28

Okla. Stat. Title 63, §§ 1-738i–1-738q.....28

STATUTES [CONT'D]

R.I. Gen. Laws § 28-34-2(26)15, 16
R.I. Gen. Laws § 28-34-2(30)–(35).....15, 16
Tex. Health & Safety Code Ann. § 171.00628
Tex. Transp. Code Ann. § 91.034(a).....16
W. Va. Code § 46A-2-119(1).....16

REGULATIONS

21 C.F.R. § 312.32(a)22, 23, 27
21 C.F.R. § 312.32(c)(1)(i).....22
21 C.F.R. § 312.32(c)(1)(iv).....23
21 C.F.R. § 312.32(c)(2)23
410 Ind. Admin. Code 15-1.3-44
410 Ind. Admin. Code 15-2.3-44
410 Ind. Admin. Code 26-3-25
410 Ind. Admin. Code 27-3-25
410 Ind. Admin. Code 27-3-34

RULES

Fed. R. Civ. P. 56(a).....11
Fed. R. Evid. 702.....11, 12
Fed. R. Evid. 703.....12

**DEFENDANTS’ MEMORANDUM
IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT
AND IN OPPOSITION TO PLAINTIFFS’ MOTION FOR SUMMARY JUDGMENT**

Defendants the Commissioner of the Indiana State Department of Health, the Prosecutors of Marion, Lake, Monroe, and Tippecanoe Counties, and the Individual Members of the Medical Licensing Board of Indiana (together, the State) respectfully submit this memorandum in support of their Motion for Summary Judgment and in opposition to Plaintiff’s Motion for Summary Judgment.

INTRODUCTION

This case concerns the constitutionality of two common-sense regulations designed to protect the health and safety of women seeking an abortion. First, the challenged statute requires physicians, hospitals, and abortion clinics to report “each case in which the person treated a patient suffering from an abortion complication,” as defined by Ind. Code § 16-34-2-4.7(b). The Indiana State Department of Health (“the Department”) will then compile that data into a report on the frequency of twenty-five specific complications after abortion, so that those who study the abortion procedure can use the information in their research and women may review this information before deciding whether to have an abortion. Second, the challenged statute requires the Department to inspect abortion clinics annually to ensure compliance with applicable health and safety regulations.

Both requirements apply to abortion clinic operations rather than the abortion procedure itself (or women seeking abortion), and Plaintiff Planned Parenthood of Ind. & Ky. (“Planned Parenthood”) does not argue that either provision imposes an “undue burden” on such women. Instead, it argues that the definition of “abortion complication” is unconstitutionally vague and that the Reporting Requirement violates equal protection because it applies only to abortion procedures and no other medical procedures—a claim it also makes against the Inspection Requirement—as

well as due process. Yet, unlike at the preliminary injunction stage of this case, the statute now clearly defines “abortion complication” to include *only* twenty-five enumerated conditions. And neither provision is irrational; both are reasonably related to the State’s interest in protecting women’s health and safety, and the legislature need not include hospitals and ambulatory surgical centers in the Inspection Requirement because they are already inspected through different programs inapplicable to abortion clinics. The State is entitled to judgment as a matter of law.

STATEMENT OF MATERIAL FACTS NOT IN DISPUTE

I. Abortion and its Complications

Planned Parenthood’s patients may choose from two different methods of first trimester abortion: chemical (medication) abortion and surgical abortion by aspiration (suction). Planned Parenthood performs chemical abortions up to ten weeks gestation involving two medications subject to FDA regulations: mifepristone and misoprostol. Mifepristone kills the fetus by blocking the effects of the mother’s progesterone, ECF No. 16-2 ¶¶ 17–18, and misoprostol induces uterine contractions, which cause the uterus to empty its contents, including the fetus, *id.* ¶ 19. 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 with a miscarriage.” Exhibit A, 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 any accompanying severe cramping, nausea, vomiting, diarrhea, dizziness, exhaustion, and fever. *Id.* at 3, 5.

Chemical abortions sometimes have serious complications, such as infection, excessive vaginal bleeding, failure to terminate the pregnancy, incomplete abortion, and in some cases, even death. ECF No. 73-3 ¶ 26; ECF No. 24-1 ¶ 12. 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 is most commonly done in a surgical facility. Ex. A at 5–6.

Aspiration abortion, on the other hand, uses suction to remove the fetus from the uterus. ECF No. 73-3 ¶ 22. “[A]n abortion provider first dilates the patient’s uterus and then inserts a suction tube through the cervix into the uterus, which is attached to a vacuum pump or manual aspirator (syringe).” *Id.* The provider then activates the vacuum pump and uses the suction tube to remove the fetus, placenta, and umbilical cord. *Id.* “Common side-effects of aspiration abortion include uterine pain, cramping, some bleeding, and possibly the passing of small blood clots.” *Id.* ¶ 23. Possible complications of aspiration abortion include uterine perforation, cervical laceration, infection, excessive vaginal bleeding, pulmonary embolism, deep vein thrombosis, cardiac arrest, respiratory arrest, renal failure, shock, amniotic fluid embolism, coma, and in some cases, even death. ECF 24-1 ¶¶ 12–14, 16; ECF No. 73-3 ¶ 27. Aspiration abortion can also result in a hemolytic reaction if the patient needs to receive a blood transfusion because of excessive bleeding, or an allergic reaction from anesthesia (if used). ECF No. 24-1 ¶¶ 12, 21, 24.

The legislature has a legitimate concern that researchers have insufficient data available to study the safety of abortion. Dr. James Studnicki, the State’s expert on largescale statistical data analysis of patient outcomes, testifies that the “incompleteness and inconsistency of state-level reporting of abortion data” has rendered national data collection systems “woefully inadequate.” Exhibit B ¶ 10, Declaration of James Studnicki, Sc. D., MPH, MBA; *see also* ECF No. 24-1 ¶ 7.

To “improv[e] the safety and quality of abortion care,” States must “establish and improve available data collection.” Ex. B ¶ 11; *see also* ECF No. 24-1 ¶ 8–9. As Dr. Christina Francis, an Indiana obstetrician-gynecologist, has testified, “even where there is an abundance of data, further data is always useful.” ECF No. 24-1 ¶ 10. Dr. Studnicki explains that “we learn about and address risks by studying them, not by ignoring them.” Ex. B ¶ 15.

II. Inspections of Abortion Clinics

The Department has a duty to license and regulate hospitals, ambulatory surgical centers (ASCs), birthing centers, and abortion clinics. Ind. Code § 16-21-2-2. At the time of licensing, the Department performs an initial licensure survey to determine that the facility complies with state law. *Id.* § 16-21-2-13(g). The Department may also conduct inspections in response to complaints against a particular facility. 410 Ind. Admin. Code 15-1.3-4 (hospitals); *id.* 15-2.3-4 (ASCs); *id.* 27-3-3 (birthing centers); Ind. Code § 16-21-2-2.6 (abortion clinics).

As the parties have stipulated, federal law dictates the minimum frequency of inspections for hospitals and ASCs, but not for abortion clinics. ECF No. 72 ¶ 2. Generally, the State must inspect hospitals at least every five years and ASCs every six years. ECF No. 72-1 at 71, 74. In practice, the Department inspects hospitals and ASCs on a roughly annual basis, ECF No. 73-1 at 28, or more precisely an average of once every 15.3 months for hospitals and once every 16.3 months for ASCs, ECF No. 74 at 15–16. Hospitals and ASCs have the option of joining private accrediting organizations, such as the Joint Commission. ECF 73-1 at 61–63. These accrediting organizations charge a fee to healthcare facilities that wish to join. *Id.* at 61. In exchange, the accrediting organization will visit the healthcare facility and perform the required federal survey. *Id.* State law requires that the Department grant licenses to all members of these organizations. Ind. Code § 16-21-2-13(b)(2). For health facilities that are members of an accrediting organization, the

Department need only inspect a 1% targeted sample of hospitals, and 5-10% of ASCs, each year. ECF No. 72-1 at 70, 74. Abortion clinics, on the other hand, have no private accrediting organization, so if such clinics are to be inspected at all, the State must do it. ECF No. 73-1 at 63.

The Department must inspect birthing centers at least once every two years. 410 Ind. Admin. Code 27-3-2. Prior to July 1, 2018, the Department also inspected abortion clinics at least once every two years, *id.* 26-3-2 (superseded by emergency rule, eff. Apr. 10, 2019), but could inspect abortion clinics as frequently as every year. Ind. Code § 16-21-2-2.6 (amended eff. July 1, 2018). As of July 1, 2018, Indiana law requires the Department to inspect abortion clinics annually. Ind. Code § 16-21-2-2.6 (eff. July 1, 2018).

Past health and safety violations prompted the increased inspection frequency for abortion clinics. In October of 2014, the Department inspected the Women’s Health Pavilion, an abortion clinic in South Bend run by Dr. Ulrich Klopfer, in response to a complaint. ECF No. 73-1 at 64. That inspection yielded a “50- or 60-page report” detailing several health and safety violations, including improper use of anesthesia and poorly kept medical records. *Id.* at 64–65. After Dr. Klopfer failed to submit an acceptable plan of correction and the Department undertook further investigations following a *second* complaint, the Department moved to revoke his license. *Id.* at 66. Dr. Klopfer voluntarily surrendered his clinic license about two weeks prior to the hearing. *Id.*

Matt Foster, the assistant commissioner for the Consumer Services and Health Care Regulation Commission at the Department, testified at deposition that the incident with Dr. Klopfer prompted the Department to conclude that “we need to get into these places more frequently because we don’t want, ever, to have another Women’s Pavilion on our hands. . . . This guy ran a very shoddy clinic, and there was just great concern that we didn’t want that kind of thing happening again.” *Id.* at 66–67. It was not just the existence of the health and safety problems that concerned

the Department, but the fact that Dr. Klopfer never fixed those problems. *Id.* at 68–69. In contrast, Foster testified, birthing centers, ASCs, and hospitals routinely fix problems identified. *Id.*

III. Procedural History

1. In the spring of 2018, the Indiana General Assembly enacted Enrolled Act No. 340 (SEA 340), including the two provisions at issue here. First, Section 9 of SEA 340 (codified as Ind. Code § 16-34-2-4.7) (the “Reporting Requirement”) adds a section to the code requiring that physicians, hospitals, and abortion clinics shall, on pain of conviction for a misdemeanor, “report to the state department each case in which the person treated a patient suffering from an abortion complication.” Ind. Code §§ 16-34-2-4.7(b), 16-34-2-4.7(j). The original statute defined “abortion complication” as “any adverse physical or psychological condition arising from the induction or performance of an abortion, including . . .” a list of twenty-six specific complications. *Id.* § 16-34-2-4.7 (amended eff. July 1, 2019).

Under the terms of the statute, the Department must make the data collected under the Reporting Requirement available to women and researchers. Each year, the Department “shall compile a public report summarizing the information collected under this section,” which “must include statistics for the previous calendar year, with updated information for the most recent calendar year.” *Id.* § 16-34-2-4.7(g). It shall also “summarize the aggregate data . . . and submit the data . . . to the United States Centers for Disease Control and Prevention for its inclusion in the annual Vital Statistics Report.” *Id.* § 16-34-2-4.7(h).

Second, Section 5 of SEA 340 (codified as Ind. Code § 16-21-2-2.6) (the “Inspection Requirement”) amended the code to require annual inspections of abortion clinics by the Department. It reads: “The state department shall inspect an abortion clinic at least one (1) time per calendar year and may conduct a complaint inspection as needed.” *Id.* § 16-21-2-2.6.

2. On April 23, 2018, Planned Parenthood filed suit against the State, alleging that the Reporting Requirement was unconstitutionally vague and violated due process and equal protection and that the Inspection Requirement violated equal protection. ECF No. 1. This Court entered a preliminary injunction against the Reporting Requirement on June 28, 2018. ECF No. 30. The Court held that Planned Parenthood had “a reasonable likelihood of success on its void-for-vagueness due process challenge,” *id.* ¶ 30, but it did not “evaluate the strength of [Planned Parenthood]’s substantive due process and equal protection claims,” *id.* ¶ 31. It held that the statutory definition of abortion complications was unconstitutionally vague because it was not limited to the twenty-six conditions enumerated in the statute. *Id.* ¶¶ 14–22. It also held that some of the enumerated complications, namely “hemorrhaging,” “blood clots,” “emotional complications,” “adverse reaction to anesthesia or other drugs,” and “physical injury associated with treatment performed at the abortion facility,” were vague. *Id.* ¶¶ 23, 26.

In response to the preliminary injunction, the legislature revised the Reporting Requirement during the next legislative session. It clarified that the definition of abortion “complication” is restricted to the enumerated list and removed or rewrote the complications that this Court identified as vague. The new statute reads, in relevant part:

As used in this section, “abortion complication” means only the following physical or psychological conditions arising from the induction or performance of an abortion:

- (1) Uterine perforation.
- (2) Cervical laceration.
- (3) Infection.
- (4) Vaginal bleeding that qualifies as a Grade 2 or higher adverse event according to the Common Terminology Criteria for Adverse Events (CTCAE).
- (5) Pulmonary embolism.
- (6) Deep vein thrombosis.
- (7) Failure to terminate the pregnancy.
- (8) Incomplete abortion (retained tissue).
- (9) Pelvic inflammatory disease.

- (10) Missed ectopic pregnancy.
- (11) Cardiac arrest.
- (12) Respiratory arrest.
- (13) Renal failure.
- (14) Shock.
- (15) Amniotic fluid embolism.
- (16) Coma.
- (17) Placenta previa in subsequent pregnancies.
- (18) Pre-term delivery in subsequent pregnancies.
- (19) Free fluid in the abdomen.
- (20) Hemolytic reaction due to the administration of ABO-incompatible blood or blood products.
- (21) Hypoglycemia occurring while the patient is being treated at the abortion facility.
- (22) Allergic reaction to anesthesia or abortion inducing drugs.
- (23) Psychological complications, including depression, suicidal ideation, anxiety, and sleeping disorders.
- (24) Death.
- (25) Any other adverse event as defined by criteria provided in the Food and Drug Administration Safety Information and Adverse Event Reporting Program.

Ind. Code § 16-34-2-4.7(a).

STATEMENT OF FACTS ASSERTED BY PLANNED PARENTHOOD AND DISPUTED BY THE STATE, BUT ULTIMATELY IMMATERIAL TO THE CLAIMS

Planned Parenthood includes several facts and legal arguments in its “[s]tatement of material facts not in dispute” that the State disputes. However, none of these facts are material. *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.” (emphasis by the Court)). The State identifies these factual disputes here in an abundance of caution.

First, Planned Parenthood’s confidence in the safety of abortions is misplaced. ECF No. 74 at 7–10. Neither the federal government nor most States mandate the collection of data on abortion complications. Dr. Francis testified that without mandatory reporting requirements, the data regarding abortion complications is incomplete: some doctors will report only the most serious

complications, and many may choose not to report at all. ECF No. 24-1 ¶ 8; *see also* Ex. B ¶ 10. She also testified that “studies show that ‘a comparison of abortion mortality and maternal mortality is complicated by methodological problems,’ including incomplete reporting, definitional incompatibilities, voluntary data collection, reliance on estimations, inaccurate/incomplete death certificates, and incompatibility with maternal mortality statistics.” ECF No. 24-1 ¶ 7. For this reason, scientists lack data regarding the types of complications that may follow abortion and the frequency with which they occur. *Id.* ¶ 9. Therefore, Planned Parenthood’s statements that “abortions . . . are extremely safe,” ECF 74 at 7, and “[c]omplications from abortions are rare,” *id.* at 9, are disputed because researchers do not have adequate data to assess the safety of abortion.

On this same topic, the Department has not conceded “that childbirth is much more likely to result in fatality than abortion.” ECF No. 74 at 15. The Department’s informed consent brochure does recite statistics from the Guttmacher Institute (Planned Parenthood’s own research wing) and the CDC concerning the relative fatality of abortion and childbirth. ECF No. 73-4 at 10. But the State has presented evidence that such data is “woefully inadequate” due to the lack of mandatory reporting for abortion complications. Ex. B ¶ 10. It is not irrational for the Department to provide women considering abortion with the only data it currently has on abortion mortality while also collecting new data on abortion complications and mortality so that in the future it may provide women with more accurate data.

Second, Planned Parenthood’s section entitled “The meaning and effect of the Complications Statute on PPINK and its patients,” ECF No. 74 at 12, includes legal arguments regarding the vagueness of the statute that are inappropriate for designation as “material facts” and that the State obviously contests. *See infra* Part II. To the extent that this section includes facts regarding the incidence of specific complications of abortion, the State contests those facts.

Far from having “nothing to do with abortion,” ECF No. 74 at 12, “hypoglycemia could occur in an already-diabetic patient as a result of fasting before the procedure.” ECF 24-1 ¶ 22. Abortion may also lead to complications with subsequent pregnancies, including both pre-term delivery and placenta previa. *Id.* ¶ 20. A missed ectopic pregnancy may occur if an ultrasound before the abortion is performed incorrectly and can lead to serious complications, including intra-abdominal hemorrhage, loss of fertility, and even death. *Id.* ¶ 17. Finally, abortion can also have adverse consequences for a woman’s psychological health. *Id.* Ex. G, Priscilla K. Coleman, *Abortion and Mental Health: Quantitative Synthesis and Analysis of Research Published 1995–2009*, 199 *Brit. J. Psychiatry* 180 (2011). Women who have had abortions have an increased risk for depression, substance abuse, anxiety, and suicide. *Id.* Ex. G at 183. However, none of these facts are material because the impossibility or infrequency of a particular complication after abortion does not render that complication vague.

Third, Planned Parenthood mischaracterizes the testimony of Matt Foster when it says that “the Department of Health does not know any reason why abortion clinics should be inspected for licensure more frequently than birthing centers, outpatient surgical centers, or hospitals.” ECF No. 74 at 17. On the contrary, Foster specifically cited the “Klopfer situation.” ECF No. 73-1 at 51–52. He also mentioned deference to what “the legislature has decided.” *Id.* at 52.

To be clear, none of these facts is material to the outcome of this case. Facts about the state of the world, such as the extent to which abortions are safe and complications rare, qualify as legislative, rather than adjudicative, facts, meaning that the court must defer to legislative judgment unless “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). Planned Parenthood has not met that bar here. Regardless, these facts are not dispositive

under the rational-basis test because the legislature “may take one step at a time, addressing itself to the phase of the problem which seems most acute to the legislative mind.” *Williamson v. Lee Optical of Okla., Inc.*, 348 U.S. 483, 489 (1955).

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) (emphasis by the Court). Critically, 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. Under Evidence Rule 702 and Controlling Precedents, Planned Parenthood’s Experts Are Not Qualified To Offer Some Opinions that They Tender

The expert reports of two of Planned Parenthood’s witnesses, Dr. Carol Dellinger, ECF No. 73-5, and Dr. Sabrina Holmquist, ECF No. 73-3, include opinions for which neither Dr. Dellinger nor Dr. Holmquist has any demonstrated expertise. The Court should exclude or ignore their unqualified opinion testimony accordingly.

Rule 702 of the Federal Rules of Evidence states that “[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if . . . 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.” Fed. R. Evid. 702. District

courts must make the following inquiries before admitting expert testimony: “First, the expert must be qualified by knowledge, skill, experience, training, or education; second, the proposed expert testimony must assist the trier of fact in determining a relevant fact at issue in the case; third, the expert’s testimony must be based on sufficient facts or data and reliable principles and methods; and fourth, the expert must have reliably applied the principles and methods to the facts of the case.” *Lees v. Carthage Coll.*, 714 F.3d 516, 521–22 (7th Cir. 2013). Federal Rule of Evidence 703 further explains that “[a]n expert may only base an opinion on facts or data in the case that the expert has been made aware of or personally observed.” Fed. R. Evid. 703. “The proponent of the expert bears the burden of demonstrating”—by a preponderance of evidence—“that the expert’s testimony would satisfy the *Daubert* standard.” *Lewis v. CITGO Petroleum Corp.*, 561 F.3d 698, 705 (7th Cir. 2009) (citing Fed. R. Evid. 702 advisory committee’s note (2000 Amends.)).

Here, Dr. Dellinger and Dr. Holmquist are licensed medical doctors qualified to testify on abortion complications generally. *See* ECF No. 73-5 ¶¶ 2–3; ECF No. 73-3 ¶ 3. But neither doctor has demonstrated qualifications to testify about (1) psychological complications or (2) the statistical significance and public health impact of the data collected by the Reporting Requirement.

1. Dr. Dellinger testifies that she is “not sure what is a ‘psychological complication’ that has to be reported.” ECF No. 73-5 ¶ 20. First, this statement is a marked departure from the statement of Planned Parenthood’s original expert on the subject, Dr. John William Stutsman, who at the preliminary injunction stage of this case stated that he was “certainly aware of what a ‘psychological complication’ is.” ECF No. 16-2 ¶ 39. More to the point for Rules of Evidence purposes, Dr. Dellinger is certified in family medicine, not psychiatry, and she lists no education or training (formal or informal) in psychiatry or psychology.

Similarly, Dr. Holmquist testifies that “there is no reliable evidence that abortion ‘creates’ or ‘causes’ psychological problems that did not already exist prior to or would have arisen regardless of having had the procedure.” ECF No. 73-3 ¶ 33. But Dr. Holmquist is an obstetrician-gynecologist, not a psychiatrist, and she lists no education or training in psychiatry or psychology.

Indeed, neither doctor asserts *any* specific expertise to opine on the frequency of psychological complications following abortion. Moreover, a woman who experiences depression, anxiety, or any other psychological complication would not seek diagnosis and treatment from Planned Parenthood, but from a licensed psychiatrist or clinical psychologist. Consequently, the requirement to report psychological complications would not likely fall on Dr. Dellinger or Dr. Holmquist. Accordingly, the un-informed views of these two physicians are unhelpful in understanding the requirement.

2. Dr. Dellinger also offers opinions critical of the reporting requirement more generally—without first demonstrating any qualifications for doing so. She testifies that a “reporting system can be successful only if *serious* problems are presented,” and that otherwise reporting “will create or feed a false and dangerous narrative.” ECF No. 73-5 ¶¶ 17, 21 (emphasis in original). But Dr. Dellinger asserts no expertise in medical reporting, public health, or the responses of future patients to reported data. Similarly, Dr. Holmquist testifies about the “public health purpose” of the statute and the “need for further data collection.” ECF No. 73-3 ¶¶ 13–15. She then opines that “the information required to be reported by the Statute will not benefit either public or individual patient health.” ECF No. 73-3 ¶ 50; *see also id.* ¶¶ 30–31. But like Dr. Dellinger, Dr. Holmquist asserts no expertise in statistical analysis, epidemiology, and public health, and therefore, she is unqualified to testify in court about the conclusions she has drawn.

For these reasons, this Court should limit Dr. Holmquist's and Dr. Dellinger's testimonies to those subjects on which they are qualified, namely, the physical complications of abortion.

II. The Reporting Requirement Is Not Unconstitutionally Vague

A statute is unconstitutionally vague if “it fails to provide ‘fair warning’ as to what conduct will subject a person to liability” or it 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). However, a court should not mechanically apply these principles because “[t]he degree of vagueness that the Constitution tolerates—as well as the relative importance of fair notice and fair enforcement—depends in part on the nature of the enactment.” *Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498 (1982).

Planned Parenthood admits that “the precise vagueness problem identified in this Court’s preliminary-injunction decision has been cured.” ECF No. 74 at 18. Nevertheless, it now contends that the phrase “arising from the induction or performance of abortion” is vague, even though it never pressed this concern before. And while Planned Parenthood previously briefed the vagueness of the specific complications “[p]sychological complications, including depression, suicidal ideation, anxiety, and sleeping disorders” and “[a]ny other adverse event as defined by criteria provided in the Food and Drug Administration Safety Information and Adverse Event Reporting Program,” Ind. Code § 16-34-2-4.7(a)(23), (25), this Court did not suggest any vagueness concerns with them even as it specified problems with several other enumerated complications targeted by Planned Parenthood. There is no reason for the Court to find new problems now.

A. The Reporting Requirement is properly read to include a *mens rea* requirement

Planned Parenthood begins its vagueness argument by pointing out that the Reporting Requirement does not include a *mens rea* requirement. ECF No. 74 at 20. First, lack of *mens rea* is

not a constitutional defect. *See Smith v. California*, 361 U.S. 147, 150 (1959) (“[I]t is doubtless competent for the States to create strict criminal liabilities by defining criminal offenses without any element of scienter.”).

Second, under Indiana law, there is a presumption that criminal statutes require proof of *mens rea*. *See State v. Keihn*, 542 N.E.2d 963, 967 (Ind. 1989). The most analogous reporting statute—which will be a key indicator for Indiana courts when they apply this statute, *see id.* at 967—imposes a duty to report child abuse and neglect if an individual “has reason to believe that a child is a victim.” Ind. Code § 31-33-5-1; *see also Sprunger v. Egli*, 44 N.E.3d 690, 693 (Ind. Ct. App. 2015) (“‘Reason to believe,’ for the purpose of the reporting statutes, ‘means evidence that, if presented to individuals of similar background and training, would cause the individuals to believe that a child was abused or neglected.’”). Applying the same standard here, a doctor would be required to report a complication if the doctor has reason to believe that it may have resulted from an abortion. Therefore, the Reporting Requirement demands no “great[er] precision” than any other criminal statute. *See* ECF No. 74 at 20.

B. The phrase “arising from the induction or performance of an abortion” is not unconstitutionally vague

Planned Parenthood next contends that the phrase “arising from the induction or performance of an abortion” is vague. ECF No. 74 at 21 (quoting Ind. Code § 16-34-2-4.7(a)). But the phrase “arising from,” which implies causation, is commonly used in both federal and state statutes. *See, e.g.*, 18 U.S.C. § 1531(a) (exempting from criminal liability physicians who perform partial-birth abortions to save the life of a mother who has “a life-endangering physical condition caused by or *arising from* the pregnancy itself” (emphasis added)); Ind. Code § 35-47-7-1 (creating a Class A misdemeanor for failure to report “a bullet wound, gunshot wound, powder burn, or any other injury *arising from* or caused by the discharge of a firearm” (emphasis added)); R.I. Gen.

Laws § 28-34-2(26), (30)–(35) (allowing workers compensation benefits for a “disability *arising from*” particular conditions” (emphasis added)); Tex. Transp. Code Ann. § 91.034(a) (giving the Texas Department of Transportation the authority to develop property for the purpose of mitigating an “adverse environmental effect *arising from* the construction, maintenance, or operation of a rail facility” (emphasis added)); W. Va. Code § 46A-2-119(1) (subjecting sellers to liability for “claims and defenses *arising from* sales” (emphasis added)).

Federal courts have upheld the use of the phrase “arising from” against allegations of vagueness. *See, e.g., CF&I Steel Corp. v. United Mine Workers of Am.*, 507 F.2d 170, 173 (10th Cir. 1974) (holding that there is “no incapacitating vagueness” in a decree applicable to “disputes *arising from* employee suspensions, employee discharges and work assignments” (emphasis added)); *Gambino v. Music Television, Inc.*, 932 F. Supp. 1399, 1401 (M.D. Fla. 1996) (holding that “[t]here is no vagueness or ambiguity” in a statement disclaiming “all claims or liabilities of any kind *arising from* my participation in this event” (emphasis added)). In contrast, Planned Parenthood cites no case where a court has held that the phrase “arising from” is unconstitutionally vague.

The Indiana Court of Appeals has defined “arising from” as “connoting the source, relating back to and tying up with the origin, basis or cause.” *Coplen v. Omni Rests., Inc.*, 636 N.E.2d 1285, 1287 (Ind. Ct. App. 1994). It is easy to determine “the extent to which a condition must be caused by the abortion itself,” ECF No. 74 at 21, by applying this definition to Planned Parenthood’s examples. “If an infection results from an examination before the abortion, but not from the abortion itself,” *id.*, the complication must be reported only if the examination is done as part of the abortion procedure (rather than on a separate occasion to determine whether the woman is pregnant). If a woman “becomes anxious simply because she has to undergo a medical procedure,” *id.*, her anxiety

is reportable as long as that procedure is an abortion. If a patient “experiences hypoglycemia . . . simply because she did not eat in advance of her appointment,” *id.*, the hypoglycemia is a complication of the abortion only if the patient was required to fast in preparation for the procedure. Similarly, a “‘hemolytic reaction’ resulting from a blood transfusion,” *id.*, is an abortion complication only if the transfusion was made necessary by the abortion.

The Reporting Requirement does not “require[] a certainty as to causation that simply does not exist.” *Id.* at 22. Instead, a physician must exercise reasonable medical judgment to determine whether a complication arises from the abortion. *See supra* Part II.A. In *Karlin*, the Seventh Circuit upheld a Wisconsin statute requiring physicians to exercise reasonable medical judgment to determine whether an emergency abortion was necessary. 188 F.3d at 468. The Court explained that “reasonable medical judgment” does not require absolute medical certainty: “In any given medical situation there is likely to be a number of reasonable medical options and disagreement between doctors over the appropriate course of action does not, of course, render one option reasonable and another unreasonable.” *Id.* at 464. The court concluded that this objective standard did not render the statute vague. *Id.* at 465. Similarly, the mere fact that a doctor will have to exercise reasonable medical judgment to determine whether a particular complication arose from an abortion does not render the Reporting Requirement unconstitutionally vague.

Finally, just because this determination may be difficult to make in some marginal situations does not make the statute facially invalid. The Seventh Circuit has identified three types of statutes for purposes of a vagueness challenge: (1) statutes that “implicate[] activities protected by the First Amendment,” for which “there is a special concern that free speech and expression not be chilled,” *United States v. Cook*, 914 F.3d 545, 550 n.2 (7th Cir. 2019); (2) statutes that “simply ha[ve] no core and lack[] any ascertainable standard for inclusion and exclusion,” *id.* at 550 (internal

quotation marks omitted); and (3) statutes with “a readily appreciable core of conduct that the statute reaches,” but that leave “uncertainty as to whether the statute might apply to certain hypothetical facts,” *id.* at 553–54. In *Cook*, the court considered a facial vagueness challenge to a federal statute prohibiting controlled substance users from possessing firearms. *Id.* at 549. The court held that Cook was not “entitled to mount a facial vagueness challenge,” *id.* at 554, because the statute had a “readily appreciable core of conduct,” *id.*, and Cook’s conduct “epitomizes that core,” *id.* at 551. The fact that “it may sometimes be difficult to determine if an individual’s” conduct falls within the statute, “does not signify that the statute is impermissibly vague.” *Id.* at 554.

At most, Planned Parenthood’s claim against the Reporting Requirement falls into this third category. Planned Parenthood makes no argument that the statute implicates any First Amendment rights, and readily admits that several of the complications listed in the statute can be easily traced to abortion. ECF No. 74 at 9–10. No doubt exists “as to the essence of what the statute forbids”: failure to report complications that can reasonably be traced to abortion. *See Cook*, 914 F.3d at 554. For this type of statute, only “a defendant whose conduct is [not] clearly prohibited by a statute can[] be the one to make a facial vagueness challenge.” *Id.* So if, for example, a prosecutor alleges that a doctor should have used reasonable medical judgment to determine that a particular complication arose from abortion, even though that complication is not definitively linked to abortion, the doctor could raise a statutory ambiguity “as-applied” defense. *See, e.g., United States v. Lim*, 444 F.3d 910, 915–16 (7th Cir. 2006) (addressing as-applied vagueness challenge to National Firearms Act); *United States v. Collins*, 272 F.3d 984, 988–89 (7th Cir. 2001) (addressing as-applied vagueness challenge to federal drug-trafficking statute). But as a matter of law, “arising from the induction or performance of an abortion” is not, on its face, unconstitutionally vague.

C. The specific listed complications are not vague

Planned Parenthood also contends that two of the specific listed complications are vague: “[p]sychological complications, including depression, suicidal ideation, anxiety, and sleeping disorders” and “[a]ny other adverse event as defined by criteria provided in the Food and Drug Administration Safety Information and Adverse Event Reporting Program.” ECF No. 74 at 23 (quoting Ind. Code § 16-34-2-4.7(a)(23), (25)). Again, this Court did not deem either of these provisions vague at the preliminary injunction stage; it should now expressly reject Planned Parenthood’s claims against them.

1. The term “psychological complications” is not vague

First, even though Planned Parenthood’s medical director, Dr. John William Stutsman, has testified that he is “certainly aware of what a ‘psychological complication’ is,” ECF No. 16-2 ¶ 39, Planned Parenthood now argues that “[t]he term ‘psychological complications’ has no established meaning in medical parlance, and is vague,” ECF No. 74 at 23. The term “psychological complication” must be understood in context of the specific examples that follow it, namely “depression, suicidal ideation, anxiety, and sleeping disorders.” Ind. Code § 16-34-2-4.7(a)(23). “[T]he commonsense canon of *noscitur a sociis* . . . counsels that a word is given more precise content by the neighboring words with which it is associated.” *United States v. Williams*, 553 U.S. 285, 294 (2008). Under this canon, “the fact that ‘several items in a list share an attribute counsels in favor of interpreting the other items as possessing that attribute as well.’” *Ctr. for Individual Freedom v. Madigan*, 697 F.3d 464, 496 (7th Cir. 2012) (quoting *Beecham v. United States*, 511 U.S. 368, 371 (1994)).

In *United States v. Johnson*, the Seventh Circuit applied *noscitur a sociis* to a statute with a similar framework to the provision at issue here. 875 F.3d 360, 366 (7th Cir. 2017). The court

interpreted a provision of the federal Animal Enterprise Terrorism Act that “prohibit[s] damaging ‘any real or personal property (including animals or records) used by an animal enterprise.’” *Id.* Applying *noscitur a sociis*, the court said that because “the phrase ‘any real or personal property’ is immediately followed by the phrase ‘(including animals or records),’” personal property must mean tangible items, like animals or records (rather than intangible items, like lost profits). *Id.*

Here, the phrase “psychological complications” is followed by the phrase “including depression, suicidal ideation, anxiety, and sleeping disorders.” Ind. Code § 16-34-2-4.7(a)(23). Depression, anxiety, and sleeping disorders are all diagnosable psychological disorders included in the DSM-5. Exhibit C, American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders* 155, 189, 361 (5th ed. 2013). Suicidal ideation, while not a separately listed disorder, is a common symptom of many psychiatric disorders and is clearly defined in the DSM-5. *Id.* at 830. Applying the principle of *noscitur a sociis*, it follows that other reportable psychological conditions would also be known psychological disorders, rather than temporary feelings of worry or sadness. Otherwise, the legislature would have had no reason to distinguish between “psychological” and “emotional” complications in the first place.

Applying this understanding, physicians may make relatively straightforward determinations whether a psychological complication is reportable. To address Planned Parenthood’s hypotheticals, “[i]f a woman is anxious prior to an abortion,” ECF No. 74 at 23, her anxiety is reportable (assuming causation can be traced to the abortion, not some preexisting anxiety disorder, *see supra* Part II.B) only if it rises to the level of a diagnosable anxiety disorder, rather than a temporary feeling of anxiousness. Similarly, “[i]f a woman reports . . . that she is relieved, sad, wary, or depressed shortly after the procedure,” ECF No. 74 at 23, those feeling are reportable only if they are symptoms of a diagnosable psychological disorder. If “a patient seeks treatment for

minor depression or anxiety,” *id.*, the treating physician must report those diagnosable conditions regardless of whether they occur “years after the fact,” *id.* Even “if the practitioner concludes that the depression or anxiety would have been more severe if the patient had continued the pregnancy,” *id.*, the complication is still reportable if the practitioner determines that it arose from the abortion (rather than some preexisting condition). If the practitioner instead concludes that “the depression results not from the abortion-as-such but rather from the reaction of a family-member,” *id.* at 23–24, then the chain of causation has been broken and the condition is not reportable. Finally, “[i]f that family member . . . seeks treatment for depression,” *id.* at 24, the family member’s depression is not an abortion complication. As Dr. Francis has testified, “from a medical standpoint, patients never have complications from another person’s procedure.” ECF No. 24-1 ¶ 27.

Again, Planned Parenthood will likely never have to make a determination whether a psychological complication is reportable. Women who experience psychological complications after abortion would likely seek treatment from their regular doctor, a psychiatrist, or a clinical psychologist. Thus, the duty to report will fall on the treating physician, not the abortion doctor. *See* Ind. Code § 16-34-2-4.7(b) (requiring physicians, hospitals, and abortion clinics to report “each case in which the person *treated* a patient suffering from an abortion complication” (emphasis added)). And even if, as Planned Parenthood claims, psychological complications are infrequent after abortion, that rarity does not render the statute vague. The State is entitled to judgment as a matter of law on this claim.

2. “Any other adverse event” as defined by the FDA is not vague

Second, Planned Parenthood argues that the phrase “[a]ny adverse event as defined by criteria provided in the Food and Drug Administration Safety Information and Adverse Event Reporting Program” is unconstitutionally vague. ECF No. 74 at 24 (quoting Ind. Code § 16-34-2-

4.7(a)(25)). As with “psychological complication,” the Court should now expressly reject the claim that “any adverse event . . .” is constitutionally unsound.

The parameters of the final complication in the Reporting Requirement are defined by federal law. FDA regulations define “adverse event” as “any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.” 21 C.F.R. § 312.32(a). Planned Parenthood argues that “even though the Adverse Event Reporting Program was designed to track drug-related occurrences for investigational new drugs, the definition of an ‘adverse event’ is itself not limited to these occurrences.” ECF No. 74 at 25. But Planned Parenthood misreads the statute. “Adverse events” must be “associated with the use of a drug in humans.” 21 C.F.R. § 312.32(a). If no drug has been administered, then any complications cannot be *associated with* the use of a drug. For instance, minor soreness after a surgical abortion cannot be an adverse event under the FDA criteria.

The second clause of the definition, “whether or not considered drug related,” *id.*, simply means that the adverse event must be reported even if it is not a complication that the physician thinks would be caused by an abortion-inducing drug. Because the FDA regulates only adverse events resulting from the administration of a drug, this complication would include adverse events arising from medication abortions or from any other drug administered during an abortion procedure, such as drugs used during sedation for a surgical abortion. Planned Parenthood counters that adverse events need not be reported under federal law, ECF No. 74 at 26, but that does not preclude the State from requiring reporting—Planned Parenthood has raised a vagueness objection, not a preemption claim. In any event, Planned Parenthood acknowledges, with seeming acceptance, three other types of events that federal law requires to be reported: (1) “any suspected adverse reaction that is both serious and unexpected,” 21 C.F.R. § 312.32(c)(1)(i); (2) “any clinically

important increase in the rate of a serious suspected adverse reaction,” *id.* § 312.32(c)(1)(iv); and (3) “any unexpected fatal or life-threatening suspected adverse reaction,” *id.* § 312.32(c)(2). ECF No. 74 at 26. *Each* of these reportable complications is defined in terms of an “adverse event.” *See* 21 C.F.R. § 312.32(a). Hence, Planned Parenthood must understand what qualifies as an adverse event to comply with both federal and state law. That obligation completely undermines the credibility of their objection to the “any other adverse event . . .” reporting requirement. The State is entitled to judgment as a matter of law on this claim as well.

D. Specific complications are severable

Even if some of the complications listed in the Reporting Requirement are vague, those complications are severable from the remainder of the statute. Whether an unconstitutional portion of a state law can be severed is a question of state law. *Exxon Corp. v. Eagerton*, 462 U.S. 176, 196–97 (1983). Indiana has a statutory presumption in favor of severability. Ind. Code § 1-1-1-8(b). A provision is presumed severable from the remainder of the statute unless: (1) “the remainder is so essentially and inseparably connected with, and so dependent upon, the invalid provision or application that it cannot be presumed that the remainder would have been enacted without the invalid provision or application;” or (2) “the remainder is incomplete and incapable of being executed in accordance with the legislative intent without the invalid provision or application.” *Id.*

Here, neither condition for defeating severability exists. First, the complications listed in the Reporting Requirement are completely independent of one another. Even if, for instance, this Court holds that the term “psychological complications” is vague and cannot be upheld, that holding would have no bearing on the validity of the requirement to report “uterine perforation” or “incomplete abortion,” or any other listed complication. Second, the purpose of the Reporting Requirement is to collect data regarding the types of complications that result from abortion and

the frequency of those complications. This purpose is best served by requiring the reporting of as many listed abortion complications as possible. Therefore, even if some specific complications are unconstitutionally vague, the remainder of the Reporting Requirement should be upheld.

III. The Reporting Requirement Does Not Violate Due Process

Planned Parenthood does not allege that a fundamental right is at stake here; it instead relies on the “residual substantive limit on government action which prohibits arbitrary deprivations of liberty by government.” *Hayden ex rel. A.H. v. Greensburg Cmty. Sch. Corp.*, 743 F.3d 569, 576 (7th Cir. 2014). Therefore, rational-basis review applies. *See* ECF No. 74 at 27–29 (applying rational basis test). “[O]rdinary rational basis review” is a “deferential test” for which “a state law need only be ‘rationally related to legitimate government interests.’” *Box v. Planned Parenthood of Ind. & Ky., Inc.*, 139 S. Ct. 1780, 1781–82 (2019) (quoting *Washington v. Glucksberg*, 521 U.S. 702, 728 (1997)).

The Supreme Court has repeatedly recognized that the State has a “compelling interest in ‘protecting the woman’s own health and safety.’” *Simopoulos v. Virginia*, 462 U.S. 506, 519 (1983) (quoting *Roe v. Wade*, 410 U.S. 113, 150 (1973)). The Reporting Requirement furthers that interest by providing more comprehensive data on the rate of complications for abortion as performed in Indiana. As Dr. Francis testified, “abortion complications are notoriously difficult to track” because “women often are not treated for abortion complications by the same doctor that performed the abortion.” ECF No. 24-1 ¶ 8. Without a reporting requirement, complications and side effects may never be traced back to the abortion. Indeed, some doctors may report only the most serious complications or may choose not to report at all. *Id.* Moreover, Dr. Studnicki testifies that “because of the incompleteness and inconsistency of state-level reporting of abortion data,” data from the CDC on the mortality of abortion is “woefully inadequate.” Ex. B ¶ 10. The additional information

collected by the Reporting Requirement will allow researchers “to perform a basic analysis on the complications identified.” *Id.* ¶ 13. This research might include “an analysis of the relationship between an abortion provider’s volume and the likelihood of an adverse outcome” or an explanation of “any racial disparities in abortion complication rates.” *Id.*

The fact that the Reporting Requirement collects data regarding complications of abortion but not complications of childbirth is irrelevant to its constitutionality. Under rational-basis review, the State “may take one step at a time, addressing itself to the phase of the problem which seems most acute to the legislative mind.” *Williamson v. Lee Optical of Okla., Inc.*, 348 U.S. 483, 489 (1955). Moreover, the Supreme Court has specifically held that “[a]bortion is inherently different,” *Harris v. McRae*, 448 U.S. 297, 325 (1980), and that the State may “express[] a preference for childbirth over abortion,” *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 883 (1992). Planned Parenthood has presented no evidence that “the true purpose of the Statute is to peddle the false narrative that abortion is dangerous.” ECF No. 74 at 29. Regardless, supposed legislative motives are irrelevant—“[a]ll it takes to defeat the plaintiffs’ claim is a *conceivable* rational basis for the difference in treatment.” *D.B. ex rel. Kurtis B. v. Kopp*, 725 F.3d 681, 686 (7th Cir. 2013) (emphasis in original).

Planned Parenthood does not contest “the propriety of requirements mandating the reporting of serious events occurring to patients.” ECF No. 74 at 27. Instead, it argues that the Reporting Requirement is not rationally related to that purpose because it “require[s] the reporting of events . . . even though they are caused by something other than the abortion itself, the reporting of minor conditions that are anticipated and routinely dealt with[,] . . . or duplicate reporting of the same ‘complication’ or by multiple providers treating the same condition in the same patient.” *Id.* at 27–28. Planned Parenthood is wrong on all three counts.

First, the Reporting Requirement demands only reports of “physical or psychological conditions *arising from* the induction or performance of an *abortion*.” Ind. Code § 16-34-2-4.7(a) (emphasis added). The phrase “arising from” denotes causation. *See supra* Part II.B. If a patient suffers from “an infection resulting from an injection or an allergic reaction to anesthesia,” ECF No. 74 at 28, these complications should be reported so long as the infection and administration of anesthesia were connected to the abortion procedure. A woman considering abortion has an interest in knowing *all* possible complications that may occur if she undertakes the procedure, including those resulting from anesthesia or other injections made necessary by the procedure. Similarly, “pelvic inflammatory disease” is an abortion complication only if it results from some part of the abortion procedure. If Planned Parenthood is correct that pelvic inflammatory disease never results from abortion, *see id.*, then it need not ever report it.

Second, “the reporting of minor conditions that are anticipated and are routinely dealt with,” *id.*, does not undercut the State’s interest. A woman who consents to an abortion has a strong interest in knowing all possible outcomes of the abortion, including “expected nausea or fatigue following a medication abortion” and “hypoglycemia in a patient that is quickly rectified with food.” *Id.* Planned Parenthood’s argument on this point amounts to an effort to substitute its own judgment for that of the legislature as to what should constitute a reportable event. Disagreement as to what should count as a reportable complication of abortion, however, does not cast constitutional doubt on the requirements imposed by the Indiana General Assembly. *See Vance v. Bradley*, 440 U.S. 93, 111 (1979) (“[T]hose 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.”).

Planned Parenthood also argues that, per complication number 25 (Ind. Code § 16-34-2-4.7(a)(25)), the term “adverse event” as defined by the FDA is broad enough to include “expected soreness or bleeding following a surgical procedure.” ECF No. 74 at 28. To be sure, the State would be within its rights to require such a report. But as it happens, complication 25 applies only to adverse events “associated with the use of a drug in humans,” 21 C.F.R. § 312.32(a), which excludes surgery. *See also supra* Part II.C.2. Therefore, expected soreness from a surgical abortion is not reportable at all, and expected bleeding following a surgical abortion is reportable only under complication 4, *i.e.*, “[v]aginal bleeding that qualifies as a Grade 2 or higher adverse event according to the Common Terminology Criteria for Adverse Events.” Ind. Code § 16-34-2-4.7(a)(4).

Finally, even if the Reporting Requirement occasionally requires duplicate reporting, either because a particular complication qualifies under more than one provision of the statute or because two doctors treat the same complication, the statute need not be “perfectly tailored” to survive rational basis review. *See Box*, 139 S. Ct. at 1782. Planned Parenthood hypothesizes imperfections, but Indiana is permitted to try one approach, see if it works, and then reevaluate. There is no chance that the Reporting Requirement will “erect[] a barrier of misinformation that women seeking abortions will be forced to confront.” *See* ECF No. 74 at 27. The reports themselves will be accurate because the doctors treating the complications will be reporting the problems that they observe. If the scientists and scholars who analyze the data believe that over-reporting has decreased its utility, then they will be free to publish articles and studies refuting the data. Indeed, this is the purpose of the scientific method. ECF No. 24-1 ¶ 10. But the *mere existence* of the data cannot possibly be a barrier to abortion. As Dr. Studnicki stated in his declaration, “we learn about and address risks by studying them, not by ignoring them.” Ex. B ¶ 15.

Nor is Indiana alone in imposing a reporting obligation regarding abortion complications. Eight other States require the reporting of abortion complications. *See* Ariz. Rev. Stat. Ann. § 36-2162; Mich. Comp. Laws § 333.2837; Minn. Stat. § 145.4132; Miss. Code Ann. § 41-41-77; N.D. Cent. Code § 14-02.1-07; Okla. Stat. tit. 63, §§ 1-738i–1-738q; 18 Pa. Cons. Stat. § 3214(h); Tex. Health & Safety Code Ann. § 171.006. Of these, only two have been challenged: North Dakota’s and Pennsylvania’s. The North Dakota statute was upheld on vagueness grounds in *Leigh v. Olson*, 497 F. Supp. 1340, 1350–51 (D.N.D. 1980). Even more on point, the Pennsylvania statute was challenged at the district court level by the plaintiffs in *Casey*. The district court upheld the statute both at preliminary injunction and summary judgment, specifically rejecting the plaintiff’s arguments that the reports would “yield scientifically inaccurate data.” *Planned Parenthood of Se. Pa. v. Casey*, 686 F. Supp. 1089, 1131 (E.D. Penn. 1988) (“It is not for this court to criticize the Commonwealth’s failure to implement a perfect system for collection of data.”); *Planned Parenthood of Se. Pa. v. Casey*, 744 F. Supp. 1323, 1393 (E.D. Penn. 1990) (“While the data gathered by these reports may not perfectly reflect all medical complications, I am not persuaded that the information is statistically meaningless.”).

Because the Reporting Requirement is rationally related to the legitimate state interest in ensuring the safety of abortion, it does not violate substantive due process.

IV. Neither the Reporting Requirement nor the Inspection Requirement Violates Equal Protection

A. The Reporting Requirement does not violate equal protection because there is no evidence that it singles out abortion providers for special treatment

Planned Parenthood also claims that the Reporting Requirement violates the Equal Protection Clause of the Fourteenth Amendment by “creat[ing] new rules for the reporting of

‘abortion complications,’ while ignoring the reporting of events following other procedures.” ECF No. 74 at 29. Planned Parenthood concedes that rational basis review again applies. *See id.* at 30.

1. Planned Parenthood argues that the Reporting Requirement violates Equal Protection because it distinguishes between abortion and other medical procedures. *See id.* at 29. But the Equal Protection Clause protects persons, not procedures. *See* U.S. Const. amend. XIV, § 1 (“[N]or shall any State deprive any *person* of life, liberty, or property, without due process of law; nor deny to any *person* within its jurisdiction the equal protection of the laws” (emphasis added)); *Adarand Constructors, Inc. v. Peña*, 515 U.S. 200, 230 (1995) (noting the “long line of cases understanding equal protection as a personal right”); *Bell’s Gap R. Co. v. Pennsylvania*, 134 U.S. 232, 237 (1890) (“The [Equal Protection Clause] was not intended to prevent a state from adjusting its system of taxation . . . [by] exempt[ing] certain classes of property from any taxation at all But clear and hostile discriminations against particular persons and classes . . . might be obnoxious to the constitutional prohibition.”).

Planned Parenthood tries to circumvent this problem by arguing that certain “*persons* will have to file reports as to ‘complications’ while *others*, whose patients have identical or much more severe results after surgery or other medical events, will not.” ECF No. 74 at 29 (emphasis added). But nothing in the Reporting Requirement distinguishes between physicians and clinics who perform abortions and those who do not. *See* Ind. Code § 16-34-2-4.7(b) (applying the Reporting Requirement to all licensed physicians, hospitals, and abortion clinics). Really, Planned Parenthood is making a disparate impact argument: in its view, abortion doctors and clinics are more likely to treat patients for the complications of abortion and therefore are more likely to shoulder the obligations of the Reporting Requirement. But Planned Parenthood has presented no evidence that this is true; “women often are not treated for abortion complications by the same doctor that

performed the abortion.” ECF No. 24-1 ¶ 8. Regardless, a disparate *impact* is not disparate *treatment* susceptible to an equal protection challenge. See *Columbus Bd. of Educ. v. Penick*, 443 U.S. 449, 464 (1979) (“[D]isparate impact and foreseeable consequences, without more, do not establish a constitutional violation.”); *Franklin v. City of Evanston*, 384 F.3d 838, 848 (7th Cir. 2004) (“[E]qual protection claims . . . require a showing of discriminatory treatment and cannot be supported by proof of disparate impact.”). Therefore, Planned Parenthood has not even alleged a cognizable equal protection claim.

2. Regardless, the statute’s distinction between abortion and other medical procedures is legitimate. Any legislative classification that does not involve a suspect class “is accorded a strong presumption of validity.” *Heller v. Doe by Doe*, 509 U.S. 312, 319 (1993). For these classifications, the challenger must show that there is no “rational relationship between the disparity of treatment and some legitimate governmental purpose.” *Id.* at 320. Manifestly, “rational-basis review in equal protection analysis ‘is not a license for courts to judge the wisdom, fairness, or logic of legislative choices.’” *Id.* at 319 (quoting *FCC v. Beach Commc’ns, Inc.*, 508 U.S. 307, 313 (1993)). The classification “must be upheld against equal protection challenge if there is any reasonably conceivable state of facts that could provide a rational basis for the classification.” *Id.* at 320 (quoting *Beach Commc’ns*, 508 U.S. at 313).

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.”).

Here, the Indiana General Assembly may legitimately be more concerned about tracking abortion complications than complications from other procedures, including child birth. It may legitimately conclude that insufficient information about abortion complications is available. As Dr. Francis explains in her declaration, women who suffer complications from abortion are not always treated for those complications by the same doctor who performed the abortion, especially if those complications arise years later in connection with a subsequent pregnancy. ECF No. 24-1 ¶ 8. Non-mandatory reporting leads to incomplete data regarding abortion complications because some doctors may report only the most serious violations or may choose not to report at all. *Id.*

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). While the Reporting Requirement does not directly protect fetal life, it aims to collect data that will better inform a woman’s choice whether to end that life. It is crucial that a woman knows the possible complications of the abortion procedure, including the psychological complications, when she makes this decision. After all, “it seems unexceptionable to conclude some women come to regret their choice to abort the infant life they once created and sustained.” *Gonzales v. Carhart*, 550 U.S. 124, 159 (2007).

Planned Parenthood argues that “it is utterly irrational to ignore non-abortion procedures that are much more likely to injure the public health than abortions.” ECF No. 74 at 31. “But the Equal Protection Clause does not require that a State must choose between attacking every aspect of a problem or not attacking the problem at all.” *Dandridge v. Williams*, 397 U.S. 471, 486–87

(1970). The legislature could have rationally concluded that because data on abortion complications is so sparse, it is an appropriate subject for increased reporting.

Planned Parenthood points to dicta in *Planned Parenthood of Wisc., Inc. v. Van Hollen*, 738 F.3d 786, 790 (7th Cir. 2013) (invalidating Wisconsin admitting privileges requirement on undue burden grounds), to support its equal protection argument. *See* ECF No. 74 at 32. But the Court in *Van Hollen* relied on Wisconsin's lack of evidence regarding the occurrence of abortion complications to invalidate a statute that imposed an undue burden on a woman's right to an abortion. 783 F.3d at 790. This is exactly the type of data the State seeks to collect here, and no undue burden has been alleged by the mere collection of that data.

Finally, Planned Parenthood argues that the Reporting Requirement is irrational because, up to this point, "the State ha[s] seen fit to impose the identical requirements concerning the reporting of extremely serious consequences on hospitals, ambulatory surgical centers and abortion clinics." ECF No. 74 at 32. But the Reporting Requirement *also* imposes identical requirements on hospitals, ASCs, and abortion clinics; all three must report abortion complications. Ind. Code § 16-34-2-4.7(b). Regardless, the legislature does not act irrationally just because it enacts different requirements than it had in the past. The Reporting Requirement does not violate the Equal Protection Clause.

B. The Inspection Requirement does not violate equal protection

Planned Parenthood's final argument is that the Inspection Requirement violates equal protection because it applies to abortion clinics but not to other health care facilities. *See* ECF No. 74 at 33–34. Notably, Planned Parenthood devotes only two pages of its memorandum to this point. Once again, rational-basis review applies.

Overall, the Inspection Requirement furthers the State’s compelling interest in protecting women’s health and safety and protecting fetal life by ensuring that abortion clinics follow applicable regulations, including both health and safety regulations and informed consent requirements. Moreover, the State need not have a “specific reason to justify the annual burden of inspections imposed on abortion clinics when no such burden is imposed on other health care facilities.” *See id.* at 32–33. Again, the State “may take one step at a time, addressing itself to the phase of the problem which seems most acute to the legislative mind.” *Williamson v. Lee Optical of Okla., Inc.*, 348 U.S. 483, 489 (1955). And the State may regulate abortion differently from other medical procedures. *See Harris*, 448 U.S. at 325. The State’s interest in fetal life alone is sufficient to regulate abortion clinics differently than other health care facilities. Inspections allow the Department to review patient files to ensure that abortion clinics follow informed consent and other regulations promoting this interest.

Regardless, the State *does* have a specific reason for requiring annual inspections of abortion clinics. Former Indiana abortion provider Dr. Ulrich Klopfer lost both his abortion clinic and medical licenses for serious violations, including failing to exercise reasonable care with patients, to timely report abortions on two girls under the age of 14, to follow proper sedation practices, to keep a log of cleaning procedure rooms, and to dispose of expired medications. ECF No. 73-1 at 43–44. Planned Parenthood points out that the State discovered Dr. Klopfer’s violations after a complaint was filed against him, rather than as part of a regularly scheduled investigation. ECF No. 74 at 17 n.15. But the point is that perhaps the State could have discovered those violations earlier if the Department had done annual inspections. Uninspected clinics pose the danger of skirting regulations aimed at women’s safety; without regular inspections, the State cannot detect violations *before* women get hurt.

Planned Parenthood also points out that first trimester abortion is less likely to result in death than childbirth. *Id.* at 33 & n.19. But “it is impossible to compare the safety of abortion against the safety of childbirth without more data.” ECF No. 24-1 ¶ 9. And even if the current data were sufficient, the State’s interest in inspecting abortion clinics derives not merely from the possibility that women may die as a result of abortion, but also from its interest in preventing non-life-threatening, but still serious, complications and its interest in protecting fetal life. Regardless, “the Equal Protection Clause does not require that a State must choose between attacking every aspect of a problem or not attacking the problem at all.” *Dandridge*, 397 U.S. at 486–87.

Planned Parenthood relies on *Planned Parenthood of Ind. & Ky., Inc. v. Comm’r, Ind. State Dep’t of Health*, in which the district court invalidated a statute prohibiting waiver of physical plant requirements for abortion clinics, but not for hospitals and ASCs. 64 F. Supp. 3d 1235, 1259–60 (S.D. Ind. 2014). In that case, the court held that “[t]he State present[ed] no rational basis for this unequal treatment” because hospitals and ASCs also performed abortions. *Id.*

Here, in contrast, hospitals and ASCs are not similarly situated to abortion clinics. First, federal law dictates the minimum frequency of inspections for hospitals and ASCs, but not for abortion clinics. ECF No. 72 ¶ 2; ECF No. 72-1. Second, the Department is required by law to issue a license to hospitals that have joined private accrediting organizations, such as the Joint Commission, which regularly inspect member facilities for health and safety violations. Ind. Code § 16-21-2-13(b)(2). There is no similar accrediting organization for abortion clinics. ECF No. 73-1 at 63. Thus, the State has a rational basis for inspecting abortion clinics, but not hospitals or ASCs, annually.

For these reasons, the Inspection Requirement does not violate the Equal Protection Clause.

CONCLUSION

Defendants respectfully request this Court grant Defendants' Motion for Summary Judgment and deny Plaintiff's Motion for Summary Judgment.

Respectfully submitted,

Curtis T. Hill
Indiana Attorney General

By: Thomas M. Fisher
Thomas M. Fisher
Solicitor General

Julia C. Payne
Deputy Attorney General

Office of the Indiana Attorney General
IGC-South, Fifth Floor
302 West Washington Street
Indianapolis, Indiana 46204-2770
Telephone: (317) 232-6255
Fax: (317) 232-7979
Email: Tom.Fisher@atg.in.gov