IN THE
UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

No. 20-2407

PLANNED PARENTHOOD OF INDIANA AND KENTUCKY, INC.,

Plaintiff/Appellee,

v.

MARION COUNTY PROSECUTOR, *et al.*,

Defendants/Appellants

On Appeal from the United States District Court for the
Southern District of Indiana, No. 1:18-cv-01219-RLY-DLP,
The Honorable Richard L. Young, Judge

BRIEF OF APPELLEE

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APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 20-2407

Short Caption: Planned Parenthood of Indiana and Kentucky, Inc. v. Marion County Prosecutor

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party, amicus curiae, intervenor or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

The Court prefers that the disclosure statements be filed immediately following docketing; but, the disclosure statement must be filed within 21 days of docketing or upon the filing of a motion, response, petition, or answer in this court, whichever occurs first. Attorneys are required to file an amended statement to reflect any material changes in the required information. The text of the statement must also be included in the front of the table of contents of the party's main brief. **Counsel is required to complete the entire statement and to use N/A for any information that is not applicable if this form is used.**

☑ **PLEASE CHECK HERE IF ANY INFORMATION ON THIS FORM IS NEW OR REVISED AND INDICATE WHICH INFORMATION IS NEW OR REVISED.**

(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P. 26.1 by completing item #3):

Planned Parenthood of Indiana and Kentucky, Inc.

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

ACLU of Indiana, Planned Parenthood Federation of America

(3) If the party, amicus or intervenor is a corporation:

i) Identify all its parent corporations, if any; and

(NEW) Planned Parenthood of the Great Northwest and the Hawaiian Islands, Inc.

ii) list any publicly held company that owns 10% or more of the party's, amicus' or intervenor's stock:

N/A

(4) Provide information required by FRAP 26.1(b) – Organizational Victims in Criminal Cases:

N/A

(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

N/A

Attorney's Signature: /s/ Kenneth J. Falk Date: November 4, 2020

Attorney's Printed Name: Kenneth J. Falk

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☑ **No** ☐

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N/A

(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

N/A

Attorney's Signature: /s/ Gavin M. Rose Date: August 26, 2020

Attorney's Printed Name: Gavin M. Rose

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☐ **No** ☑

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N/A

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N/A

Attorney's Signature: /s/ Carrie Y. Flaxman Date: August 7, 2020

Attorney's Printed Name: Carrie Y. Flaxman

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☐ **No** ☑

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Jurisdictional Statement

The jurisdictional summary in the appellants' brief is complete and correct.

Statement of the Issues

1. Is Indiana House Enrolled Act 1211, which requires the reporting of certain "physical or psychological conditions arising from the induction or performance of an abortion," unconstitutionally vague as the statute fails to define or give any meaningful guidance as to what is meant by "arising from the induction or performance of an abortion," particularly because failure to adhere to the statute is a crime and may lead to loss of licensure for both medical practitioners and abortion facilities?

2. Regardless of the vagueness of the entire statute, are two of the specific conditions enumerated by the Act, "psychological complications" and "other adverse events" as defined by criteria provided by the Food and Drug Administration, unconstitutionally vague, inasmuch as in the context of the statute the term "psychological complications" has no clear meaning and the term "adverse events" is defined so broadly by the Food and Drug Administration, in regulations that do not require their reporting, that it includes any "untoward" events?

3. If the Court chooses to proceed further and review an issue not reached by the district court, is the Act fundamentally irrational as it requires that certain conditions be reported as abortion complications, even though many of the conditions

are not associated with abortion and are, instead, far more common following other procedures for which reporting is not required?

Statement of the Case

I. Indiana House Enrolled Act 1211

The challenged statutory provision here provides that

> [a]s 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) (amended eff. July 1, 2019).[1]

The now-enjoined statute ("Complications Statute" or "Statute") provides that "abortion complications" are to be reported to the Indiana State Department of Health ("Department") by physicians, hospitals, and abortion clinics that treat the patient suffering from one of the complications, Ind. Code § 16-34-2-4.7(b), and at some point before February 1, 2020, the Department was to provide information as to the new requirements concerning reporting of abortion complications, Ind. Code § 16-34-2-4.7(f). Rules to implement the section were to be adopted by the Department before January 1, 2020. Ind. Code § 16-34-2-4.7(k).

The "abortion complications" were to be reported to the Department on a form it was to develop. Ind. Code § 16-34-2-4.7(c),(d). This report would include demographic information, information as to the place and date of the abortion, the type of abortion performed, and the following information:

> (9) Whether the complication was previously managed by the abortion provider or the abortion provider's required back-up physician.

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[1] As noted by the State (Appellants' Brief at 5), the 2019 House Enrolled Act 1211 amended an earlier version of Indiana Code § 16-34-2-4.7(a) (amended eff. July 1, 2019), Senate Enrolled Act No. 340, that was preliminarily enjoined by the district court in this case. (Appellants' Appendix [A.A.] 101). The chief difference between the earlier statute and the current statute is that in the earlier statute, "abortion complications" were defined as "any adverse physical or psychological condition arising" from an abortion with a list of illustrative, but not exclusive, "complications." (A.A. 103-04).

> (10) The name of the medications taken by the patient as part of the pharmaceutical abortion regimen, if any.
> (11) A list of each diagnosed complication.
> (12) A list of each treated complication, with a description of the treatment provided.
> (13) Whether the patient's visit to treat the complications was the original visit or a follow-up visit.
> (14) The date of each follow-up visit, if any.
> (15) A list of each complication diagnosed at a follow-up visit, if any.
> (16) A list of each complication treated at a follow-up visit, if any.

Ind. Code § 16-34-2-4.7(e). Not later than June 30th of each year, the Department was to compile a public report summarizing the data collected concerning abortion complications and was to submit it to the United States Centers for Disease Control and Prevention ("CDC") for inclusion in the CDC's annual Vital Statistics Report. Ind. Code § 16-34-2-4.7(g), (h). However, as the appellants ("State") concede, the CDC does not seek any information from the states concerning the abortion complications noted in the Statute. (District Court Docket ["Dkt."] 73-1 at 25).[2] The information the CDC requests from states concerning abortion is limited to: patient age; gestational age; patient race and ethnicity; abortion method; patient marital status; state of residence, and the patient's number of previous live birth and abortions. (Dkt. 73-1 at 84).[3]

If the Statute is allowed to go into effect, failure to report an "abortion complication" will be a Class B misdemeanor. Ind. Code § 16-34-2-4.7(j). This is in

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[2] The page numbers noted in references to the filings in the district court are the page numbers assigned by the court's electronic filing system.

[3] An expert utilized by the State, Dr. James Studnicki, criticizes the utility of the CDC's collection of data as it is voluntary. (A.A. at 180-81). However, Indiana does report its data. The CDC reports data in its Abortion Surveillance Report on abortion mortality utilizing sources other than voluntary state-level reporting. (Dkt. 86-1 at 7).

addition to other penalties to which Planned Parenthood of Indiana and Kentucky ("PPPINK") and its physicians may be subject.[4]

II. General background as to PPINK

PPINK operates numerous health centers in Indiana where thousands of women, men, and teens receive reproductive health services and comprehensive sexuality education annually. (Dkt. 73-2 at 1). One health center provides only medication abortions. (*Id.* at 2). Three health centers provide both surgical and medication abortion services. (*Id.* at 1-2). Surgical abortions are available through the first trimester of pregnancy, 13 weeks and 6 days after the first day of a woman's last menstrual period ("LMP"). (*Id.* at 1). The medication abortions are available for only up to 70 days post-LMP. (*Id.* at 2).

PPINK's health centers providing abortions are all licensed by the Indiana State Department of Health. (Dkt. 73-1 at 26; 410 IAC 26-2-1). The physicians providing abortions at PPINK's health centers are all licensed by the Indiana Medical Licensing Board. (Dkt. 73-2 at 2).

III. Abortion methods

A. Medication abortions

[4] An abortion clinic may lose or be denied a license for violating any provision of Indiana Code § 16-21, et seq., if it permits, aids, or abets the commission of any illegal acts in the clinic; engages in conduct or practices found to be detrimental to its patients. 410 IAC 26-2-5(3), (4), (6). Physicians are regulated by the Indiana Medical Licensing Board. Ind. Code § 25-22.5-2-7; 844 IAC 5-2-1. The Board has the power to discipline any physician who, among other things, "knowingly violate[s] any state statute or rule, or federal statute or regulation, regulation the profession." Ind. Code § 25-1-9-4(a)(3).

In a medication abortion, the patient ingests two medications in pill form: mifepristone (also known as "RU-486") and misoprostol. (A.A. 127). As the Department notes in its *Abortion Informed Consent Brochure* ("Department Brochure") that Indiana law requires patients to receive, Ind. Code § 16-34-2-1.5, mifepristone "blocks progesterone, a hormone needed for pregnancy. Without progesterone, the lining of the uterus breaks down and the pregnancy cannot continue. The drug mifepristone is followed in a few days by another drug, misoprostol, which causes cramps, heavy bleeding, and expulsion of the embryo." (Dkt. 73-4 at 9). The medications therefore induce a miscarriage. (A.A. 127).

The Department Brochure acknowledges that in addition to the cramping and bleeding noted above, a woman who has had a medication abortion "may experience dizziness, nausea, diarrhea, or vomiting; feel temporary abdominal pain; or have mild fever or chills. It is normal to have spotting or bleeding for up to four weeks." (Dkt. 73-4 at 9-10). These are not considered to be "complications," but are the expected effects of a medication abortion, are temporary, and are generally not a cause for concern, although routine aftercare may require counseling, provision of pain medications, and reassurance. (A.A. 127). PPINK provides this continuing care to its patients. (Dkt. 73-2 at 3).

B. Surgical abortions

The surgical abortion method used by PPINK involves the dilation of a patient's cervix and the use of suction and/or instruments to aspirate—or empty—the contents of the uterus. (A.A. 127-28). Although labelled "surgical," the abortion does

not involve what is generally considered to be surgery as it does not involve making an incision into the patient's skin. (*Id.* 128). General anesthesia is not used, although a sedative may be given if the patient elects to receive it. (Dkt. 73-2 at 2; A.A. 127-28). The patients are given an antibiotic prior to the abortion as a prophylaxis against infection. (Dkt. 73-2 at 2). After the abortion is completed, the patient will be monitored in a recovery area. (Dkt. 73-4 at 8).

The Department Brochure recognizes that following a surgical abortion the patient may have "cramping and bleeding," although "[i]t is also normal to have no bleeding." *Id.* After the abortion the patient "may pass a few blood clots and experience heavy bleeding for a few days . . . [and] may have spotting for up to six (6) weeks." *Id.* Again, these are the typical and temporary effects of surgical abortions. (A.A. 128). They are not cause for concern and generally do not require additional medical interventions beyond the typical counseling provided by the health center, provision of over-the-counter pain medications, and reassurance—all of which is part of the aftercare provided by PPINK. (Dkt. 73-2 at 3; A.A. 128). This also includes talking to patients about anxiety or other emotions they experience. (Dkt. 73-2 at 3).

IV. The safety of abortions

The Supreme Court has recognized that "abortions taking place in an abortion facility are safe—indeed, safer than numerous procedures that take place outside hospitals." *Whole Woman's Health v. Hellerstedt*, __U.S.__, 136 S. Ct. 2292, 2315 (2016). The Department Brochure concurs, noting that the risk of death from childbirth greatly exceeds that of death from an abortion. (Dkt. 73-4 at 11). Abortions

are far safer than surgical procedures that take place in ambulatory surgical centers or in hospitals. (Dkt. 73-5 at 3).

In 2018, responding to a charge to "conduct a comprehensive review of the state of the science on the safety and quality of legal abortion services in the United States," the National Academy of Sciences, Engineering, and Medicine issued its report entitled *The Safety and Quality of Abortion Care in the United States* ("National Academies Report") (Dkt. 73-6 at 15). The Report finds that abortion is "among the most regulated medical procedures in the nation." (*Id.* at 20). It concludes that "[t]he clinical evidence clearly shows that legal abortions in the United States . . . are safe and effective. Serious complications are rare." (*Id.* at 175-76).[5]

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[5] The National Academies Report specifies that

> [d]eath associated with a legal abortion in the United States is an exceedingly rare event . . . . [T]he risk of death subsequent to a legal abortion (0.7 per 100,000) is a small fraction of that for childbirth (8.8. per 100,000). Abortion-related mortality is also lower than that for colonoscopies (2.9 per 100,0000, plastic surgery (0.8 to 1.7 per 100,000), dental procedures (0.0 to 1.7 per 100,000), and adult tonsillectomies (2.9 to 6.3 per 100,000). Comparable data for other common medical procedures are difficult to find.

(Dkt. 73-6 at 88-89) (internal citations and footnotes omitted). "Numerous peer-reviewed studies have found that major complications following first-trimester abortion occur at a rate of less than 0.5." (Dkt. 73-3 at 7).

The appellants ("State") introduced a declaration from Dr. Studnicki, who opines that "the 'safety' of induced abortion is far from 'settled' science." (A.A. 177, 184). He cites to material prior to the 2018 National Academies Report. (A.A. 184, n.6-9). On the other hand, PPINK introduced a rebuttal declaration from a researcher on abortion safety at the University of California, San Francisco, School of Medicine, who reported that "[a]bortion is one of the most studied procedures in outpatient medicine, and the studies, published in peer-reviewed journals, show that abortion is extremely safe with a low rate of complications." (Dkt. 86-1 at 1, 4). A 2018 study that she had authored noted that a review of "nearly 55,000 abortions found a major adverse event rate of less than one-third of one percent. The rate of overall adverse events and morbidities was also low at 2%." (*Id.* at 4-5) (footnote omitted).

V. Abortion complications and the "complications" noted in the Statute

There are potential complications from the performance of medication and surgical abortions. After a medication abortion there is the rare possibility of infection; prolonged heavy bleeding beyond that which is normally expected; or an incomplete abortion, where the uterus continues to retain the product of conception or an ongoing pregnancy. (A.A. 129; Dkt. 73-5 at 2). An incomplete abortion, which is by far the most frequent form of complication, is generally resolved through a surgical abortion and the other complications are also generally managed without any significant or long-lasting damage to the patient's health. (A.A. 130; Dkt. 73-5 at 2). The Department Brochure notes that "[c]omplications of abortions by abortion inducing drugs performed before 9 weeks of pregnancy occur in less than 0.5% of procedures." (Dkt. 73-4 at 10).[6]

The possible, but rare, complications from an aspiration or surgical abortion include infection; prolonged heavy bleeding beyond what is normal and expected; and

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Given its vagueness ruling, the district court did not comment on the differing opinions offered. Nor did the parties contend that the differing opinions preclude summary judgment. In any event, the Supreme Court's 2016 conclusion about the safety of abortions and the fact that they are "safer than numerous procedures that take place outside hospitals." *Whole Woman's Health*, 136 S. Ct. 2315, is a legislative fact about which "lower courts must accept findings by the Supreme Court." *Frank v. Walker*, 768 F.3d 744, 750 (7th Cir. 2014).

[6] The State notes that mifepristone is subject to the Food and Drug Administration's ("FDA's") Risk Evaluation and Mitigation Strategies. (Brief of Appellant at 3). To the extent that the State is attempting to imply from this that medication abortions are not safe, it is ignoring its own conclusions as noted in the Department Brochure as well as the current FDA label for Mifeprex (mifepristone) that states "[s]erious adverse reactions were reported in <0.5% of women." *Highlights of Prescribing Information - MIFEPREX® (mifepristone) tablets, for oral use*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf at 7 (last visited Nov. 2, 2020).

retained tissue. (A.A. 130). Most infections are treated with oral antibiotics and retained tissue is resolved by re-aspiration, with no need for hospitalization. (*Id.* at 130-31). There is also a minimal risk of cervical laceration and uterine perforation, although the majority of recent studies of aspiration abortions discovered either no uterine perforations or, in the rare cases where they occurred, that they were successfully and safely managed without the need for surgery or hospitalization (*Id.* 130, 139). According to the Department Brochure, "[s]erious complications occurring during aspiration procedures performed before 13 weeks of pregnancy also occur in less than 0.5% of procedures." (Dkt. 73-4 at 10).

A number of the complications noted in the Complications Statute—cardiac arrest, respiratory arrest, renal failure, shock, amniotic fluid embolism, coma, hemolytic reaction due to administration of ABO incompatible blood products, and allergic reaction to anesthesia—are not abortion-specific complications and almost never occur as a result of abortions. (A.A. 136-37).[7] These complications are general risks of almost any medical procedure and occur much more frequently following, for instance, plastic surgery, orthopedic surgery, hysterectomy, cesarean section, and vaginal birth. (A.A. 136).

In its brief the State lists the conditions in the above paragraph, without qualification, as "[p]ossible complications of aspiration abortion" (Appellants' Brief at

[7] This information was provided by Dr. Sabrina Holmquist, who has 19 years of experience providing obstetrical and gynecological care and has provided abortions for more than 15 years. (A.A. 123-24). She also teaches abortion methods and supervises the provision of abortion services, some as a faculty member at the Pritzker School of Medicine in Chicago. (*Id.*). In her career she has never had a patient experience any of the above-noted conditions as the result of an abortion. (A.A. 123-24, 136).

4), citing to the declaration of Dr. Christina Francis, which also questions the safety of abortions. (A.A. 24, 26). As set out below in Section III(A) of PPINK's argument, Dr. Francis does not meet the standards to render her opinions as required by Federal Rule of Evidence 702 and by *Daubert v. Merrell Dow Pharm. Inc.,* 509 U.S. 579, 589 (1993).

The statute also lists as complications other conditions that are not abortion specific. For example, it requires that hypoglycemia, low-blood sugar, be reported if it occurs during a visit to an abortion facility, Ind. Code § 16-34-2-4.7(a)(21), although this has nothing to do with abortions. (Dkt. 73-3 at 135).[8] It lists "deep vein thrombosis" and "pulmonary embolism" as reportable complications, Ind. Code § l6-34-2-4.7(a)(5), (6), even though they are linked not to abortion but to pregnancy as the risks of developing these conditions are 4-5 time greater in pregnancy than when a person is not pregnant, peaking in the post-partum period. (A.A. 136-37). "Placenta previa" is a pregnancy condition, diagnosed in the second trimester of pregnancy, where the placenta lies low in the uterus, can occur spontaneously in any pregnancy, is not associated with abortion, and is more likely when the woman has had a prior cesarean section. (A.A. 136).[9] The statute requires the reporting of a "missed ectopic pregnancy." Ind. Code § 16-34-2-4.7(a)(10). An ectopic pregnancy occurs when a

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[8] "Hypoglycemia refers to low blood sugar, a condition often associated with insulin dependent diabetics, and is completely independent of abortion—indeed it has nothing at all to do with abortion. Low blood sugar in a non-diabetic patient is a condition referred to as hunger, and is generally not a complication of abortion or any other procedure, but a consequence of not eating, and doesn't pose harm to the patient." (A.A. 135).

[9] Dr. Francis argues that it is "occasionally" associated with abortion. (A.A. 32).

fertilized egg attaches itself somewhere other than the uterus. (A.A. 134). This would be identified during the patient's pre-abortion ultrasound and the abortion would not be performed. (*Id.*).

A number of the events that are listed in the Complications Statute are duplicative of each other. For example, "free fluid in the abdomen," Ind. Code § 16-34-2-4.7(a)(19), would be due to bleeding into the abdomen caused by a uterine perforation, which must also be reported, Ind. Code § 16-34-2-4.7(a)(1). (A.A. 140). Similarly, "pelvic inflammatory disease," Ind. Code § 16-34-2-4.7(a)(9), "is an ascending, polymicrobial infection that is most often generated by other infections, such as sexually transmitted diseases" (A.A. 138). However, it is an infection, so it is duplicative of the statutory requirement that "infections" be reported. Ind. Code § 16-34-2-4.7(a)(3).

VI. Existing reporting requirements independent of the Complications Statute

Regulations of the Indiana State Department of Health that pre-date the Complications Statute require that hospitals, ambulatory outpatient surgical centers, birthing centers, and abortion clinics inform the Department of "reportable events." 410 IAC 15-1.4.-2.2 (hospitals); 410 IAC 15-2.4-2.2 (ambulatory outpatient surgical centers)[10]; 410 IAC 26-6-2 (abortion clinics); 410 IAC 27-6-2 (birthing centers). The Department requires that 28 specific events be reported under the general headings of surgical events, products or device events, patient protection

[10] These are defined as places that are "established, equipped, and operated primarily for purpose of performing surgical procedures and services." Ind. Code § 16-18-2-4(a)(1). Anesthesia may be utilized in the center. Ind. Code § 16-18-2-4(a)(4).

events, care management events, environmental events, and criminal events. (Dkt. 73-7 at 16-18). These are matters "that pertain[] to a serious issue concerning the health of the patients or residents involved, whether a medical error or some kind of adverse complication from a surgery, those are the kind of events envisioned." (Dkt. 73-1 at 17). The public report compiled from this mandatory reporting of adverse events available as of the summary judgment briefing discloses that from 2006 through and including 2017, abortion clinics in Indiana had no reportable events, while hospitals averaged 99.8 annually and ambulatory surgery centers averaged 6.6 a year. (Dkt. 73-7 at 33).

In addition to the above reporting requirements, abortion clinics must also report certain complications for each abortion to the Department of Health through terminated pregnancy reports. (Dkt. 73-2 at 3, 7). The reports require the following to be reported under the heading of "Complication(s) of Pregnancy Termination": none, hemorrhage, infection, uterine perforation, cervical laceration, retained product, other (specify). (Dkt. 73-2 at 7). The data collected from these reports is made public annually and is submitted to the CDC for inclusion in its Vital Statistics Report. Ind. Code § 16-34-2-5(e), (f), although, as noted, the CDC does not collect detailed information concerning complications. (*Supra* at 4).

Other than the above requirements imposed by the Indiana regulations governing "reportable events," there are no other complication reporting requirements for hospitals and ambulatory surgical centers. (Dkt. 73-1 at 18). There

are no requirements comparable to the Complications Statute imposed on any other area of medicine. (Dkt. 73-5 at 5).

VII. The effect of the Complications Statute on PPINK and its patients

The labelling of items as "abortion complications" when they are not a direct complication of the abortion or are easily and quickly resolved, such as minor infections, will make abortions appear more dangerous than they are and will fuel an anti-abortion narrative that will be used to discourage women from obtaining abortions (Dkts. 73-2 at 4-5; 73-5 at 4-5). The same is true of the redundant reporting that, for example, requires the reporting of both infections and the infection pelvic inflammatory disease as this will result in inaccurate information and repetitive overreporting, again making abortions appear more dangerous. (Dkts. 73-2 at 4-5; 73-3 at 18).

This places PPINK and its practitioners in a difficult situation. They certainly do not want to discourage women from obtaining abortions through the spread of false information concerning their risk. (Dkt. 73-2 at 4-5). But they are inclined to read the Complications Statute broadly so as to avoid even the possibility of criminal penalties or disciplinary and licensing complaints. (Dkts. 73-3 at 18; 73-5 at 4). The desire to broadly report is especially strong for PPINK inasmuch as it and its employees are routinely exposed to scrutiny by anti-abortion groups that review all public records submitted by PPINK and file complaints if they perceive that the records have not been properly completed. (Dkt. 73-2 at 4).

VIII. Procedural history

PPINK filed its Complaint for Declaratory and Injunctive Relief / Notice of Challenge to Constitutionality of Indiana Statute on April 23, 2018, seeking to enjoin the new requirements for the reporting of abortion complications contained in Senate Enrolled Act 340, Ind. Code § 16-34-2-4.7 (eff. July 1, 2018) and the annual inspection requirement for abortion clinics, Ind. Code § 16-21-2-2.6 (eff. July 1, 2018). (A.A. 1, 12). On June 28, 2018, the district court entered a preliminary injunction, enjoining the State from enforcing the reporting requirements of the previous iteration of the Complications Statute. (*Id.* at 101, 118).

After the amendment of the statute by House Enrolled Act 1211, Ind. Code § 16-34-2-4.7 (amended eff. July 1, 2019) (note 1, *supra*), the parties filed cross-motions for summary judgment (*Id.* at 120, 154). The Court entered its Entry on Cross-Motions for Summary Judgment on July 8, 2020, concluding that the Complications Statute was unconstitutionally vague but rejecting PPINK's claim that the annual inspection requirement was unconstitutional. (Short. App. 1, 21-22).[11] The district court did not reach PPINK's arguments that two discrete provisions of the Complications Statute were unconstitutionally vague or that the Statute was irrational and violated equal protection and due process. (*Id.* at 17). The district court issued final judgment on July 14, 2020. (*Id.* at 23). However, that final judgment did not contain an injunction and the district court entered its amended final judgment, permanently enjoining the enforcement of the Complications Statute, on July 28, 2020. (*Id.* at 25). This appeal ensued.

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[11] PPINK is not appealing the district court's decision upholding the annual inspection requirement.

Summary of the Argument

The void-for-vagueness doctrine "rests on the basic due process principle that a law is unconstitutional if its prohibitions are not clearly defined." *Hegwood v. City of Eau Claire*, 676 F.3d 600, 603 (7th Cir. 2012). Here, the Complications Statute requires the reporting of certain conditions when those conditions "aris[e] from the induction or performance of an abortion," and punishes physicians with penal sanctions and the possibility of licensing sanctions (and does the same to PPINK) if they guess erroneously at the meaning of this phrase. The Statute's verbiage is unconstitutionally vague in two respects. First, the extent to which a condition must be caused by the abortion itself is not at all clear. And second, the Statute requires a certainty as to causation that simply does not exist in a large number of cases. Apparently recognizing these shortcomings, the State insists that this Court should read into the statute the requirement that a "complication" is reportable if it "arises from" an abortion based on "the physician's reasonable medical judgment." As the district court properly found, there is no basis for reading this language into the statute.

Given that the district court did not err in enjoining the entirety of the Statute, there is no reason for this Court to proceed further. However, even if the Statute as a whole survives, two specific "complications" are unconstitutionally vague. First, the phrase "[p]sychological complications, including depression, suicidal ideation, anxiety, and sleeping disorders" is vague. The term "psychological complications" has no established meaning in medical parlance. While the State insists that the term

refers only to diagnosable psychiatric disorders, clearly that is not the case: three of the examples of "psychological complications"—depression, suicidal ideation, and anxiety—are *symptoms*, not disorders. And second, the phrase "[a]ny other adverse event as defined by criteria provided [by the FDA]" is vague. The problem for the State is that an "adverse event" under these criteria is defined in the broadest possible terms 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)—indeed, the FDA does not require reporting of "adverse events" but simply employs the term to define more specific terms that must be reported. "[A]ny untoward medical occurrence" is entirely bereft of meaning and is seemingly broad enough to swallow the other twenty-four statutory "complications." This phrase, too, is vague.

The unconstitutional vagueness of the Complications Statute means that there is no need to address PPINK's arguments that the Statute is irrational as violative of both due process and equal protection. The district court did not address these arguments and if the Court finds that the Statute is not vague it should remand the case to the district court so that it may consider these arguments in the first instance. Nevertheless, the State argues that the statute is rationally related to a legitimate interest. Despite the very deferential standard that is applicable here, *Box v. Planned Parenthood of Indiana and Ky., Inc.*, --U.S.--, 139 S. Ct. 1780, 1782 (2019), the Complications Statute fails low-level scrutiny. While the State certainly has a legitimate interest in providing information about the safety of abortions, the

information must be accurate. Here the information that will be generated is inaccurate and misleading. This is not rational.

Argument

I. Standard of review

This Court "review[s] a district court's grant of summary judgment *de novo*." *Golla v. Office of Chief Judge of Cook Co., Ill.*, 875 F.3d 404, 407 (7th Cir. 2017) (further citation omitted). "The question on a motion for summary judgment is whether the moving party has shown there is 'no genuine dispute as to any material fact,' and is entitled to summary judgment as a matter of law." *Id.* (quoting Fed. R. Civ. P. 56(a)). When a case is decided on cross-motions for summary judgment this Court will "construe all facts and draw[ ] all reasonable inferences in favor of the party against whom the motion under consideration was filed." *Hess v. Board of Trustees of Southern Illinois University*, 839 F.3d 668, 673 (7th Cir. 2016) (further citations omitted).

II. The Complications Statute provides no meaningful guidance on when "complications" must be reported and is therefore unconstitutionally vague

After the district court concluded in its preliminary injunction that the State's first attempt to provide a meaningful definition of an "abortion complication" was unconstitutionally vague in violation of due process (A.A. 114-15), the Indiana General Assembly enacted the current version of the statute, which re-defines the term to mean only twenty-five specific conditions "arising from the induction or performance of an abortion." *See* Ind. Code § 16-34-2-4.7(a) (eff. July 1, 2019). While

the precise vagueness problem identified in the district court's preliminary-injunction decision was cured by this amendment, vagueness problems remain. First, as the district court properly found, the phrase "arising from the induction or performance of an abortion" lacks a readily ascertainable meaning and is therefore unconstitutional. And second, even were that not so, two of the specific conditions that must be reported—"psychological conditions" (subsection 23) and "other adverse events" defined by criteria provided by the Food and Drug Administration (subsection 25)—are also unconstitutionally vague.

A. Introduction to the vagueness doctrine

"Living under a rule of law entails various suppositions, one of which is that 'all persons are entitled to be informed as to what the State commands or forbids.'" *Papachristou v. City of Jacksonville*, 405 U.S. 156, 162 (1972) (quoting *Lanzetta v. New Jersey*, 306 U.S. 451, 453 (1939)) (internal alteration omitted). Accordingly, "[t]he void-for-vagueness doctrine rests on the basic due process principle that a law is unconstitutional if its prohibitions are not clearly defined." *Hegwood*, 676 F.3d at 603. While the Constitution does not demand "perfect clarity and precise guidance" of legislative enactments, *see Sherman ex rel. Sherman v. Koch*, 623 F.3d 501, 519 (7th Cir. 2010) (quoting *Ward v. Rock Against Racism*, 491 U.S. 781, 794 (1989)), it does require that penal statutes define offenses "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) (citing cases). *See also Sessions v. Dimaya,* __ U.S. __, 138 S. Ct.

1204, 1212 (2018) (plurality) ("the doctrine guards against arbitrary or discriminatory law enforcement by insisting that a statute provide standards to govern the action of police officers, prosecutors, juries and judges").

Although the void-for-vagueness doctrine focuses "both on actual notice to citizens and arbitrary enforcement," the U.S. Supreme Court has recognized

> that the more important aspect of vagueness doctrine is not actual notice, but the other principle element of the doctrine—the requirement that a legislature establish minimal guidelines to govern law enforcement. Where the legislature fails to provide such minimal guidelines, a criminal statute may permit a standardless sweep that allows policemen, prosecutors, and juries to pursue their personal predilections.

Kolender, 461 U.S. at 358 (internal quotations, citations, and alteration omitted). At the same time, the Court has noted that "[t]hese standards should not . . . be mechanically applied," and that "[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." *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498 (1982). Thus, while "economic regulation," "enactments with civil rather than criminal penalties," and statutes containing "a scienter requirement" might be subject to "a less strict vagueness test," a penal statute without those procedural safeguards demands far greater precision. *Id.* at 498-99.[12]

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[12] However, it is incorrect to draw a bright line that alters the vagueness analysis to be applied depending on whether or not the statute is deemed criminal. As Justice Gorsuch noted in a case where a non-criminal statute was found to be unconstitutional,"[t]his Court has made clear, too, that due process protection against vague laws are 'not to be avoided by the simple label a State chooses to fasten upon its conduct or its statute.'" *Dimaya*, 138 S.

B. The phrase "arising from the induction or performance of an abortion" is unconstitutionally vague

1. The phrase lacks a readily ascertainable meaning

The Statute requires the reporting of physical or psychological conditions "arising from the induction or performance of an abortion." This language is unconstitutionally vague in two respects.

i. First, the extent to which a condition must be caused by the abortion itself is not at all clear. If an infection results from an injection of local anesthesia rather than from the procedure, is this a complication that must be reported? What about a woman who becomes anxious simply because she has to undergo a medical procedure, even if that anxiety has nothing to do with the *specific* procedure she is undergoing? Or a diabetic patient who experiences hypoglycemia—low blood sugar—simply because she did not eat in advance of her appointment (*see* A.A. 137)? None of this has anything to do with the abortion itself, but the Complications Statute is unclear on whether it must nonetheless be reported. This is particularly troubling given that the precise cause of a "complication" may never be known.

The Statute's vagueness in this regard is exacerbated, rather than cured, by several of the specific "complications" identified. For instance, the Statute requires

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Ct. at 1229 (internal citation omitted) (Gorsuch, J., concurring). In any event, the State does not deny that the Complications Statute qualifies as a penal statute. Clearly it does: the failure to report an abortion complication is a Class B misdemeanor. Ind. Code § 16-34-2-4.7(j). And, even were that not so, the failure to report a complication may have licensing consequences for both PPINK and its physicians (*see supra* n.3), and this Court has been clear that sanctions to a person's professional license are sufficiently severe to implicate void-for-vagueness concerns as well, *see United States ex rel. Fitzgerald v. Jordan*, 747 F.2d 1120, 1129-30 (7th Cir. 1984); *Baer v. City of Wauwatosa*, 716 F.2d 1117, 1123-24 (7th Cir. 1983).

the reporting of a "[h]emolytic reaction" resulting from a blood transfusion, even though such a reaction would obviously not result from the abortion itself but rather from a separate medical intervention (the transfusion). (*See* A.A. 136; Dkt. 73-5 at 5). Similarly, even though an "abortion" is defined in terms of "the *termination* of human pregnancy," Ind. Code § 16-18-2-1 (emphasis added), the Complications Statute requires the reporting of a "[m]issed ectopic pregnancy" arising from the induction or performance of an abortion. (A.A. 12 ["If the pregnancy . . . is discovered to be ectopic, the abortion would not be performed."]). And, although the State spills much ink insisting that the term "arising from" is a generally accepted phrase of causation, "hypoglycemia" must be reported whenever it occurs "while the patient is being treated at the abortion facility" irrespective of the actual cause. These apparent contradictions in the Statute only underscore the vagueness inherent in the phrase "arising from the induction or performance of an abortion."

ii. This language is unconstitutionally vague for a second reason as well, for the Complications Statute requires a certainty as to causation that simply does not exist. For example, if a patient experiences a complication that could be statistically linked to abortion, must the practitioner report this complication as "arising from" the abortion even though medical science cannot be certain of the precise cause? The Complication Statute's requirement that PPINK and its physicians report "[p]lacenta previa" or "[p]re-term delivery" in subsequent pregnancies is a perfect example. While Dr. Holmquist states that the medical community does not consider either of these conditions or events to constitute

complications of abortion (A.A. 135-36), Dr. Francis notes that, in her opinion, studies "show[] a significantly increased risk of very preterm birth in future pregnancies." (A.A. 32-33). But at what point does a pre-term delivery require reporting? Given the State's belief in a potential causal connection, must a report be filed every time a former abortion patient experiences a pre-term delivery? Insofar as even the State would appear to concede that certainty of a causal link can never be established for a particular patient, need a report ever be filed? If the answer is "somewhere in between," how in the world is a physician to determine the circumstances in which a report is necessary? So too with the mental-health consequences of an abortion, where—in contravention of well-accepted opinions and relying on thoroughly debunked studies (*see* A.A. 133-34; Dkt. 73-6 at 163-166, 175)—the State, as noted, argues that "depression, substance abuse, anxiety and suicide are significantly increased in women who have had abortions." (A.A. at 34). Psychological symptomology can of course have myriad causes, so what degree of certainty is necessary before a report is required?

While PPINK and its experts maintain that the State's expert's medical opinions are erroneous, their truth or falsity is not relevant here. The phrase "arising from" does not answer that fundamental question: is a practitioner required to report only those complications that definitely arise from the abortion procedure, or is a practitioner also required to report complications that the State (or its experts) considers to be linked, however remotely, to abortion even if the precise cause of the complication in a specific patient cannot be known?

iii. Apparently recognizing that the Complications Statute places PPINK and its physicians in the impossible position of answering these questions and countless more—at risk of criminal sanctions or the loss of professional licensure if they answer incorrectly—the State resorts instead to oft-cited principles that facial vagueness challenges are disfavored. (Appellants' Brief at 16-17). Here, it reads too much into this Court's recent decision in *United States v. Cook* ("*Cook II*"), 970 F.3d 866 (7th Cir. 2020).[13] To be sure, *Cook II* and similar cases reiterate that a plaintiff may not mount a successful vagueness challenge when a statute "undoubtedly applies to his conduct" and when he is only able to suggest that it might be vague "as to one or more hypothetical scenarios." *Id.* at 873 (citing cases). But this is not a case where the challenged statute is only vague around the edges: the uncertainties that PPINK has underscored throughout this litigation are those that its physicians must answer every single time they treat a patient with one of the twenty-five listed conditions. The notion of causation—statutorily described as conditions "arising from the induction or performance of an abortion"—is at the very heart of the Complications Statute, and this case thus fits squarely in the category of cases amenable to a facial

[13] In passing, the State appears to suggest that the district court's decision cannot be sustained because it relied on this Court's earlier, and since-vacated, decision in *United States v. Cook* ("*Cook I*"), 914 F.3d 545 (7th Cir. 2019), *vacated and remanded*, 140 S. Ct. 41 (2019). But *Cook I* was vacated for reconsideration in light of the Supreme Court's decision in *Rehaif v. United States*, __U.S. __ , 139 S. Ct. 2191 (2019), which simply concerned whether the *mens rea* requirement contained in 18 U.S.C. § 924(a)(2) applies to each of the statutory elements of the criminal offense. On remand, this Court faithfully applied *Rehaif* and determined that an erroneous jury instruction entitled the defendant to a new trial. *See Cook II*, 970 F.3d at 880-885. On the vagueness issue, this Court reached the same conclusion as it had in *Cook I*, and the State does not explain its apparent belief that *Cook I* and *Cook II* applied different vagueness standards.

challenge. PPINK is not voicing a hypothetical grievance but rather is highlighting real uncertainties that exist nearly every time a patient presents with a potential "complication." Is an infection reportable even though it is caused not by the abortion procedure itself but by the introduction of foreign agents? Must complications resulting from a blood transfusion be reported? How should a practitioner report a "complication" that has or could have a wide array of different causes and may not have a single cause at all? PPINK is left to guess at the answers to these questions, but if it guesses wrong it is subject to actions against its license, and its physicians are subject to licensure actions and criminal liability.

In *Cook II*, this Court underscored that concerns occasioned by "a standardless statute"—which "poses a trap for the person acting in good faith, who is given no guidepost by which he can divine what sort of conduct is prohibited"—are heightened when a statute lacks a *mens rea* requirement or when it "threatens to inhibit the exercise of constitutionally protected rights." *Id.* (citation omitted). Here, unlike in *Karlin v. Foust*, 188 F.3d 446, 466-67 (7th Cir. 1999), on which the State relies, the Complications Statute provides criminal penalties while lacking a *mens rea* requirement altogether. And, while the Complications Statute does not directly burden women's right to choose abortion, the inevitable over-reporting of "complications" resulting from practitioners' attempts to avoid criminal liability will doubtless fuel a false narrative concerning the safety of abortion that *will* impair abortion access. In other words, the facets of the statute at issue in *Cook II* that rendered inappropriate a facial vagueness challenge are entirely absent here. The

phrase "arising from the induction or performance of an abortion" is vague and thus unconstitutional, and there is nothing improper with this facial challenge.

iv. The State nonetheless contends at length that the challenged phrase cannot be vague because "arising from" is a frequently employed statutory term denoting causation. (Appellants' Brief at 11-15, 26-27). The fact that states have employed similar verbiage in requiring reporting in unrelated contexts is obviously of no moment: those statutes do not raise the same vagueness problems that have been identified throughout this litigation.

While the State identifies statutes from other states that also require the reporting of abortion complications, the vast majority of these statutes are materially distinguishable. Of the eight statutes cited by the State (*see* Appellants' Brief at 14-15), three explicitly allow physicians to exercise their own medical judgment. *See* Ariz. Rev. Stat. § 36-2162 ("in the good faith judgment of the health professional"); Minn. Stat. § 145.4132(2) ("in the physician's medical judgment"); 18 Pa. Cons. Stat. § 3214(h) ("in the good faith judgment of the physician"). One imports a standard of objective reasonableness absent from Indiana's statute. *See* Okla. Stat. § 63-1-738l(C) ("that a reasonably knowledgeable physician would judge"). Two minimize vagueness concerns by strictly curtailing the penal consequences of a violation: one does not appear to come with any penal consequences at all, *see* Mich. Comp. Laws § 333.2837, and the other imposes penal consequences only upon a physician's "willful violation," *see* Miss. Code §§ 41-41-77, 41-41-79. And one only appears to require the reporting of complications from medication abortions. *See* N.D. Cent Code 14-02.1-07. In other

words, of the statutes cited by the State only Texas's appears to be remotely comparable to Indiana's, *see* Tex. Health & Safety Code § 171.006, and that statute has never been tested in court and does not appear to impose criminal penalties.[14]

Certainly PPINK does not deny that statutes often employ the phrase "arising from" or similar verbiage to denote causation. (*See* Appellants' Brief at 26-27). But those two words do not stand in isolation and cannot be divorced from the context in which they are employed. For all of the reasons described above, the Complications Statute raises more questions than it answers and is void for vagueness.

2. The district court properly found that the State's attempt to read "reasonable medical judgment" into the Complications Statute is without merit

The State contends at length that the imprecision of the Complications Statute is minimized by the fact that it contains a tacit requirement that reporting of abortion complications must be informed by a physician's "reasonable medical judgment." (Appellants' Brief at 20-25). This attempt to save the Statute by re-writing it is clearly off-base, and the State's argument fails for multiple reasons.

i. Most notably, the State is wrong when it claims that *State v. Keihn*, 542 N.E.2d 963 (Ind. 1989), requires reading this nonexistent language into the statute, as the district court properly held. The State insists that the objective standard, "reasonable medical judgment," is a scienter requirement that a court might presume

[14] Additionally, the articulated "complications" in the Texas statute – shock, uterine perforation, cervical laceration, hemorrhage, aspiration or allergic response, infection, sepsis, death of the patient, incomplete abortion, damage to the uterus, or an infant born alive after the abortion—omit many of the most problematic "complications" in the Indiana statute. Tex. Health & Safety Code § 171.006

in a criminal statute. This is incorrect. After all, while, as the State notes, a *mens rea* requirement might under appropriate circumstances be deemed implicit in a criminal statute—more on that below—there is absolutely no basis in Indiana law for implying an objective "reasonable medical judgment" standard into a statute or for arguing that the standard is equivalent to scienter. The State's attempt to import the reasonable medical judgment standard is confusing: it cites several other Indiana abortion statutes that explicitly permit the exercise of "reasonable medical judgment" (Appellants' Brief at 21) and details at length this Court's decision in *Karlin v. Foust*, 188 F. 3d 446 (7th Cir. 1999) (which addressed the vagueness of a statute explicitly defining a "medical emergency" in terms of a "physician's reasonable medical judgment"). (Appellants' Brief at 23-24). But these citations only demonstrate that when the legislature (including the Indiana General Assembly) intends to create such a standard, it does so explicitly. The State is not offering an interpretation of the Complications Statute: it is attempting to add statutory language that pointedly does not exist.

Indeed, in addressing the vagueness of separate statutory provisions, this Court in *Karlin* concluded that the fact that several informed-consent provisions contained an explicit objective standard meant that other provisions could *not* be deemed to contain such a standard:

> [T]he district court's construction that a physician is entitled to use his best medical judgment in determining the content of the information to be conveyed does not amount to a re-writing of AB 441, but rather flows naturally from the informed consent requirements themselves. As we indicated above, two of the requirements provide that the information conveyed is subject to the "reasonable medical judgment of the

> physician." *See* Wis. Stat. § 253.10(3)(c)1.a ("Whether or not, according to the reasonable medical judgment of the physician, the woman is pregnant."); *id.* § 253.10(3)(c)1.i ("If, in the reasonable medical judgment of the physician, the woman's unborn child has reached viability . . ."). *By implication, the Wisconsin legislature must have intended that some other standard apply to the provision of information under AB 441's remaining informed consent requirements*.

188 F.3d at 475 (emphasis added).

To be sure, *Karlin* deferred to the district court's determination that a subjective standard would instead apply, and that physicians would be permitted to provide information consistent with their own medical judgment. *See id.* at 471-75. But this is a construction that not even the State suggests to be appropriate here, and the reasons for imposing such a standard on an informed-consent provision impacting the physician's relationship with her own patient do not exist when a state creates a reporting requirement through which it hopes to obtain meaningful data.

In any event, contrary to the suggestion of the State, a reasonable medical judgment standard does not equate to *mens rea*. This Court made that point in *Karlin*. *Id.* at 467 (equating the objective standard to statutes imposing liability without *mens rea*). Indeed the Court in *Karlin* only upheld the portion of the challenged statute that did not have a scienter requirement, but did have an objective standard, by noting it only provided for a fine in the case of violation, without the risk of misdemeanor or felony conviction or incarceration, *id.* at 465, 477. This makes sense, as "reasonable medical judgment" is not a mental state (that is, a *mens rea*) at all.

Throughout this litigation, the parties have vigorously disputed the existence and prevalence of adverse medical and psychiatric conditions following abortion: the

State insists that several conditions have been linked to the abortion decision; PPINK has contended to the contrary. These disputes are clearly not relevant to the vagueness issue, which hinges on the clarity of the statute itself. But under this statute, a physician seeking to avoid criminal liability does not have the luxury of deciding that her determinations fall within a generally accepted spectrum of reasonableness: the Statute provides absolutely no safety net for a physician that the State determines to have guessed wrong. The State, therefore, is just wrong when it claims that "even if Planned Parenthood physicians would hypothetically disagree with [the] assessment [of another practitioner that a certain complication 'arises from' the abortion], they would not be exposed to legal liability." (Appellants' Brief at 17). The State's attempt to add language to a vague statute has no basis in the law.

ii. Even were "reasonable medical judgment" a scienter requirement that could be implied from Indiana law, the State's argument is off base. To be sure, the Indiana Supreme Court has established a rebuttable presumption that criminal statutes silent on the issue must be interpreted as requiring a culpable mental state. *See State v. Keihn*, 542 N.E.2d at 967. Certain factors articulated in *Keihn* that are capable of rebutting this presumption appear to be present here: the severity of punishment is comparably minimal (a statutory violation is only a misdemeanor), for instance, and, once again, the Indiana General Assembly has explicitly imposed a "reasonable medical judgment" standard in other abortion statutes (*see* Appellants' Brief at 21 [citing statutes]). But ultimately this Court need not consider whether the presumption has been rebutted here. After all, even if a tacit *mens rea* requirement

exists before criminal liability may be imposed, certainly *Keihn* imposes no such requirement before PPINK may be exposed to actions against its license (*see* 410 IAC 26-2-8(b)) or its physicians are subject to licensure sanctions. Ind. Code § 25-1-9-4(a)(3). As noted above, statutes impacting licensure raise significant vagueness concerns whether or not they also expose persons to criminal liability. *See, e.g.*, *United States ex rel. Fitzgerald v. Jordan*, 747 F.2d 1120, 1129-30 (7th Cir. 1984). Given this, the point of the State resting on its attempt to read reasonable medical judgment into the Complications Statute and conclude that the statute has a scienter requirement is not clear.

That issue (ignored by the State) aside, *Keihn*'s presumption does not save the Complications Statute: there is simply no basis in the law for the leap that the State takes from *Keihn*'s recognition that a *mens rea* requirement could be implied to its conclusion that the Complications Statute allows for the exercise of physicians' "reasonable medical judgment." Even if a *mens rea* requirement were implied, the Complications Statute might simply be read to require that a practitioner be aware that she failed to file a report (or be aware that a patient experienced an enumerated condition) without permitting the exercise of medical judgment in determining what is reportable in the first place. On top of this, earlier in this litigation the State acknowledged that states may, if they choose, create strict liability offenses (*see* Dkt. 78 at 22-23 [citing *Smith v. California*, 361 U.S. 147, 150 (1959)]). If that is so (and it is), it is difficult to imagine how the Indiana General Assembly might draft a strict liability offense other than through language substantially identical to that in the

Complications Statute.

C. Two specific conditions—"psychological complications" and "other adverse events" defined by criteria provided by the Food and Drug Administration—are unconstitutionally vague

Because the Complications Statute only requires the reporting of conditions "arising from the induction or performance of an abortion," and because that phrase is unconstitutionally vague, the entire statute must be enjoined and there is no need for this Court to proceed further. If it chooses to do so, however, two specific conditions in the Statute's enumerated list of reportable "abortion complications" are also vague.[15]

1. The term "psychological complications" is vague

Subsection 23 of the Complications Statute requires the reporting of "[p]sychological complications, including depression, suicidal ideation, anxiety, and sleeping disorders." The term "psychological complications" has no established meaning in medical parlance and is vague.

i. Several examples suffice to demonstrate the term's vagueness. If a woman is anxious prior to an abortion—as a patient might be anxious prior to *any* medical procedure—does that constitute a "psychological complication" arising from the abortion that must be reported? If a woman reports to one of PPINK's physicians that she feels relieved, sad, wary, or depressed shortly after the procedure, must that

[15] The phrase "arising from the induction or performance of an abortion" is applicable to all of the specifically listed conditions, and so if this phrase is deemed unconstitutional the entire statute must fall. However, if this Court concludes that only specifically listed conditions are unconstitutionally vague, PPINK does not dispute that these conditions would be severable from the remainder of the Statute.

be reported? When a patient seeks treatment for minor depression or anxiety, perhaps years after an abortion, does that qualify as an "abortion complication"? Does that change if the practitioner concludes that the depression or anxiety would have existed or been more severe if the patient had continued the pregnancy (*see* A.A. 133-34) ["{S}tudies indicate being denied an abortion . . . may be associated with greater risk of anxiety."])?

PPINK and its practitioners—indeed, all practitioners in Indiana who see women seeking treatment—are left to guess at the answers to all of these questions, a task made even more difficult by the fact that they are not mental health professionals.

ii. The State nonetheless attempts to salvage its vague requirement by relying on the canon of *noscitur a sociis*, the common-sense notion that "a word is given more precise content by the neighboring words with which it is associated." (Appellants' Brief at 28 [quoting *United States v. Williams*, 553 U.S. 285, 294 (2008)]). There are numerous problems with this argument. First, this canon, as its literal translation ("it is known by its associates") implies, only serves to give meaning to a term by reference to other statutory terms that stand on equal footing. *See, e.g.*, *Graham Cty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 287 (2010). In other words, it is "typically applied to a series of coequal terms that are in syntactically equivalent position." *Guardian Indus. Corp. v. C.I.R.*, 143 T.C. 1, 16 (U.S. Tax Ct. 2014) (citing cases). In *Williams*, for instance, the canon was relied upon to ascertain the meaning of "promotes" and "presents" in the federal

statute imposing criminal penalties against one who "advertises, promotes, presents, distributes, or solicits" child pornography. 553 U.S. at 294-95. And in *Center for Individual Freedom v. Madigan*, 697 F.3d 464 (7th Cir. 2012)—also cited by the State—the canon was relied upon to interpret the word "knowledge" in an electioneering statute concerning communications made "at the request, suggestion, or knowledge" of a candidate. *Id.* at 495-96. The interpretive canon on which the State relies simply does not shed light on the meaning of a term that does not stand in a co-equal position with surrounding terms—"depression, suicidal ideation, anxiety, and sleeping disorders" are simply examples of what are considered to be "psychological complications"—and the State's reliance on this canon is off-base.

Second, even were this not so, the manner in which the State suggests that the statutory examples of "psychological complications" are related to one another is by no means apparent. The State suggests that three of these terms—depression, anxiety, and sleeping disorders—are all "diagnosable psychological disorders included in the DSM-5," whereas "suicidal ideation" is a "common symptom of many psychiatric disorders and clearly defined in the DSM-5." (Appellants' Brief 29). Initially, neither depression nor anxiety is a "diagnosable psychological disorder": while certain depressive disorders and anxiety disorders *are* clinically diagnosable, depression and anxiety may themselves be symptoms rather than conditions. (Dkt. 77-3 at 6-9, 12, 15). Anticipating this argument, the State suggests that the statutory terms "depression" and "anxiety" may be read to refer not to the symptoms to which the words refer but to the disorders themselves. But that is simply not what the

statute says: anxiety (and not an "anxiety disorder"), depression (and not a "depressive disorder"), and "suicidal ideation" (which the State acknowledges is a symptom and not a disorder) are all provided as examples of "psychological conditions." Although under certain circumstances courts may interpret statutes so as to avoid constitutional concerns, "a court cannot rewrite a statute under the guise of construing it." *Wynn v. Carey*, 599 F.2d 193, 195 (7th Cir. 1979). The fact that the State is required to go to such lengths to attempt to salvage its statute, of course, only underscores the vagueness problem.

In any event, not only is the State offering an interpretation that contradicts the statutory language itself, but here its own canon of *noscitur a sociis* may properly be employed. The State itself acknowledges that "suicidal ideation" is a symptom rather than a clinically diagnosable disorder: why, then, should one assume that the legislature intended "depression" and "anxiety"—both symptoms themselves—to refer, in contravention to their established meaning, only to clinically diagnosable disorders? The State is left with a definition of "psychological complications" that includes *symptoms* of known disorders and not merely the disorders themselves. This definition is clearly broad enough that it could include sadness, worry, apprehension, temporary loss of sleep, irritability, euphoria, or any of a thousand other symptoms. A practitioner treating an abortion patient simply has no way to determine when such an "abortion complication" must be reported. There is no basis for the leap the State takes from the legislature's inclusion of four terms appearing in the DSM-5 to its conclusion that the statutory term "psychological complications" applies only to

conditions or symptoms identified in the DSM-5. After all, the Indiana General Assembly was certainly aware of the existence of that publication, *see, e.g.*, Ind. Code § 27-1-1.5-14, and had it chosen to do so it clearly could have made specific reference to conditions within the DSM-5.[16]

iii. The State is left, then, with its contention that, in addressing the since-amended version of the Complications Statute, Dr. Stutsman previously affirmed that he was "aware of what a 'psychological complication' is." (Dkt. 16-2 at 8 [¶ 39]). Of course, he did so at a time when the Complications Statute required the reporting of "[p]sychological or emotional complications, including depression, suicidal ideation, anxiety, and sleeping disorders." Ind. Code § 16-34-2-4.7(a)(24). At that time, the four examples provided (depression, suicidal ideation, anxiety, and sleeping disorders) could properly be understood as falling under the umbrella of "emotional complications" rather than "psychological complications," such that "psychological complications" might have referred simply to clinically diagnosed mental health disorders resulting from an abortion. The removal of any reference to "emotional complications" without altering the statutory examples, however, makes clear that Dr. Stutsman's understanding of "psychological complications" is not the same as the

[16] In the district court the State insisted that an abortion patient's relief, sadness, wariness, or depression would only reportable if it is a "*symptom*[] of a diagnosable psychological disorder." (Dkt. 78 at 28) (emphasis supplied). This interpretation would mean that PPINK or another provider would be required to report the sadness or anxiety of a patient with a previously diagnosed psychological disorder but would not be required to report the exact same sadness or anxiety of a patient without such a diagnosis. The State does not repeat this argument, but the fact that the State itself is unable to offer a consistent interpretation of the term "psychological complications" is powerful evidence of the term's vagueness.

interpretation of that phrase necessitated by the Complications Statute. The State ignores this fundamental point. The term in the Statute is bereft of established meaning and is vague.

2. The term "any other adverse event" is vague

Subsection 25 of the Statute requires the reporting of "[a]ny other adverse event as defined by criteria provided in the Food and Drug Administration Safety Information and Adverse Event Reporting Program." By regulation, this program establishes "procedures and requirements governing the use of investigational new drugs," *see* 21 C.F.R. § 312.1(a), although in operation it appears to allow for reports concerning established drugs as well. (*See* A.A. 134-35).[17]

The problem for the State is that an "adverse event" under the criteria of this program is defined in the broadest possible terms 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). "Any untoward medical occurrence" certainly lacks the requisite specificity. This is particularly so given that the "adverse event" need not even be considered "drug related": even though the Adverse Event Reporting Program was designed to track drug-related occurrences, the definition of an "adverse event" is itself not limited to these occurrences. Minor vomiting, nausea, depression, or tiredness might all be considered "untoward medical occurrences" that are "associated with the use of a drug in humans" even though they did not result from a

[17] *See generally* Thomas Sullivan, *FDA MedWatch Safety and Adverse Event Reporting Program Expands Patient Resources*, Policy and Medicine, May 6, 2018, *at* https://www.policymed.com/2013/07/fda-medwatch-safety-and-adverse-event-reporting-program-expands-patient-resources.html (last visited Oct. 25, 2020).

drug in any particular instance. Is minor soreness such an untoward medical occurrence? How about expected bleeding following a medication abortion? What about bloating or tiredness that might occur if a patient is provided ibuprofen before or after the procedure? In other words, the inclusion of subsection 25 in the Complications Statute renders any limitation imposed by the other twenty-four reportable "complications" meaningless; this provision is hopelessly vague.

The State resists this conclusion by suggesting that the examples offered by PPINK of the term's vagueness "are not untoward complications, but rather unpleasant and expected side effects." (Appellants' Brief at 30). But the challenged term does not refer to "untoward *complications*" or to "*unexpected* occurrences": it refers to "any untoward medical occurrence." Bleeding, nausea, soreness, and the like—whether or not they are the known and expected side-effects of an abortion—are certainly untoward medical occurrences.

Nor may the State salvage the statutory term, as it attempts to do, by resort to the fact that the federal government itself employs the term. (*Id*. 30-31). After all, the State and the federal government employ the term for dramatically different purposes. The federal government does not rely on the term "adverse event" in any manner that would require definiteness: not only do no penal consequences attach to the federal definition, but an "adverse event" need not even be reported under federal law. To the contrary, the FDA only mandates the reporting of (a) "any suspected adverse reaction that is both serious and unexpected" (21 C.F.R. § 312.32(c)(1)(i)); (b) "any clinically important increase in the rate of a serious suspected adverse reaction"

(21 C.F.R. § 312.32(c)(1)(iv)); and (c) "any unexpected fatal or life-threatening suspected adverse reaction" (21 C.F.R. § 312.32(c)(2)). But the terms that trigger the FDA's reporting requirement—"unexpected suspected adverse reaction," "serious suspected adverse reaction," and "life-threatening suspected adverse reaction"—are all defined in terms far more specific than is "adverse event." *See* 21 C.F.R. § 312.32(a). The State's attempt to re-purpose a term from federal law in a manner other than that which it was intended fails.[18]

The Statute's requirement that all "adverse events" be reported is also unconstitutional.

III. Although the Court need not reach the issue, the Complications Statute is irrational and violates due process[19]

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[18] Indeed, even for the more serious events that *are* reportable under federal law, *see* 21 C.F.R. § 312.32(c), the FDA is clear that the reporting of an event "does not establish causation": "[T]he reaction may have been related to the underlying disease being treated, or caused by some other drug being taken concurrently, or occurred for other reasons." *See* U.S. Food & Drug Admin., *FDA Adverse Event Reporting System (FAERS) Public Dashboard*, *at* https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard (last visited Oct. 25, 2020). This is clear from federal regulations themselves, which utilize a separate term—"suspected adverse reaction" to refer to "any adverse event for which there is a reasonable possibility that the drug caused the adverse event." 21 C.F.R. § 312.32(a).

The fact that the Complications Statute imports a term not designed to imply a causal connection into a reporting requirement designed exclusively to track causation demonstrates how dramatically the State's use of the term differs from the federal government's use of the term.

[19] PPINK argued to the district court that the Complications Statute was irrational, in violation of both substantive due process and equal protection. The district court reached neither issue. The State argues only that the Statute is rational and does not address the equal protection issue. Given that the Statue is unconstitutionally vague, there is no need to address the irrationality of the statute and PPINK suggests, in the event that this Court disagrees with the district court concerning the vagueness of the statute, that the issue of whether or not the statute satisfies due process or equal protection be remanded to the district court to be initially decided by it. *See. e.g., FMS, Inc. v. Volvo Const. Equipment North American, Inc.*, 557 F.3d 758, 763 (7th Cir. 2009) ("When the parties brief an issue that has not been addressed by the district court, it is not unusual for this court to remand so that the

A. This Court should not consider the opinions rendered by Dr. Francis

Both in the district court and in its appeal, the State has relied upon the declaration of Dr. Francis. Given the district court's vagueness ruling, it did not find it necessary to consider the objections raised by PPINK to her declaration under Federal Rule of Evidence 702 and *Daubert*. (Dkt. 86 at 11-12). However, her declaration should not be considered.

"Under the *Daubert* gatekeeping requirement, the district court has a duty to ensure that expert testimony offered under Federal Rule of Evidence 702 is both relevant and reliable." *Jenkins v. Bartlett*, 487 F.3d 482, 488-89 (7th Cir. 2007) (further citation omitted). This, includes a consideration of "the proposed expert's full range of experience and training in the subject area, as well as the methodology used to arrive at a particular conclusion." *Gayton v. McCoy*, 593 F.3d 610, 616 (7th Cir. 2010) (further citation omitted). Although Dr. Francis is an obstetrician-gynecologist, her curriculum vitae is bereft of any publications she has authored on any subject or any research studies concerning abortion. (A.A. 24, 37-39). She cannot claim that she must be aware of the risks and benefits of abortion as a function of providing informed consent to her patients, as she does not claim to perform abortions.

Dr. Francis also opines about the potential that abortions can have on a woman's psychological health, relying not on her experience or any expertise, but on

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district court may consider the issue in the first instance."). PPINK will limit its argument below to responding to the State's contention that the Statue is rationally related to a legitimate governmental interest, therefore satisfying due process.

studies by Dr Phyllis Coleman. (*See* Appellants' Brief at 4). Dr. Coleman's conclusions, noted by Dr. Francis and Dr. Studnicki (A.A. 184-85), are vigorously contested. There are numerous studies noting that there are no serious psychological consequences to abortion. (A.A. 123-124, 133). Dr. Coleman's conclusions were rejected by the National Academies report that considered her studies and dismissed her opinions, instead concluding that abortion does not increase the risk of depression, anxiety, and/or post-traumatic stress disorder. (Dkt. 73-6 at 163-64, 175).[20]

Dr. Francis has no training or experience concerning abortions or psychology and her "methodology" appears to be limited to selectively citing articles that support her point of view. A literature review does not equate to expertise as "a person does not become an expert in an area outside his regular field merely by 'reading up' for the specific purpose of testifying." *In re Welding Fume Products Liability Litigation*, No. 1:03-CV-17000, MDL 1535, 2005 WL 1868046, *12 (N.D. Ohio Aug. 8, 2005) (footnote omitted). "The question, then, is whether the expert's literature review is the *sole* basis for his opinion, or instead, helps inform an opinion he reaches though his own experience, research, or tests in related arenas." *Id.* (emphasis in original).

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[20] In another Indiana case where Dr. Coleman presented her arguments that abortion was related in some way to later mental health issues, the court noted that Dr. Coleman has made these contentions "in the face of severe and so far unremitting methodological criticism." *Bernard v. Individual Members of Indiana Medical Licensing Bd.*, 392 F. Supp. 3d 935, 959 (S.D. Ind. 2019). Recently, another district court found that "[p]laintiffs have presented persuasive evidence that Dr. Coleman's opinions lack support and that her work has serious methodological flaws." *Adams & Boyle, P.C. v. Slatery*, __F. Supp. 3d. __, No. 3:15-cv-00705, 2020 WL 6063778, *40 (M.D. Tenn. Oct. 14, 2020).

Dr. Francis has no apparent experience, research, or tests in the area of abortion study. It is the State's burden to establish that Dr. Francis is competent to render the opinions that she has set out in her declaration. *Gopalratnam v. Hewlett-Packard Co.*, 877 F.3d 771, 782 (7th Cir. 2017). It has failed to do so, and her opinions should not be considered.

B. The Statute is irrational and violates due process

At a minimum, the Fourteenth Amendment prohibits "the exercise of power without any reasonable justification in the service of a legitimate governmental objective." *County of Sacramento v. Lewis*, 523 U.S. 833, 846 (1998). If the "legislature has acted in an arbitrary and irrational way," substantive due process has been violated. *Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1, 15 (1976). Admittedly, the standard is quite "deferential" to the State. *Box*, 139 S. Ct. at 1782. "To survive under that standard, a state law need only be rationally related to legitimate government interests." *Id.* (internal quotation marks and citation omitted). However, the standard is not toothless, and courts do strike down governmental enactments that are fundamentally irrational, arbitrary, or capricious. *See, e.g., Berger v. City of Mayfield Heights*, 154 F.3d 621, 624-26 (6th Cir. 1998).

The State argues that it has a rational reason to seek "more comprehensive data on the rate of complications for abortion procedures performed in Indiana where that data has otherwise been insufficient and incomplete." (Appellants' Brief at 33). It argues further that the annual report summarizing the data may be used "to better understand the choices [the patient] may confront regarding a medical procedure" so

she is aware of "*all* possible complications that may occur if she undertakes the procedure." (*Id.* at 34) (emphasis in original). As support for its claim concerning insufficient reporting the State relies on the objected-to declaration of Dr. Francis (*id.* at 35).[21] However, Dr. Francis's opinion, whatever its value, is certainly not shared by all. In fact, the National Academies Report finds that "[a]bortion is among the most regulated medical procedures in the nation," noting further that there is "a plethora of related scientific research, including well-designed randomized controlled trials (RCTs), systematic reviews, and epidemiological studies examining abortion care" and that "[t]oday, the available scientific evidence on abortion's health effects is quite robust." (Dkt. 73-6 at 31, 33, 36).[22]

Regardless, assuming that the State has a legitimate interest in providing more information about the safety of abortion, even if there is a plethora of information already, to be rational the Statute must produce information that actually informs women accurately about the complications that may occur as the result of an abortion. *See, e.g., Buquer v. City of Indianapolis*, No. 1:11-cv-00708-SEB-MJD, 2013 WL 1332158, *13 (S.D. Ind. Mar. 28, 2013) (noting, in finding a state law violative of due process, "[a]lthough we do not dispute that the stated purpose . . . is a legitimate governmental purpose, the breadth of the [statute] . . . far exceeds its

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[21] Dr. Francis also opines that the Statute "helps to protect the health and safety of women by collecting more data with which to compare the relative risks of abortion and childbirth." (A.A. 35).

[22] The references reviewed by the National Academies demonstrate the "robust" nature of this evidence. For example, the report's chapter concerning the long-term health effects of abortion is followed by nearly 100 references. (Dkt. 73-6 at 167-172).

stated purpose and therefore is not rational"). Here, compelling the production of faulty information is not only not useful, but is actually harmful as it is uncontested that the faulty information may not only misinform women, but will result in discouraging woman from obtaining abortions.

Several examples suffice to demonstrate the extreme disconnect in the Complications Statute between the State's articulated purpose and what the statute actually does.

- It is uncontested that the Statute requires double counting of certain "complications." Practitioners are required to report "infections," Ind. Code § 16-34-2-4.7(a)(3). But they are also required to report "[p]elvic inflammatory disease," Ind. Code § 16-34-2-4.7(a)(9), an infection. (Dkt. 73-3 at 16). Similarly, "free fluid in the abdomen must be reported." Ind. Code § 16-34-2-4.7(a)(19). However, this is caused by a uterine perforation, which must be separately reported. Ind. Code § 16-34-2-4.7(a)(1). (Dkt. 73-3 at 17). By definition, a double count does not produce accurate information.

- The Statute will ensure double counting, or more, of complications in another way as well. The Statute requires a report from each practitioner or facility that treats an "abortion complication." Ind. Code § 16-34-2-4.7(b). What this necessarily means is that if a woman seeks treatment from multiple practitioners, each must file a report, thus guaranteeing overreporting and the skewing of statistical information.

- The Statute requires the reporting of events that are minor and are the expected temporary effects of abortions. For instance, the Department of Health recognizes that expected side effects of a medication abortion are temporary cramping and heavy bleeding, nausea, diarrhea, or vomiting. (Dkt. 73-4 at 8). As noted practitioners and facilities must report "adverse events" under the FDA's criteria, Ind. Code § 16-34-2-4.7(a)(25), defined as "any untoward medical occurrence," 21 C.F.R. § 312.32(a), a term that is certainly broad enough to include the above, and other expected consequences of an abortion.

- The Statute requires the reporting of "complications" that may occur in women seeking abortions, but that are completely unrelated to abortions. It requires the reporting of "[h]ypoglycemia occurring while the patient is being treated at the abortion facility." Ind. Code § 16-34-2-4.7(a)(21). However, as noted,

> hypoglycemia is low blood sugar that has nothing to do with abortion and may be caused by something as simple as not eating. (A.A. 135). In the district court the State argued that if a woman experiences anxiety when she must undergo any medical procedure and experiences anxiety when she seeks abortion care, it must be reported as a complication (Dkt. 78 at 24-25), even though she presumably would suffer the same anxiety if she had visited the doctor for the much more statistically dangerous colonoscopy.

The State argues that the problems that PPINK notes are illusory as the statute only requires the reporting of conditions that arise from abortions, and practitioners and facilities need not report complications "which provide no causal connection." (Appellant's Brief 35-36). The vagueness of the statutory language "arising from the induction or performance of an abortion," Ind. Code 16-34-2-4.7(a), is hardly going to assist those trying to figure out if there is a causal connection. But the State's argument misses the point. It is certainly possible that a person obtaining an abortion can have an infection, although this is rare and can generally be treated with oral antibiotics. (A.A. 129-130). But, "the risk of infection exists for every surgical procedure and many non-surgical procedures, including term delivery." (A.A. 138). Given this, it is not rational to argue that reporting infections will improve abortion safety, or the information given to women considering abortion, when infections are a potential risk of all procedures and where there is no information given as to the frequency of infections in other medical contexts, including delivery. The information generated is therefore skewed and misleading.

The State argues that the low-level scrutiny here does not require perfect tailoring and that it has the right to "take one step at a time" to address a problem. (Appellant's Brief at 34-35) (quoting *Williamson v. Lee Optical of Okla., Inc.,* 348 U.S.

483, 489 (1955)). PPINK acknowledges that the deferential review here allows the State to both seek to provide more information to women seeking abortion services and to determine, within broad boundaries, what type of information should be provided. But there are boundaries. Allowing the State discretion as to how it chooses to articulate the problem, it nevertheless has to be addressed by the transmission of accurate and non-misleading information. Otherwise, there is no reasonable justification or connection between the statute and "the service of a legitimate governmental objective." *Lewis*, 523 U.S. at 846.

In support of its argument, the State cites to the district court in *Planned Parenthood of Se. Pa. v. Casey*, 686 F. Supp. 1089 (E.D. Pa. 1988) and 744 F. Supp. 1323 (E.D. Pa. 1990), *aff'd in part, rev'd in part*, 947 F. 2d 682 (3d Cir. 1991), *aff'd in part, rev'd in part*, 505 U.S. 833 (1992), as a case that permits reporting requirements in the face of a constitutional challenge. (Appellants' Brief at 36). However, in that case the statute required that medical complications of the pregnancy be reported along with known complication "which resulted from the abortion itself." 686 F. Supp. at 1114. This assessment had to made "in the good faith judgment of the physician." *Id.* at 1118. Unlike the Indiana statute, the Pennsylvania statute allowed the physician to use his or her judgment to determine if the complication was directly from the "abortion itself." Here, the Complications Statute dispenses with the good faith judgment of the doctor and includes "complications" that will not arise directly from the abortion itself (*e.g.*, hypoglycemia, missed ectopic pregnancy) or that

certainly cannot be determined with any degree of medical certainty as arising from the abortion itself (*e.g.*,, anxiety, pre-term delivery in subsequent pregnancies).

The Pennsylvania statute also required the reporting of complications from pregnancy, or at least pregnancy through the time of the abortion. The current Pennsylvania statute requires the reporting of deaths arising from pregnancy or childbirth. 18 Pa. Cons. Stat. § 3214(g). This demonstrates a recognition that the Indiana statute elides. Barring a miscarriage, any pregnancy has two possible outcomes: abortion or childbirth. Any information concerning the risks of the former is worthless if similar information is not collected about the latter. This can most easily be seen by looking at the uncontested evidence concerning the "abortion complications" of pulmonary embolism and deep vein thrombosis, both of which are linked to pregnancy, not abortion. (Dkt. 73-3 at 137). Without the comparator of the risk of having the identical complication when pregnant, the risk of this occurring after an abortion is meaningless and certainly does not advance the State's interest of presenting truthful, accurate, and useful information about abortion complications.

This is not an instance where Indiana has chosen to pass legislation to address only part of a problem. Rather Indiana has created a statutory scheme that will dispense misleading and inaccurate information, to the detriment of women who are trying to determine if they should undergo an abortion. The State may not assert that its interest in better informing women's decision-making is advanced by a statute that cannot possibly inform a woman's decision.

Conclusion

The district court correctly concluded that the Complications Statute is unconstitutionally vague. This Court need go no further and should affirm the district court.

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