IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PAUL A. ISAACSON, M.D., *et al*., Plaintiffs-Appellees and Cross-Appellants, v. MARK BRNOVICH, Attorney General of Arizona, in his official capacity, *et al*., Defendants-Appellants and Cross-Appellees.	Case Nos. 21-16645, 21-16711 MOTION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF IN SUPPORT OF PLAINTIFFS-APPELLEES AND CROSS-APPELLANTS

Pursuant to Federal Rule of Appellate Procedure 29, *amici* American College of Obstetricians and Gynecologists, American College of Medical Genetics and Genomics, American College of Osteopathic Obstetricians and Gynecologists, American College of Physicians, American Gynecological and Obstetrical Society, American Medical Association, American Psychiatric Association, American Society for Reproductive Medicine, American Urogynecologic Society, Council of University Chairs of Obstetrics and Gynecology, National Association of Nurse Practitioners in Women's Health, North American Society for Pediatric and Adolescent Gynecology, Society for

Academic Specialists in General Obstetrics and Gynecology, Society for Maternal-Fetal Medicine, Society for Reproductive Endocrinology and Infertility, Society of Gynecologic Oncology, and Society of OB/GYN Hospitalists hereby move this Court for an order granting them leave to file the attached *amicus curie* brief in support of Plaintiffs-Appellees and Cross-Appellants. In support of this motion, *amici* state:

1. *Amici* are major national organizations representing physicians and other medical professionals who serve patients in Arizona and beyond. *Amici* are dedicated to health care, research, and evidence-based health policy. *Amici* are committed to improving health care and preserving access to health care, including reproductive health care.

2. *Amici* seek to file this *amicus* brief in the above-captioned case to assist the Court by providing their unique perspective on the harms of Senate Bill 1457, which is based on their collective expertise and experience in providing care to millions of Americans each year. Specifically, through this *amicus* brief, *amici* express their concern that Senate Bill 1457 imposes vague restrictions on physicians and other medical professionals that may significantly impede access to medically appropriate and necessary health care in Arizona. In addition, this *amicus* brief will help the Court to understand the harm that Senate Bill 1457 may

cause to the patient-physician relationship. *Amici* can provide the Court with insight and perspective not available from the parties.

3. As required by Circuit Rule 29-3, *amici* endeavored to obtain the consent of all parties to the filing of this *amicus* brief. *Amici* have only received consent from the Plaintiffs-Appellees and Cross-Appellants.

4. A copy of *amici's* proposed *amicus* brief is attached. It discusses the vagueness of the restrictions that Senate Bill 1457 places on physicians and other health care professionals, the undue interference that certain provisions of Senate Bill 1457 place on physicians' ability to act in the best interest of their patients, the intrusion of the State in the patient-physician relationship, and the substantial obstacles Senate Bill 1457 creates for patients seeking abortion care in Arizona.

5. Accordingly, *amici* respectfully proffer their brief to the Court and ask that the Court grant leave to file the same for the Court's consideration.

Dated: December 27, 2021

Respectfully submitted,

FRIED, FRANK, HARRIS, SHRIVER
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Nos. 21-16645, 21-16711
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PAUL A. ISAACSON, M.D., *et al.*,

Plaintiffs-Appellees and Cross-Appellants,

v.

MARK BRNOVICH, Attorney General of Arizona, in his official capacity, *et al.*,

Defendants-Appellants and Cross-Appellees.

On Appeal from the United States District Court for the
District of Arizona,
No. 2:21-cv-01417-DLR

BRIEF OF *AMICI CURIAE* AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN COLLEGE OF MEDICAL GENETICS AND GENOMICS, AMERICAN COLLEGE OF OSTEOPATHIC OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN COLLEGE OF PHYSICIANS, AMERICAN GYNECOLOGICAL AND OBSTETRICAL SOCIETY, AMERICAN MEDICAL ASSOCIATION, AMERICAN PSYCHIATRIC ASSOCIATION, AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE, AMERICAN UROGYNECOLOGIC SOCIETY, COUNCIL OF UNIVERSITY CHAIRS OF OBSTETRICS AND GYNECOLOGY, NATIONAL ASSOCIATION OF NURSE PRACTITIONERS IN WOMEN'S HEALTH, NORTH AMERICAN SOCIETY FOR PEDIATRIC AND ADOLESCENT GYNECOLOGY, SOCIETY FOR ACADEMIC SPECIALISTS IN GENERAL OBSTETRICS AND GYNECOLOGY, SOCIETY FOR MATERNAL-FETAL MEDICINE, SOCIETY FOR REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY, SOCIETY OF GYNECOLOGIC ONCOLOGY, AND SOCIETY OF OB/GYN HOSPITALISTS IN SUPPORT OF PLAINTIFFS-

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IDENTITY AND INTEREST OF *AMICI CURIAE*

Amici are major national organizations representing physicians and other medical professionals who serve patients in Arizona and beyond.[1] *Amici* oppose any law that gives the state effective control over the ability of medical professionals to care for their patients, substituting the opinion of state lawmakers for the considered decisions made by patients after informed discussions with their medical professionals. *Amici* also oppose any law that places their members at risk of criminal liability without fully and fairly informing those members of the behaviors that could violate the law.

The **American College of Obstetricians and Gynecologists** ("ACOG") is the nation's leading group of physicians providing health care for women. With more than 60,000 members—representing more than 90% of all board certified obstetricians-gynecologists in the United States—ACOG advocates for quality health care for women, maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of changing issues facing women's

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[1] Pursuant to Federal Rule of Appellate Procedure 29, undersigned counsel for *amici* certify that: no party's counsel authored this *amicus* brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting this *amicus* brief; and no person or entity, other than *amici*, its members, or its counsel, contributed money intended to fund the preparation or submission of this *amicus* brief.

health care. ACOG is committed to ensuring access to the full spectrum of evidence-based quality reproductive health care, including abortion care. ACOG has appeared as *amicus curiae* in courts throughout the country. ACOG's briefs and medical practice guidelines have been cited by numerous authorities, including the Supreme Court of the United States, as a leading provider of authoritative scientific data regarding childbirth and abortion.

The **American College of Medical Genetics and Genomics** is the only nationally recognized medical professional organization solely dedicated to improving health through the practice of medical genetics and genomics, and the only medical specialty society in the United States that represents the full spectrum of medical genetics disciplines in a single organization.

The **American College of Osteopathic Obstetricians and Gynecologists** ("ACOOG") is a non-profit, non-partisan organization committed to excellence in women's health representing over 2,500 providers. ACOOG educates and supports osteopathic physicians to improve the quality of life for women by promoting programs that are innovative, visionary, inclusive, and socially relevant. ACOOG is likewise committed to the physical, emotional, and spiritual health of women.

The **American College of Physicians** ("ACP") is the largest medical specialty organization in the United States and has members in more than 145

countries worldwide. ACP membership includes 159,000 internal medicine physicians, related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

The **American Gynecological and Obstetrical Society** is the premier national organization comprised of leading experts in Obstetrics and Gynecology. For over a century it has championed the highest quality of care for women and the science needed to improve women's health.

The **American Medical Association** ("AMA") is the largest professional association of physicians, residents, and medical students in the United States. Through the AMA's House of Delegates, substantially all physicians, residents, and medical students in the United States are represented in the AMA's policymaking process. The AMA was founded in 1847 to promote the art and science of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in all fields of medical specialization and in every state. The federal courts have cited the AMA's publications and *amicus curiae* briefs in cases implicating a variety of medical questions. The AMA appears on its own behalf and as a representative of the Litigation Center of the American Medical Association and the State Medical Societies (the "Litigation

Center"). The Litigation Center is a coalition among the AMA and the medical societies of each state, plus the District of Columbia, whose purpose is to represent the viewpoint of organized medicine in the courts.

The **American Psychiatric Association** ("APA") is a non-profit organization representing over 38,800 physicians who specialize in the practice of psychiatry. APA members engage in research into and education about diagnosis and treatment of mental health and substance use disorders, and are front-line physicians treating patients who experience mental health and/or substance use disorders.

The **American Society of Reproductive Medicine** ("ASRM") is a multidisciplinary not-for-profit organization dedicated to the advancement of the science and practice of reproductive medicine. Its members include approximately 8,000 professionals. ASRM accomplishes its mission through the pursuit of excellence in education and research and through advocacy on behalf of patients, physicians, and affiliated health care providers.

The **American Urogynecologic Society** ("AUGS") is the premier non-profit organization representing professionals dedicated to treating female pelvic floor disorders. Founded in 1979, AUGS represents more than 1,900 members, including practicing physicians, nurse practitioners, physical therapists, nurses and health care professionals, and researchers from many disciplines.

The **Council of University Chairs of Obstetrics and Gynecology** ("CUCOG") is a nationwide membership association promoting excellence in medical education in the fields of obstetrics and gynecology. CUCOG has 146 members representing the departments of obstetrics and gynecology within or affiliated with schools of medicine in 48 states, the District of Columbia, Puerto Rico, and Canada, with the department chair as the acting liaison. CUCOG convenes university chairs of obstetrics and gynecology in order to support the major missions of academic medicine: the provision of high-quality, safe, effective, and compassionate clinical care, including reproductive health care, in academic settings; the provision of high-quality medical education; and the cultivation of useful, reliable research.

The **National Association of Nurse Practitioners in Women's Health** ("NPWH") is a national non-profit educational and professional organization that works to ensure the provision of quality primary and specialty health care to women of all ages by women's health and women's health-focused nurse practitioners. Its mission includes protecting and promoting a woman's right to make her own choices regarding her health within the context of her personal, religious, cultural, and family beliefs. Since its inception in 1980, NPWH has been a trusted source of information on nurse practitioner education, practice, and women's health issues. In keeping with its mission, NPWH is committed to

ensuring the availability of the full spectrum of evidence-based reproductive health care for women and opposes unnecessary restrictions on access that serve to delay or prevent care.

The **North American Society for Pediatric and Adolescent Gynecology** is dedicated to providing multidisciplinary leadership in education, research, and gynecologic care to improve the reproductive health of youth. With its diverse membership including gynecologists, adolescent medicine specialists, pediatric endocrinologists, and other medical specialties, its focus is to be the leading provider in pediatric and adolescent gynecology ("PAG") education, research, and clinical care; conduct and encourage multidisciplinary and interprofessional programs of medical education and research in the field of PAG; and advocate for the reproductive well-being of children and adolescents and the provision of unrestricted, unbiased, and evidence-based practice of PAG.

The **Society for Academic Specialists in General Obstetrics and Gynecology** seeks to enhance women's health by supporting academic specialists in General Ob/Gyn in all phases of their careers.

The **Society for Maternal Fetal Medicine** ("SMFM"), founded in 1977, is the medical professional society for obstetricians who have additional training in high-risk, complicated pregnancies. SMFM represents more than 5,000 members who care for high-risk pregnant people and provides education, promotes research,

and engages in advocacy to reduce disparities and optimize the health of high-risk pregnant people. SMFM and its members are dedicated to optimizing maternal and fetal outcomes and assuring medically appropriate treatment options are available to all patients.

The **Society for Reproductive Endocrinology and Infertility** ("SREI") is a professional group of Reproductive Endocrinologists within ASRM. SREI's mission is to serve a leadership role in reproductive endocrinology and infertility by promoting excellence in patient care; fostering the training and career development of students, residents, associates, members, and affiliates; developing new initiatives in basic and clinical research; and supporting ethical practice and advocacy for the subspecialty.

The **Society of Gynecologic Oncology** ("SGO") is the premier medical specialty society for health care professionals trained in the comprehensive management of gynecologic cancers. With 2,000 members representing the entire gynecologic oncology team in the United States and abroad, the SGO contributes to the advancement of women's cancer care by encouraging research, providing education, raising standards of practice, advocating for patients and members and collaborating with other domestic and international organizations. In that mission, the SGO strives to ensure access to women's health care as part of an overall prevention strategy for gynecologic cancer.

The **Society of OB/GYN Hospitalists** ("SOGH") is a rapidly growing group of physicians, midwives, nurses and other individuals in the health care field who support the OB/GYN Hospitalist model. SOGH is dedicated to improving outcomes for hospitalized women and supporting those who share this mission. SOGH's vision is to shape the future of OB/GYN by establishing the hospitalist model as the care standard and the SOGH's values of excellence, collaboration, leadership, quality and community.

SUMMARY OF ARGUMENT

Senate Bill 1457 imposes vague restrictions on physicians that may have the effect of severely limiting access to, or entirely eliminating, medically appropriate and necessary health care. The State of Arizona, under Section 2 of Senate Bill 1457, forbids physicians from providing an abortion if they have some uncertain level of knowledge when patients seek such care motivated, to some uncertain extent, by a state-defined prohibited reason—*e.g.* a fetal genetic abnormality (the "Reason Regulation"[2]).[3] Under Section 1 of Senate Bill 1457 (the "Personhood Provision"), the State severely limits the types of medical care accessible to all patients who are or could become pregnant—not just those electing pregnancy termination—by redefining "person" in Arizona's existing laws to include an "unborn child" of any gestational age.[4]

The Reason Regulation and the Personhood Provision are efforts to permit the State to effectively control physicians' ability to care for patients without any

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[2] The "Reason Regulation" also includes §§ 10, 11, 13, A.R.S. §§ 13-3603.02(A)(2), (B)(2), (D), (E), 36-2157(A)(1), 36-2158(A)(2)(d), 36-2161(A)(25).

[3] While the District Court found that Section 2 of Senate Bill 1457 was a regulation, there are many instances where it will serve as a ban, as explained by this *amicus* brief.

[4] "Unborn child" is state-defined as the offspring of human beings from the moment of conception. This includes a fertilized egg (regardless of whether it results in pregnancy from implantation), an embryo, and a fetus of any gestational age. *See* Ariz. Rev. Stat. § 36-2151(16) (2021).

scientific or medical basis. The Reason Regulation outright replaces the judgment of trained medical professionals with that of the state legislature. A patient's decision to terminate a pregnancy or continue it to term in circumstances where a fetal genetic abnormality is or may be present is highly complex and generally requires advice from a multidisciplinary group of physicians and specialists. The State ignores this reality and instead criminalizes abortion care—one of the safest available medical procedures—when a physician "knows" his or her patient is seeking an abortion solely because of a fetal genetic abnormality. The Personhood Provision regulates not only physicians providing abortion care, but also all physicians and other medical professionals who interact in any capacity with patients who are pregnant, and the patients themselves.

In an environment where fetuses of all gestational ages have personhood rights, physicians may need to refrain from providing care that may have a negative impact on a fetus, even when the interests of the pregnant person and the fetus do not align. If a pregnant person develops a serious medical condition requiring surgery or medication that may negatively impact a fetus, the Personhood Provision could force physicians to withhold care or risk civil and/or criminal penalties under existing Arizona law. In this way, the Personhood Provision could result in catastrophic injuries to pregnant people by eliminating treatment options that could potentially harm a fetus. For example, pregnant people with chronic

diseases like lupus and asthma, or requiring surgery to remove a ruptured appendix or gallbladder, may need to treat those conditions with a course of treatment that could negatively impact a fetus.

Senate Bill 1457 provides no clarity on the scope of these vague prohibitions, leaving physicians in the dark as to what conduct violates the law. For example, within Senate Bill 1457 and within the Reason Regulation, it is unclear when a physician will be deemed to know that a patient is seeking an abortion "solely because of" or "because of" a fetal genetic abnormality. These inconsistent and vague statements of the *mens rea* required to violate the law creates an environment encouraging arbitrary prosecution of medical professionals. Moreover, it fails to provide a workable definition of a "genetic abnormality."[5] The Personhood Provision likewise fails to set forth standards on whether and when physicians can be held liable for providing medically appropriate treatment to pregnant patients. As a result of this vagueness, physicians have no guidance on

[5] The vague language of the Reason Regulation is further compounded by the multiple inconsistent physician knowledge and patient motivation standards included throughout Senate Bill 1457. For example, some sections require the physician to know an abortion is being sought "solely because of" a fetal genetic abnormality, whereas other sections require the physician to know an abortion is being sought "because of" a fetal genetic abnormality. In addition, Senate Bill 1457 also requires a physician to attest that they have "no knowledge" that the abortion is sought "because of" a "genetic abnormality." *See* Plaintiffs-Appellees/Cross-Appellants' Principal and Response Brief at 33-34, *Isaacson v. Brnovich*, Nos. 21-16645, 21-16711 (9th Cir. Dec. 20, 2021).

how to balance the rights of a fetus with that of a pregnant patient so as not to risk criminal and civil penalties.

Equally problematic is the chilling effect both the Reason Regulation and the Personhood Provision will have on the practice of medicine, the integrity of the medical profession and the patient-physician relationship. Both discourage open and frank communications between patient and physician and potentially discourage patients from receiving care. Moreover, physicians may have to choose between providing medically appropriate, essential care that they ethically are required to administer, or obeying the law. Physicians face serious criminal and/or civil penalties for violations under the Reason Regulation and under a broad variety of state statutes covering any number of topics, as a result of the Personhood Provision. In this environment, many physicians understandably may be unwilling to offer any health care to pregnant patients out of fear of prosecution, civil penalties, fines, and loss of licensure. This dynamic only exacerbates the shortage of physicians in Arizona who provide abortion care and creates a substantial obstacle for patients seeking constitutionally protected medical care, as well as prenatal care. *Amici* therefore ask this Court to affirm the District Court's decision to preliminarily enjoin the Reason Regulation and reverse the denial of the Plaintiffs' motion to preliminarily enjoin the Personhood Provision.

I. THE REASON REGULATION AND PERSONHOOD PROVISION CRIMINALIZE ROUTINE MEDICAL PRACTICES AND ARE UNWORKABLE

The State seeks to hold physicians criminally liable for providing abortion care and for providing care that may negatively impact a fetus, yet they do not provide constitutionally sufficient guidance on how physicians can perform their duties as medical professionals while abiding by the law.

A. The Reason Regulation is Vague

Notwithstanding the other provisions of Senate Bill 1457 that impose inconsistent and even broader *mens rea* standards, the Reason Regulation prohibits physicians from providing abortion care when they "know" an abortion is being sought "solely because of" a fetal "genetic abnormality."[6] No part of the Reason Regulation makes clear when a physician might be subject to criminal prosecution, civil penalties or loss of licensure under this provision.

1. Knowledge Element

First, the scope of the Reason Regulation's knowledge element is unclear. If a patient discloses that the reason they are seeking an abortion is because of a fetal genetic abnormality, it is clear the physician will be prohibited from providing such care, unless one of the narrow exceptions to the Reason Regulation applies. But this circumstance will be the exception because patients may not express their

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[6] 3-ER-368.

motivation for obtaining an abortion—nor are they required to under controlling Supreme Court precedent. And even absent an express statement of intention, if a pregnant patient is seeking abortion care and a fetal genetic abnormality is present, it is at least possible that the patient is seeking abortion care due to a fetal genetic abnormality. It is not clear whether a physician would be charged with knowledge if that inference is possible. In addition, the Reason Regulation does not state whether physicians are or are not expected to probe the reasons a patient is seeking an abortion to avoid criminal liability. This is a fatal flaw because criminal statutes must give reasonable notice as to what conduct they proscribe.[7]

It is not appropriate for the State to task physicians with policing patient motivations and guessing why a patient is seeking care, particularly when such information is not clinically required. Requiring physicians to second guess a patient's reason for a necessary and safe procedure will inevitably have a chilling effect on the patient-clinician relationship and erode trust. In light of the unclear scope of the Reason Regulation, a physician who provides abortion care in any circumstance where a fetal genetic abnormality is present may be accused of breaking the law and may face criminal or civil penalties and loss of licensure.

[7] *See, e.g.*, *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972) (ruling that a law is unconstitutionally vague if it fails to provide explicit standards for those who apply them).

Existing Arizona law regarding state of mind does not alleviate the confusion. Arizona's Revised Statute states that "knowingly" means "a person is aware or believes that the person's conduct is of that nature or that the circumstance exists."[8] This definition, however, does not resolve the issue of vagueness, because it requires a physician to guess the subjective motivations of the pregnant patient. It does not provide sufficient, workable guidance to determine when knowledge will be imputed to a physician when a fetal genetic abnormality is present.

During the normal course of prenatal care, ACOG, SMFM, and the Royal College of Obstetricians and Gynaecologists—three of the premier medical professional societies in the world for obstetrician-gynecologists—all recommend that physicians provide clear, objective, and non-directive counseling to their patients concerning the option to obtain fetal genetic testing, so as to allow patients to make informed decisions about testing.[9] If a patient decides to obtain genetic testing, the physician then must interpret the results. For patients who receive test results indicating a genetic abnormality, the physician explains the consequences

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[8] Ariz. Rev. Stat. § 13-105(10)(b) (2021).

[9] ACOG and SMFM, *Prenatal Diagnostic Testing for Genetic Disorders*, Practice Bulletin 162, at 5 (May 2016); *see also See* ACOG and SMFM, *Screening for Fetal Chromosomal Abnormalities*, Practice Bulletin 226, at e9 (2020); RCOG, *Termination of Pregnancy for Fetal Abnormality in England, Scotland and Wales*, at 20 (May 2010) ("Screening for trisomy 21 and fetal anomalies is universally offered to women.").

of those results and provides non-directive counseling on the patient's options.[10] These options could include seeing another physician or specialist and/or obtaining additional screenings, testing, and counseling.[11] It is standard medical practice for physicians to also discuss pregnancy termination in these scenarios.[12] If a patient later elects to obtain an abortion, but chooses not to disclose the motivations for her choice, a physician could be deemed to "know" that the patient's decision must have been for a prohibited reason.

Moreover, the testing for predicting, detecting, and diagnosing a fetal genetic abnormality is a multi-step, complex process. The Reason Regulation gives physicians no notice as to when in this process they will be deemed to have knowledge that could result in their arrest. Consider the following scenario: routine testing, performed on most pregnant patients, detects or suggests the possibility of a fetal genetic abnormality. At some later point in time after

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[10] *See* ACOG and SMFM, *Screening for Fetal Chromosomal Abnormalities*, Practice Bulletin 226, at e2 (2020).

[11] *See, e.g.*, *id.* at e10; ACOG and SMFM, *Screening for Fetal Aneuploidy*, Practice Bulletin 163 (May 2016).

[12] *See* SMFM, *SMFM Fetal Anomalies Consult Series #2: Extremities*, at B6 (Dec. 2019) ("Pregnancy termination is an option that should be discussed with all patients in whom a fetal anomaly is detected."); *see also* ACOG and SMFM, *Screening for Fetal Chromosomal Abnormalities*, Practice Bulletin 226, at e10 (2020) ("When a screen positive test result is obtained, patients should be counseled regarding their revised risk of carrying a fetus with a chromosomal abnormality.").

receiving those test results, a patient seeks to end the pregnancy. Knowing that the routine testing was performed and the results of the test could be seen as sufficient to impute "knowledge" under the Reason Regulation, whether or not the patient expresses a different reason for seeking an abortion, physicians may be prohibited from providing such care.

The same confusion would apply to clinicians who were not involved in some earlier fetal genetic testing process. If the physician providing the abortion was not involved in the fetal genetic testing, but subsequently becomes aware of the test results, then that may also be construed as sufficient "knowledge." For example, a physician may learn of positive test results from medical records shared by another physician with patient consent, a common and encouraged practice in the medical profession.[13] Or, a physician may have reason to believe a fetal genetic abnormality exists based on information learned during routine medical examinations, such as an ultrasound.[14] This dynamic is nearly inevitable for

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[13] *See* AMA, Code of Medical Ethics, Opinion 3.3.1; *see also* Troy Parks, *Sharing Health Data: HIPAA May Allow More Freedom Than You Think*, AMERICAN MEDICAL ASSOCIATION, (Mar. 18, 2016) (noting that HIPAA gives health care professionals certain permissions to share personal health information for patient care).

[14] ACOG and SMFM, *Prenatal Diagnostic Testing for Genetic Disorders*, Practice Bulletin 162, at 7 (May 2016) (noting that some structural malformations or patterns of malformations visible on an ultrasound are characteristic of fetal genetic disorders).

physicians providing abortion care in Arizona who are required to perform an ultrasound at least 24 hours before an abortion.[15] If a physician identifies a structural malformation indicative of a fetal genetic abnormality during a routine ultrasound prior to providing abortion care, then the physician could also be deemed to possess the requisite "knowledge" of the reason to trigger liability. These examples illustrate the vagueness of the "knowledge" element and the precarious position in which it places health care professionals and the patient-clinician relationship.

2. "Genetic Abnormality" Element

Second, similar to the "knowledge" element, the Reason Regulation is vague as to which fetal conditions fall within the scope of its prohibition. The Reason Regulation defines "genetic abnormality" as the "presence or presumed presence of an abnormal gene expression in an unborn child, including a chromosomal disorder or morphological malformation occurring as the result of abnormal gene expression."[16] The Reason Regulation provides no guidance to help a physician determine what suffices to show a "presence or presumed presence of an abnormal gene expression." "Genetic abnormality" also excludes a "lethal fetal condition," defined as a fetal condition that is diagnosed before birth and that will result, "with

[15] Ariz. Rev. Stat. § 36-2153(A) (2021).

[16] 3-ER-368, 369.

reasonable certainty" in the death of the unborn child within three months after birth but may result in physical or mental disability or abnormality.[17] The State provides no guidance on how physicians will be deemed to know with "reasonable certainty" that such a condition exists and the exception applies. The Reason Regulation was drafted by state legislators—not physicians—and it fails to account for the inherent limitations and uncertainties associated with fetal genetic testing.

There are two main types of fetal genetic testing that may help identify a fetal genetic abnormality: screening tests and diagnostic tests. Screening tests, which are usually based on a blood draw, a tissue sample and/or an ultrasound, are used to identify pregnant patients with an increased chance of carrying a fetus with certain chromosomal abnormalities.[18] Screening tests do not identify genetic abnormalities with certainty; a positive result means only that a fetus is at a higher risk of carrying a genetic abnormality compared with the general population.[19] Upon receiving a positive screening test result, physicians then provide non-directive counseling to patients about additional tests that they may or may not elect to obtain.

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[17] 3-ER-378.

[18] ACOG and SMFM, *Screening for Fetal Chromosomal Abnormalities*, Practice Bulletin 226, at e10 (2020); *see also* ACOG, *Prenatal Genetic Screening Tests, Frequently Asked Questions*, https://www.acog.org/womens-health/faqs/prenatal-genetic-screening-tests (last visited Dec. 21, 2021).

[19] ACOG, *Prenatal Genetic Screening Tests, Frequently Asked Questions*.

Diagnostic testing can more conclusively determine whether a fetus has a genetic abnormality, although even these results are not always definitive. Diagnostic testing itself is not without risk because it requires the direct collection of placental or fetal cells either through chorionic villus sampling (a transcervical or transabdominal sampling of the placenta tissue) or amniocentesis (sampling of amniotic fluid through a fine needle inserted into the uterus through the abdomen).[20] Some patients may forego diagnostic testing, even if after receiving a positive screening test result, because of the risks inherent in such testing.[21]

Under the vague Reason Regulation, positive screening test results alone may or may not be sufficient to satisfy the element of physician knowledge of a "genetic abnormality." In that case, a physician may or may not be prohibited from providing abortion care, although critical clinical decisions should not be based solely on screening test results due to their inherent uncertainties and limitations.[22] In addition, with both screening and diagnostic tests, the results are not always clear as to whether a given abnormality arose partially or solely from a

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[20] ACOG and SMFM, *Prenatal Diagnostic Testing for Genetic Disorders*, Practice Bulletin 162, at 4-5 (May 2016).

[21] *Id.*

[22] *See* ACOG and SMFM, *Screening for Fetal Chromosomal Abnormalities*, Practice Bulletin 226, at e10 (2020).

genetic cause.[23] A fetal abnormality that is only partially the result of a genetic cause might or might not fall within the scope of the Reason Regulation, but it is unclear.

Without knowing what constitutes a "genetic abnormality" under the law, physicians cannot comply with other sections of the Reason Regulation. This vagueness leaves physicians unsure of whether they need to inform pregnant patients of whether their abortion is prohibited (or permitted). Section 11, for instance, requires physicians to inform their pregnant patients "diagnosed" with a "nonlethal fetal condition" that abortions sought because of a fetal genetic abnormality are prohibited.[24] The State defines "nonlethal fetal condition" as a fetal condition that is diagnosed before birth and is not reasonably certain to result in death within three months after birth.[25] The lack of precision in defining fetal "genetic abnormality" makes it even more difficult to determine whether a given abnormality would be considered "nonlethal"—a subjective layperson's term that has no medical or scientific definition. Again, physicians have no notice regarding

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[23] ACOG and SMFM, *Prenatal Diagnostic Testing for Genetic Disorders*, Practice Bulletin 162, at 9 (May 2016) ("Prenatal tests of all types, including ultrasonography, screening tests, and diagnostic tests, can provide results of uncertain significance.").

[24] 3-ER-377.

[25] 3-ER-378.

what information constitutes a legal "certainty" to determine whether a condition is "nonlethal."

3. "Because of" Element

Third, it is unclear when a physician knows a patient is seeking an abortion "because of" a fetal genetic abnormality. Many factors influence a patient's decision to have an abortion.[26] These factors may include financial limitations, emotional reasons, familial considerations, life circumstances, maternal health risks, and personal choice, among others.[27] Thus after receiving positive screening or diagnostic test results, a patient will weigh a variety of factors in determining whether to terminate a pregnancy: the definitiveness or uncertainty of the test results, the likely or possible diagnosis of an abnormality, and/or the resources, including financial and emotional support, needed to raise a medically complex child with increased needs.

Physicians, like all citizens, must be put on notice as to what is prohibited by the law. The Reason Regulation fails to do this and opens up medical professionals to arbitrary enforcement including prosecution. Without knowing what is prohibited by the Reason Regulation, other health care professionals cannot

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[26] *See* ACOG, Committee on Health Care for Underserved Women, *Increasing Access to Abortion*, Committee Opinion 815, at e108 (Dec. 2020).

[27] *Id.*

abide by Senate Bill 1457, which imposes civil penalties for failure to report known violations of the Reason Regulation.[28] Physicians and other health care professionals should not be forced to guess when their conduct will trigger liability.[29]

B. The Personhood Provision is Vague and Could Force Physicians to Avoid Providing Medically Indicated Care to Pregnant Patients

Arizona has redefined "natural person" to include "an unborn child at every stage of development."[30] By expanding personhood rights to fetuses of all gestational ages under all of its hundreds of laws and regulations, the State has indirectly imposed an unknowably complicated and vague restriction on physicians. Every time the terms "person," "child," and "human being" appear in the Arizona Revised Statutes, the terms must now be read to include fertilized eggs, embryos, and fetuses, thereby giving a fetus of any gestational age a multitude of potential rights and protections.

A fetus of any gestational age cannot exist apart from a pregnant person. By granting "all rights, privileges and immunities" to fetuses, the Personhood Provision deeply impacts the "rights, privileges and immunities" of pregnant

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[28] 3-ER-368.

[29] *See, e.g.*, *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972).

[30] 3-ER-368.

people in innumerable ways.[31] As is relevant to *amici*, physicians can no longer provide care to pregnant patients without giving equal (or possibly greater) weight to the potential impact on the fetus. When the interests of the pregnant person and the fetus do not align, any incidental impact on a fetus that results from treating a pregnant person could subject the physician to arbitrary criminal prosecution and/or civil penalties.[32] Further, Senate Bill 1457 does not provide explicit standards for physicians to follow.

To illustrate, a person commits "endangerment" under Arizona law when they "recklessly endanger[] another person with a substantial risk of imminent death or physical injury."[33] As a result of the Personhood Provision, it is unclear whether and when physicians could be charged with "endangerment" for providing medical treatment unrelated to pregnancy to pregnant patients where the treatment could incidentally harm a fetus. For example, pregnant people can commonly develop serious medical problems like appendicitis or cholecystitis (inflammation of the gallbladder) during pregnancy. Both conditions can be serious and at times require surgery for survival. Yet, physicians could be held criminally liable for

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[31] *Id.*

[32] In addition to physicians, *all* pregnant patients themselves must consider the rights of fetuses in making decisions about health care. Pregnant patients, for example, who choose a course of action that has a negative impact on a fetus may now be subject to criminal prosecution under Arizona law.

[33] Ariz. Rev. Stat. § 13-1201(A) (2021).

"endangerment," among other existing Arizona statutes, by performing a medically necessary surgery to remove the patient's infected gallbladder or appendix, knowing that the anesthesia medications and the surgery itself may negatively impact the fetus.

Furthermore, many people have underlying medical conditions that frequently worsen and become life-threatening during pregnancy. Examples of these conditions include congenital heart disease, postpartum cardiomyopathy (a form of heart failure), and pulmonary hypertension (a type of high blood pressure). Due to the potential risks to a fetus, the Personhood Provision prevents physicians from appropriately counseling and treating patients with these types of conditions who become pregnant with potentially dire consequences for the pregnant person. The Personhood Provision could require people to continue pregnancies that put their own lives at risk.

Similarly, pregnant people with conditions like lupus, inflammatory bowel disease, and asthma may need to take oral steroids to prevent significant worsening of their disease conditions, even though long-term steroid courses can have negative effects on a developing fetus. Pregnant people with cancer may require therapeutic treatment that could carry risks for the fetus. Here too, the Personhood Provision could prevent physicians from treating disease, causing harm to the pregnant person in order to avoid violating Arizona law.

These examples make clear that through the Personhood Provision, the State could restrict (or outright prohibit) appropriate, and even essential, medical care that is otherwise regularly provided to pregnant patients, irrespective of whether the patient is seeking to terminate their pregnancy.[34] Even if the Personhood Provision does not outright prohibit care, medical uncertainty regarding actual risk will only dissuade physicians from providing appropriate care due to unknown consequences.[35]

There are already examples, such as in the context of childbirth, where tort law problematically requires physicians to prioritize a fetus over a pregnant patient because physicians can be subjected to huge monetary damages for any harm suffered by the fetus during the birthing process.[36] As such, the law incentivizes physicians to recommend care that minimizes fetal risks at all costs, rather than conform to the best clinical approach.[37] The effect of the Personhood Provision

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[34] For reproductive health care, the Personhood Provision will have a profound impact far beyond abortion care. For example, it would likely ban many forms of contraception, could potentially ban any biomedical research related to a fetus, and can affect the use of assisted reproductive technology. NARAL Pro-Choice America, *"Personhood" Measures: Extreme and Dangerous Attempts To Ban Abortion* (Jan. 2017).

[35] Developments in the Law-Intersections in Healthcare and Legal Rights: Chapter 3: The Legal Infrastructure of Childbirth, 134 Harv. L. Rev. 2209, 2230 (Apr. 12, 2021).

[36] *Id.* at 2214.

[37] *Id.*

would be much broader—threatening all forms of health care at any stage of pregnancy where there is any potential risk, even nominal, to a fetus.

The State provides no guidance to physicians on how to satisfy their ethical obligations to their pregnant patients under this vague expansion of personhood rights. In failing to provide physicians with notice of what conduct is forbidden or required under the law, Arizona places physicians in vulnerable, ethically challenging positions.

II. THE REASON REGULATION AND PERSONHOOD PROVISION IMPINGE UPON THE INTEGRITY OF THE MEDICAL PROFESSION

The Supreme Court has consistently held that laws regulating abortion that unduly interfere with physicians' ability to act in the best interest of their patient are unconstitutional.[38] Physicians are bound by ethical obligations to their patients and required to exercise sound judgment grounded in medicine and science. Medical *amici* oppose legislation that interferes with physicians' ability to provide medical care and intrudes into the patient-physician relationship.[39] The Reason Regulation and the Personhood Provision do just that by impeding access to

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[38] *See, e.g.*, *June Med. Servs. L.L.C. v. Russo*, 140 S. Ct. 2103 (2020); *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016); *Planned Parenthood v. Casey*, 505 U.S. 833 (1992).

[39] ACOG, *Legislative Interference with Patient Care, Medical Decisions, and the Patient-Physician Relationship* (May 2013, amended & re-affirmed Aug. 2021).

evidence-based medical care and by forcing physicians to put the State's interests above their patients' interests. For this reason, both laws should be invalidated.

A. The Reason Regulation and Personhood Provision are Contrary to Bedrock Principles of Medical Ethics

The Reason Regulation and the Personhood Provision will effectively prevent physicians from obeying their ethical obligations by frustrating their ability to exercise all reasonable means to ensure that their patients receive the most appropriate and effective care. As members of the medical profession, physicians commit to practice by certain values. At their core, physicians should practice in alignment with the principles of patient autonomy, beneficence, and non-maleficence.[40]

Principles of patient autonomy dictate that patients have ultimate control over their bodies and a right to a meaningful choice when making medical decisions.[41] Physicians must honor and respect patient decisions about the course of their care. The prohibitions in the Reason Regulation and in other Arizona statutes in light of the Personhood Provision may deter physicians from providing patient-elected care, such as an abortion, that may otherwise be medically appropriate and safe.

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[40] *See* ACOG, *Ethical Decision Making in Obstetrics and Gynecology*, Committee Opinion No. 390, at 3–5 (Dec. 2007, re-aff'd 2016); *see also* AMA, Code of Medical Ethics, Opinion 1.1.3.

[41] ACOG, *Ethical Decision Making in Obstetrics and Gynecology*, Committee Opinion No. 390, at 3 (Dec. 2007, re-aff'd 2016).

Beneficence requires physicians to act in a way that is likely to benefit patients.[42] Non-maleficence requires physicians to refrain from acting in ways that might harm patients unless the harm is justified by simultaneous benefits.[43] The Reason Regulation's unclear provisions effectively prevent physicians from abiding by these foundational concepts. Under the Reason Regulation, a physician who has reason to believe a patient is seeking an abortion because of a fetal genetic abnormality will risk civil and criminal penalties for providing such care unless, and until, the patient's health deteriorates so substantially that a "medical emergency" occurs or a "a fetal condition…is diagnosed before birth and…with reasonable certainty, [will result] in the death of the unborn child within three months after birth."[44] The Reason Regulation puts physicians in a position of having to choose between following the law and acting in accordance with foundational medical ethics that prioritize patient wellbeing.[45]

Physicians are put in the same position when they must decide between withholding medical care that is unrelated to pregnancy, but medically appropriate

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[42] *Id.*

[43] *Id.*

[44] 3-ER-368, 369.

[45] *See* AMA, Code of Medical Ethics, Opinion 1.1.6 (noting that physicians should be dedicated to promoting the well-being of patients and should ensure that the care patients receive is patient centered); *see also* AMA, Code of Medical Ethics, Opinion 1.1.1; AMA, Code of Medical Ethics, Principles of Medical Ethics, Principle 8.

for their pregnant patient, and violating the law by providing care that might negatively impact the fetus. This is illustrated by cases in other jurisdictions with laws similar to Senate Bill 1457 where pregnant patients have died because physicians are prohibited, or believe they might be prohibited, from treating them.

In August 2012, a 16-year-old pregnant patient in the Dominican Republic died from complications due to acute leukemia after chemotherapy treatment was withheld.[46] Her physicians knew that the patient needed chemotherapy to treat the cancer, but withheld it out of fear of criminal prosecution, because the Dominican Republic's constitution—like the Personhood Provision here—recognizes personhood from the moment of conception. The physicians sought clarity from the government of the Dominican Republic, which delayed the patient's essential chemotherapy while determining whether she had a right to receive it despite ill effects on the fetus. By the time the government ultimately determined that this patient could have crucial cancer treatment, the patient's health had deteriorated so substantially that she and the fetus both died.

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[46] Rafael Romo, *Pregnant Teen Dies After Abortion Ban Delays Her Chemo Treatment for Leukemia*, CNN (Aug. 18, 2012), https://www.cnn.com/2012/08/18/world/americas/dominican-republicabortion/index.html; *see also* Center for Reproductive Rights, *Rights at Risk: The Truth About Prenatal Personhood*, at 10 (2012).

Similarly, in 2004, a pregnant patient living in Poland sought treatment for ulcerative colitis, an inflammatory bowel disease.[47] Poland recognizes the personhood rights of fetuses—again, as Arizona does here—so physicians were unable to provide her with necessary medical care for this treatable condition. Predictably, her condition worsened and she was transferred from hospital to hospital, each time being denied essential care. Because physicians could not provide the care without violating Polish law, both the pregnant patient and the fetus died.

In both examples, it was medically possible for physicians to try to save the life of the pregnant patient. But the laws that prevented them from doing so also did not save the lives of the fetuses either. Physicians could not fulfill their obligations of beneficence and non-maleficence to the pregnant patient, nor could they respect patient autonomy; they were hamstrung by their respective governments. If the Reason Regulation goes into effect, coupled with the Personhood Provision, pregnant individuals in Arizona will face the same risks (including death) and Arizona's physicians could be forced to withhold critical, lifesaving care.[48] This directly conflicts with the objective of the medical

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[47] Center for Reproductive Rights, *Rights at Risk: The Truth About Prenatal Personhood*, at 17 (2012).

[48] The effect of which is likely to produce "moral injury" to physicians—the perpetrating, failing to prevent, bearing witness to, or learning about acts that transgress deeply held moral beliefs and expectations. *See generally* Wendy Dean

profession to heal and preserve life. Physicians cannot effectively care for their patients and prevent avoidable loss of life without the authority to make safe, clinically sound decisions without interference from the State.[49]

B. The Reason Regulation Improperly Intrudes Upon the Patient-Physician Relationship

The Reason Regulation drives a wedge between patients and physicians.[50] This relationship is built upon trust.[51] When this trust is established, patients may share deeply personal secrets, worries, and fears with their physicians. The Reason Regulation adversely influences, and may even destroy, this profound bond.

The patient-physician relationship is a collaborative effort between patient and physician in a mutually respected alliance.[52] Patients contribute to this alliance

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et al., *Reframing Clinician Distress: Moral Injury Not Burnout*, 36(9) Fed. Pract. 400 (Sept. 2019). The State subjects physicians to moral injury by effectively forcing them to withhold medically appropriate care—abortions or otherwise—and to bear witness to suffering patients or death from treatable medical conditions.

[49] *See* AMA, Code of Medical Ethics, Opinion 1.1.6 (noting that physicians should ensure that the care their patients receive is safe, effective, patient centered, and equitable).

[50] The patient-physician relationship is essential for the provision of safe and quality medical care. ACOG, *Legislative Interference with Patient Care, Medical Decisions, and the Patient-Physician Relationship* (May 2013, amended & re-affirmed Aug. 2021); *see also* ACOG, *Effective Patient-Physician Communication*, Committee Opinion 587, at 1 (2014, re-aff'd 2016); AMA, Code of Medical Ethics, Opinion 1.1.1.

[51] *See* AMA, Code of Medical Ethics, Opinion 1.1.1.

[52] *Id.* at Opinion 1.1.3; *see also* ACOG, *Effective Patient-Physician Communication*, Committee Opinion 587, at 1 (2014, re-aff'd 2016) ("Patient outcomes depend on successful communication. The physician who encourages

when they are candid with their physicians.[53] Instead of promoting open and frank communication, the Reason Regulation coerces patients into limiting, concealing, or even misrepresenting test results in order to safeguard their abortion rights. The Reason Regulation also encourages physicians to pry in order to second-guess a patient's reasoning. A patient who wants, or does not want to foreclose the possibility of obtaining an abortion, must either give up their right to communicate information about a detected or possible fetal genetic abnormality or give up their right to obtain an abortion. The Reason Regulation pits a patient's right to abortion against their right to speak openly with their physician.

The Reason Regulation further poisons the patient-physician relationship by requiring physicians to disclose patient confidences and sensitive medical information. Physicians have an ethical obligation to preserve the confidentiality of the information gathered in association with the care of their patient.[54] Confidentiality is essential for building trust between a patient and their physician, as well as with the medical profession more broadly. Under Senate Bill 1457, if a physician becomes aware that a patient sought an abortion solely because of a fetal genetic abnormality, the physician would be required to report that abortion to the

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open communication may obtain more complete information, enhance, the prospect of a more accurate diagnosis, and facilitate appropriate counseling.").

[53] AMA, Code of Medical Ethics, Opinion, 1.1.3.

[54] *Id.* at Opinion 3.2.1.

State or suffer serious penalties.[55] By requiring physicians to report to the State private, sensitive, and confidential information about patients, the State is shattering the trust fostered by the patient-physician relationship and makes patients less likely to share information with their physicians.

III. THE REASON REGULATION WILL LIMIT ACCESS TO ABORTION CARE IN ARIZONA

The Reason Regulation creates substantial obstacles for patients seeking abortion care. Under the Reason Regulation, patients will need to find a physician who has no knowledge that they are seeking abortion care because of a fetal genetic abnormality. This means that a patient may be unable to obtain an abortion from any physician who is aware that fetal genetic testing revealed any possible abnormalities, even if the patient is seeking the abortion for an unrelated reason. As a practical matter, pregnant people who do not have access to resources will not be able to switch providers, and will be unable to access abortion care in Arizona.

Even now, Arizona—the sixth largest state in the country by area and the fourteenth most populous with over seven million people—has only five clinics that offer abortion care.[56] Over 80% of Arizona counties have *no* clinics that

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[55] 3-ER-368.

[56] *State Facts About Abortion: Arizona*, GUTTMACHER INSTITUTE (Jan. 2021), https://www.guttmacher.org/fact-sheet/state-facts-about-abortion-arizona.

provide abortion care.[57] The pre-existing barriers to abortion access in Arizona will no doubt worsen as a result of the Reason Regulation by deterring doctors from providing abortion services for fear of criminal prosecution. The uncertainties in the proposed statutory schemes coupled with the threat of serious penalties and prosecution will drive physicians away from providing abortion care.

This shortage of clinicians providing abortion care means that many patients will be required to travel long distances to access care in the state. This is particularly onerous for patients seeking abortions who are disproportionately adolescents, people of color, individuals living in rural areas, and/or individuals of low income who already face barriers to abortion access.[58] Existing Arizona law further creates barriers by, for example, requiring state-directed counseling at least 24 hours before the care can be provided.[59] This means that, at a minimum, a patient needs to make two trips to the abortion clinic.

Even after expending the time and money to find a physician, there is still no guarantee that the patient will be able to obtain an abortion, given the risk that the physician learns information that could trigger liability under the Reason Regulation. A physician who violates the Reason Regulation may be guilty of one

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[57] *Id.*

[58] *See* ACOG, Committee on Health Care for Underserved Women, *Increasing Access to Abortion*, Committee Opinion 815, at e111-112 (Dec. 2020).

[59] Ariz. Rev. Stat. § 36-2153(A) (2021).

of multiple felonies, including, for example, Class 3 and/or Class 6 felonies.[60] The mere possibility of criminal prosecution, and civil penalties, including large fines and licensing penalties, will almost inevitably deter physicians from providing abortions in situations where it is impossible to determine what might violate the amorphous Reason Regulation.[61]

Pregnant patients who are unable to find a physician who is able or willing to perform an abortion will be forced to continue their pregnancy to term. Forcing people to continue pregnancies to term under these circumstances will only expose Arizona citizens to otherwise avoidable risks, including severe health consequences for the patients and their fetuses.[62]

CONCLUSION

This Court should affirm the District Court's decision to preliminarily enjoin the Reason Regulation and reverse its denial of the motion to preliminarily enjoin the Personhood Provision.

Dated: December 27, 2021

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[60] 3-ER-368.

[61] *See, e.g.*, 2-ER-279 (Decl. of Dr. Paul A. Isaacson).

[62] *See* Lidia Casas & Lieta Vivaldi, *Pregnancies and Fetal Anomalies Incompatible with Life in Chile: Arguments and Experiences in Advocating for Legal Reform*, 19(1) Health & Hum. Rts. J. 95 (June 2017).

Respectfully submitted,

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