Refocusing the Undue Burden Test: Inconsistent Interpretations Pose a Substantial Obstacle to Constitutional Legislation

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ABSTRACT: Decades after *Roe*, debate over abortion remains as contentious as ever. States continue to pass regulations burdening the abortion right, but lack clear guidance on how to evaluate such regulations using the undue burden test. This Article chronicles Supreme Court jurisprudence on abortion and examines how the current circuit split surrounding FDA-protocol legislation fits within the larger framework. Finally, this Article applies the proper version of the undue burden test to FDA-protocol legislation, which resolves the circuit split and provides lower courts with a clear means of analyzing abortion issues moving forward.

In August of 2003, Holly Patterson was a beautiful young girl living in the suburbs of San Francisco.[1] She was an over-achiever who graduated a year early from high school and "enjoyed writing…, loved music, cooking, eating and playing softball and Powder Puff football."[2] Tragically, Holly's life must be described in the past tense because Holly Patterson died on September 17, 2003. She was only eighteen years old.[3]

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[1] Brief of Women and Families Hurt by RU-486 as Amici Curiae Supporting Petitioners, Cline v. Okla. Coalition for Reproductive Justice, 133 S. Ct. 2887 (2013) (No. 12–1094), 2013 WL 1450985, at *1 [hereinafter *Cline Amici Brief*].

[2] *Holly Patterson Dead from Safe & Legal Abortion*, PregnantPause (Oct. 16, 2013), http://www.pregnantpause.org/safe/patterson.htm.

[3] *Cline Amici Brief*, *supra* note 1, at app. 32.

In the weeks leading up to her death, Holly learned she was pregnant and sought a purely elective medicinal abortion at Planned Parenthood.[4] The clinic provided a non-FDA approved dosage of Mifeprex (also known as mifepristone or RU-486) and its companion drug, misoprostol, to terminate her early pregnancy. However, Holly experienced severe health complications. This forced her to twice visit an emergency room, which she only walked out of once.[5] Holly's untimely death was the result of septic shock, due to endomyometritis, a uterus-related blood infection.[6] For Holly, this complication occurred seven days after the termination of her pregnancy was initiated through the use of a non-FDA approved medicinal abortion regimen prescribed to her by Planned Parenthood.[7] As her father, Monty, put it, "medical abortion is promoted as safe and effective," however "[t]he information [Holly] was able to obtain about medical abortion cost her life."[8]

Unfortunately, Holly's story is not as uncommon as one might think. The United States Food and Drug Administration ("FDA") reported in 2011 that 14 women in the United States died from using the mifepristone abortion drug and an additional 2,207 women have been injured by it since the drug's approval in 2000.[9] In response to these events, five states passed laws prohibiting the off-label use of mifepristone in the past decade.[10] The legislation (known as "FDA-protocol legislation") restricts the use of the abortion pill regimen to only what is approved by the FDA in terms of dosage, time of use, and required physician oversight.[11]

The purpose of this Article is to examine those five state regulations within the larger abortion debate, as well as the resulting legal challenges that are currently pending. In this Article, I will argue that the undue burden test, under current United States

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[4] *Id*. at app. 27; Medicinal abortion can also be referred to as a "medical" abortion or "chemical" abortion.

[5] *Id*. at app. 29-30.

[6] Sepsis is a medical condition triggering widespread inflammation as a result of an overwhelming immune response to infection. In the most severe sepsis cases, infection leads to a life-threatening drop in blood pressure, called septic shock. Over one million Americans are affected by severe sepsis each year with up to half of those cases resulting in death. *See Sepsis (Blood Infection) and Septic Shock*, WebMD, http://www.webmd.com/a-to-z-guides/sepsis-septicemia-blood-infection. More information on abortion with septic shock can be found here: http://www.healthline.com/health/abortion-with-septic-shock#Causes2.

[7] *Cline Amici Brief, supra* note 1, at app. 33-34.

[8] Monty L. Patterson, *Just the Facts,* Abortion Pill Risks, http://abortionpillrisks.org/?doing_wp_cron=1413181968.6179850101470947265625.html (last updated Sept. 17, 2012).

[9] *Cline Amici Brief, supra* note 1, at *9.

[10] Ams. United for Life, Abortion-inducing Drugs Safety Act (RU-486 & Response to "Telemed" Abortions) at 12 (2012), http://www.aul.org/wp-content/uploads/2012/11/Abortion-Inducing-Drugs-Safety-Act-2013-LG.pdf. As of November 1, 2014, these states are Arizona, North Dakota, Ohio, Oklahoma, and Texas.

[11] *The Abortion Pill (Also Known as RU-486 or Mifeprex)*, Center For Arizona Policy (Jan., 2014), http://azpolicypages.com/life/the-abortion-pill-also-known-as-ru-486-or-mifeprex/ ("Despite the pill only being approved for use through the first seven weeks of pregnancy, Planned Parenthood prescribes it through nine weeks of pregnancy, does not require a follow-up visit, and uses non-doctors to prescribe the abortion pill[.]").

Supreme Court jurisprudence, provides that abortion regulations are valid unless they place a substantial obstacle on a woman's ability to obtain a safe abortion and the proper standard of review is heightened rational basis.[12] This standard gives states broad latitude to regulate the means of abortion in order to protect patient health and safety, while also advancing their legitimate interest in fetal life.[13]

Part I outlines the abortion debate and explores why this is such a hotly contested issue. Part II analyzes Supreme Court jurisprudence on abortion and the inconsistent standards of review that the Court has applied. Part III explores the specifics of abortion-inducing drugs, while Part IV explains state legislation targeted at regulating those drugs. Part V identifies the inconsistent holdings in challenges to those state regulations, which create a circuit split ripe for Supreme Court review. Finally, Part VI clarifies the present state of the undue burden test and applies the test before concluding with the potential consequences of the judicial response. Here, the restrictions placed on medicinal abortions advance the government's interest in protecting women's health and do not pose a substantial obstacle to a woman's right to an abortion. Surgical abortions remain legally available, even when medicinal abortions are subject to regulatory scrutiny. As a result, the Court must uphold FDA-protocol legislation as constitutional at a level of scrutiny most similar to rational basis.[14]

I. Framing the Abortion Debate

For many, the approach to the abortion issue is derived from one's ideology, definition of a "human-being," and values regarding life at the different stages of a pregnancy.[15] Although Supreme Court justices decide cases based on law, they too are not immune from allowing ideological preferences to interplay with rational thought in guiding their decisions.[16] Therefore, through understanding the mainstream ideological leanings and biases that come into play when examining abortion, one can best examine the issue from a more rational perspective.

For the purposes of this Article, "abortion" refers to the deliberate termination of a human pregnancy; excluding miscarriages and negligent acts that result in termination.

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[12] Planned Parenthood Ariz., Inc. v. Humble, 753 F.3d 905 (9th Cir. 2014), *petition for cert. filed*, 2014 WL 4467076 at 24 (U.S. Sept. 2, 2014) (No. 14-284).

[13] *Id*. at 23-24.

[14] The rational basis test, in its traditional form, is extremely deferential to any proffered governmental interest. As the Supreme Court has noted, a classification "must be upheld against equal protection challenge if there is any reasonably conceivable state of facts that could provide a rational basis for the classification." *See* Jeremy B. Smith, *The Flaws of Rational Basis with Bite: Why the Supreme Court Should Acknowledge Its Application of Heightened Scrutiny to Classifications Based on Sexual Orientation*, 73 Fordham L. Rev. 2769, 2773 (2005) (citing FCC v. Beach Communications, Inc., 508 U.S. 307, 313 (1993)).

[15] Before entering into the abortion debate, it is necessary to frame the discussion and to define commonly used terms. This Article does not attempt to scrutinize every wrinkle in the abortion debate that could impact judicial review, but to provide a general understanding of the main stakeholders and commonly held positions.

[16] Carolyn Shapiro, *The Context of Ideology: Law, Politics, and Empirical Legal Scholarship,* 75 Mo. L. Rev. 79,126 (2010).

Abortion is the use of any means to terminate a diagnosable pregnancy, thus intentionally causing, with reasonable likelihood, the death of the unborn child.[17] Proponents ("pro-choice") of the controversial procedure argue that choosing to have an abortion is a fundamental right of an expectant mother; derived from the rights to privacy and of personal autonomy.[18] On the other hand, opponents ("pro-life") argue that abortion is the immoral killing of an innocent human-being, wherein the State's interest in protecting the life of the pre-born baby outweighs that of the mother's interest in choosing whether to carry the baby to term.[19]

The divide has traditionally centered on the definition of personhood; the crux of *Roe v. Wade*.[20] The more universal understanding that a fetus is undoubtedly alive shifts the debate to the value of a life-in-formation.[21] Pro-choice advocates, thus, also now argue that although a fetus is a living organism, "it" is not yet developed enough to be considered "human."[22] This argument rests on scientific evidence that fetuses cannot feel pain and are entirely dependent on a single, specific individual from which they cannot be physically separated or live without until after at least 20 weeks of gestational development.[23] Pro-life supporters, on the other hand, argue that a life is a life, regardless of neurological development. Therefore, the argument follows that fetuses should be protected under the law to a similar extent to that of all other living human beings.[24] Thus, a significant divide exists over the meaning of "alive," which has created irreconcilable differences within the two main camps in the abortion debate.

Furthermore, the value of a life in the womb relative to the interests of the mother is debated with extreme fervor. As one pro-choice leader put it, "I would put the life of a mother over the life of a fetus every single time—even if I still need to acknowledge my conviction that the fetus is indeed a life. A life worth sacrificing."[25] To counter that perspective, pro-life advocates assert that the rights of the unborn trump an expectant

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[17] Ariz. Rev. Stat. § 36-2151 (2012).

[18] *See* Michael Tooley, *A Defense of Abortion and Infanticide, in* The Problem of Abortion 51, 51-52 (Joel Feinberg ed., 1973); Mary Anne Warren, *On the Moral and Legal Status of Abortion,* 57 Monist 43, 57-59 (1973).

[19] *See* John Finnis, *The Rights and Wrongs of Abortion: A Reply to Judith Thomson*, 2 Phil. & Pub. Aff. 117, 144-45 (1973); Patrick Lee & Robert P. George, *The Wrong of Abortion, in* Contemp. Debates in applied Ethics 13 (Andrew I. Cohen & Christopher Health Wellman eds., 2005).

[20] Roe v. Wade, 410 U.S. 113, 156 (1973).

[21] Mary Elizabeth Williams, *So what if abortion ends life?* Salon (Jan. 23, 2013, 8:43 AM), http://www.salon.com/2013/01/23/so_what_if_abortion_ends_life/.html ("I believe that's what a fetus is: a human life. And that doesn't make me one iota less solidly pro-choice.").

[22] Joyce Arthur, *Personhood: Is a Fetus a Human Being?* Pro-Choice Action Network (Aug. 2001), http://www.prochoiceactionnetwork-canada.org/articles/fetusperson.shtml.

[23] *See generally* Sheila Page, D.O., AOBNMM, *The Neuroanatomy and Physiology of Pain Perception in the Developing Human*, 30 Issues L. & Med. 227 (2015); I. Glenn Cohen, Sadath Sayeed, *Fetal Pain, Abortion, Viability, and the Constitution*, 39 J.L. Med. & Ethics 235 (2011); K.J.S. Anand & P.R. Hickey, *Pain and Its Effects in the Human Neonate and Fetus*, 317 New Eng. J. Med. 1321 (1987).

[24] Kevin Kelly, *The consequences of treating a fetus as a human being*, No Violence Period (June 22, 1986), http://groups.csail.mit.edu/mac/users/rauch/nvp/consistent/whole-earth.html.

[25] Williams, *supra* note 21.

mother's right to have an abortion. Thus, the right to an abortion should "collapse" under the belief that a fetus is indeed a human life and that there is an inherent interest in preserving human life whenever possible.[26] Spurred by this re-framing of a contentious debate is a flood of state legislation restricting abortion, which is now under the microscope of federal courts.[27]

In summary, there is a substantial chasm between pro-choice and pro-life supporters. The split stems from what one considers an existing life—whether a fetus is a human-being or something less. This valuation, in turn, determines the requisite legal protections that are due to fetal life and the latitude that a mother is given to make choices relating to her own privacy and personal autonomy. This necessarily impacts the fate of the life forming inside of her. Therefore, because these distinct and irreconcilable ideological viewpoints are always lurking in the background behind any Supreme Court decision relating to abortion, it is important to understand each of these interests and how they impact the overall discussion.

II. The Murky Waters of Supreme Court Abortion Jurisprudence

The Supreme Court's reasoning in past abortion cases is essential to any discussion regarding the current undue burden test and how it applies to recently enacted abortion restrictions. From at least 1900 until the 1970s, every single state penal code included a section banning abortion except in certain narrowly defined instances.[28] In 1965, the Court recognized marital privacy as a fundamental right, which would later be used to create the right of a woman to have an abortion.[29] The Court attempted to refine abortion rights throughout the 20th century, which produced ambiguity as to the strength and legal sustainability of the right.

*A. Pre-*Roe *Privacy Rights*

A constitutional right to privacy, from which the right to have an abortion arises, was first recognized in *Griswold v. Connecticut*. In *Griswold*, the Court created a constitutional privacy right that protected the right of married couples to use contraception to prevent pregnancy or for therapeutic purposes.[30] In doing so, the Court found that there were a number of guarantees found within the penumbras of the Bill of Rights,

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[26] Rachel Warren, Note, *Pro (Whose?) Choice: How the Growing Recognition of A Fetus' Right to Life Takes the Constitutionality Out of Roe*, 13 Chap. L. Rev. 221, 247 (2009).

[27] Elizabeth Nash et al., *Laws Affecting Reproductive Health and Rights: 2013 State Policy Review,* Guttmacher Institute, http://www.guttmacher.org/statecenter/updates/2013/statetrends42013.html (last visited Nov. 2014) (asserting that more state abortion restrictions were enacted between 2011 and 2013—205 in total—than were adopted during the whole previous decade—189 in total).

[28] Mark A. Graber, *The Ghost of Abortion Past: Pre-Roe Abortion Law in Action*, 1 Va. J. Soc. Pol'y & L. 309, 313 (1994).

[29] Griswold v. Connecticut, 381 U.S. 479, 479 (1965) (holding that the substantive due process right of privacy includes at least privacy of marriage relations in the marital bedroom).

[30] *Id*. at 480.

thus creating zones of privacy.[31] The Court then extended that zone of privacy in 1972 to protect unmarried individuals' right to use contraception in *Eisenstadt v. Baird*.[32] There, the Court redefined the right of privacy recognized in *Griswold* to necessarily apply to unmarried individuals: "If the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."[33] Consequently, *Griswold* and *Eisenstadt* introduced the idea that the Court could extend a newly recognized zone of privacy to protect an individual's procreative decision, which could include the decision to terminate a pregnancy.[34]

B. The Fundamentals of Roe v. Wade

In 1970, a woman appealed to the Supreme Court when she was denied the right to have an abortion in her home state of Texas.[35] Her case, *Roe v. Wade,* is touted as the landmark case wherein the Court expanded the right of women to have an abortion.[36] In *Roe*, the Court held that women's access to abortion procedures involve an unenumerated, fundamental right to privacy under the 14th Amendment's Due Process Clause.[37] A "fundamental" right ordinarily requires that any regulation limiting that right must be justified by a compelling state interest and narrowly tailored as the least restrictive alternative to express only the actual, legitimate state interest at stake.[38] *Roe* indicated that strict scrutiny would apply to abortion restrictions going forward; a high bar for any restriction on abortion to be upheld as constitutional.[39] However, the Court later narrowed its holding in *Roe* and applied a lower level of scrutiny to abortion regulations, thus confusing the standard of review in abortion cases.[40]

C. The Companion of Roe*:* Doe v. Bolton

This muddling of the standard of review in abortion cases began in *Roe*'s companion case, *Doe v. Bolton*. There, the Court indicated that any restrictions on access to abortions must include a health exception, whereby the restriction would be lifted if necessary to preserve the health of the mother.[41] In providing guidance on when the exception may apply, the Court explained that a doctor's medial judgment as to the health of the mother may be "exercised in the light of all factors—physical, emotional, psychological, familial,

[31] Jennifer L. George, *The United States Supreme Court Failed to Follow over Thirty Years of Precedent by Replacing Individualized Medical Judgment with Congressional Findings*, 41 Creighton L. Rev. 219, 224-25 (2008) (citing Griswold v. Connecticut, 381 U.S. 479, 484 (1965)).

[32] Eisenstadt v. Baird, 405 U.S. 438, 483 (1972).

[33] *Id*. at 453.

[34] Emily Blistein, Esq., *Revisiting* Roe*: The Language of Privacy and Isolation in U.S. and Vermont Case Law*, 34 SPG Vt. B.J. 42, 42 (2008).

[35] *Roe*, 410 U.S. at 113.

[36] *Id*. at 170.

[37] *Id*.

[38] *Id*. at 155. (citing *Griswold*, 381 U.S. at 485).

[39] *Id*. at 170.

[40] Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 839 (1992).

[41] Doe v. Bolton, 410 U.S. 179, 191-92 (1973).

and the woman's age—relevant to the wellbeing of the patient."[42] Therefore, through the inclusion of "emotional" and "psychological" well-being as legitimate factors, the health exception established in *Doe* may be interpreted in a sweepingly broad manner.[43] As such, the exception could seemingly be used to justify an abortion as "necessary in order to preserve the life or health of the mother" in nearly *any* unwanted pregnancy.[44] This seemed to foreshadow the Court's desire to create a nearly unfettered right to abortion.[45] However, the Court did not maintain this position for long.

D. Changing the Standard in Casey

Nearly two decades after *Doe*, the Supreme Court narrowed its broader holdings in *Roe* and *Doe* in *Planned Parenthood of Southeastern Pennsylvania v. Casey*. There, the Court also established the modern framework for evaluating abortion restrictions. In *Casey*, the Court affirmed the core of *Roe*, but reclassified the abortion right from a fundamental right to only a "protected liberty interest."[46] This decision signaled a dramatic shift in the standard of review for abortion regulations—if abortion was no longer a fundamental right, then courts need not apply strict scrutiny when reviewing intrusions upon it.[47] As a result, legislation that might be struck down under strict scrutiny could be upheld, so long as the legislation maintains a valid purpose and has only an incidental, not purposeful, effect on a woman's decision to procure an abortion.[48] As the Court explained in its joint opinion:

> Numerous forms of state regulation might have the incidental effect of increasing the cost or decreasing the availability of medical care, whether for abortion or any other medical procedure. The fact that a law which serves a *valid purpose*, one not designed to strike at the right itself, has the *incidental effect* of making it more difficult or more expensive to procure an abortion *cannot be enough to invalidate it.* Only where state regulation imposes an *undue burden* on a woman's ability to make this decision does the power of the State reach into the heart of the *liberty protected* by the Due Process Clause.[49]

Thus, *Casey* did not overturn *Roe*—as pro-lifers hoped it would—but it did soften the Court's stance against regulation by indicating that a state could discourage abortion with a valid purpose.[50] Many wondered if *Casey* would allow for new constitutional

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[42] *Id*. at 192.

[43] *Judicial Activism*: Doe v. Bolton, The Heritage Foundation, http://www.heritage.org/initiatives/rule-of-law/judicial-activism/cases/doe-v-bolton.html (last visited Oct. 12, 2014).

[44] *Id*.

[45] *Id*.

[46] *Casey*, 505 U.S. at 859 (while also implementing pre and post-viability distinctions).

[47] *Id*. at 874.

[48] Gonzales v. Carhart, 550 U.S. 124, 157-58, (2007) (citing *Casey*, 505 U.S. at 871).

[49] *Casey*, 505 U.S. at 874 (emphasis added).

[50] Mark H. Woltz, *A Bold Reaffirmation?* Planned Parenthood v. Casey *Opens the Door for States to Enact New Laws to Discourage Abortion*, 71 N.C. L. Rev. 1787, 1788 (1993).

abortion regulations, but the Court took several years before revisiting *Casey*'s newly introduced "Undue Burden Test."[51]

E. The Importance of Women's Health in Stenberg v. Carhart

Surprisingly, in the next seminal abortion case, *Stenberg v. Carhart*, the Court strengthened *Casey*; further confusing the standard of review.[52] In *Stenberg*, the Court invalidated Nebraska's criminal ban on intact dilation and evacuation ("D&E") abortions and declared that the Court would not "revisit those legal principles" determined by *Roe* and reaffirmed in *Casey*.[53] The rationale for striking down the law was due to its vagueness and absence of a health exception,[54] harkening back to the focal point of *Doe*.[55] With the Court now indicating that an explicit statutory health exception was a per se requirement of abortion regulations, dissenters claimed that the Court opened an "ever-expanding loophole" in abortion jurisprudence; giving the doctor unconstrained discretion to perform any procedure deemed necessary for any imaginable patient health reason.[56]

Also, in *Stenberg* the Court designated women's health as the main interest that a state regulation cannot infringe upon—substantially constraining the power of the state.[57] The Court further applied a standard of review that appeared to be similar to strict scrutiny, as in *Roe*, with any substantial burden being grounds for invalidation.[58] Had *Stenberg* been the last time the Court spoke on abortion, it would appear that the status of a woman's right to an abortion as a fundamental right would have been re-conferred and that regulations, such as FDA-protocol legislation, would be struck down by the Court. But once again, the Court would soon revisit the abortion issue and change course on the standard of review for abortion restrictions.

F. Court Reverses Course in Gonzales v. Carhart

Following a change in membership on the Court, and with Justice Kennedy now joining the majority, the Court reversed course on abortion once again.[59] The last time the Court examined a major abortion restriction, in *Gonzales v. Carhart*, the Court upheld the Partial Birth Abortion Ban Act of 2003 in the face of familiar challenges for vague-

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[51] *Id*. at 1788.

[52] Linda J. Wharton et. al., *Preserving the Core of* Roe*: Reflections on* Planned Parenthood v. Casey, 18 Yale J.L. & Feminism 317, 346 (2006).

[53] Stenberg v. Carhart, 530 U.S. 914, 921 (2000).

[54] In *Doe*, the Court seemed to mandate that all statutory abortion restrictions include a health exception to allow a mother to have the contemplated abortion if medically necessary for her health. Barbara Jean Bailey, *Congress Ignores the Parameters of the Health Exception Judicial Responses to Congressional Evidence and Partial-Birth Abortion in the Wake of* Stenberg v. Carhart, 27 J. Legal Med. 71, 73 (2006) (citing *Doe*, 410 U.S. at 192).

[55] *Stenberg*, 530 U.S. at 916.

[56] Wharton *supra* note 52, at 347.

[57] *Id*. at 348.

[58] *Id*. at 347.

[59] Katia Desrouleaux, *Banning Partial-Birth Abortion at all Costs—Gonzales v. Carhart: Three Decades of Supreme Court Precedent "Down the Drain,"* 35 S.U. L. Rev. 543, 561 (2008).

ness and the absence of a health exception.[60] The Court reasoned that the Act would be unconstitutional "if its purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability," but that was not the case.[61] The *Gonzales* result came about, in part, due to the fact that women seeking the type of abortion prohibited by the 2003 Act—although a popular method—had alternative abortion procedures available.[62] Thus, in upholding the law, the Court quashed the idea that a health exception is a requirement for facially constitutional abortion regulations.[63]

Instead, the Court explained that, while women's health is still a primary concern, the State is not required to account for every possible scenario wherein a certain type of abortion could be in the best interest of a woman's health when deciding whether a law restricting a certain type of abortion would be upheld.[64] Therefore, *Gonzales* demonstrated that when alternative, safe abortion methods remain available to women, restricting access to another method of abortion does not necessarily create a substantial obstacle.[65] Abortion restrictions can, indeed, co-exist with the right to an abortion as recognized by the Court.[66]

Additionally, the Court in *Gonzales* made it a point to explain that the State may use its regulatory authority to show its profound respect for the life of the unborn.[67] The Court even went so far as to say that the government's "legitimate, substantial interest in preserving and promoting fetal life" was a central premise of *Casey*, which could not be repudiated.[68] As such, regulations which only create a structural mechanism by which the State may express profound respect for the life of the unborn are permitted, so long as they are not a substantial obstacle to a woman's right to choose.[69] The joint authors[70] in *Casey* defined a "substantial obstacle" as one that *prohibits a woman from making the ultimate decision* to terminate her pregnancy before viability.[71] Therefore, so long as the decision as to whether a woman wants to terminate a pre-viability pregnancy is not usurped, and a woman still has access to a legitimate abortion method, the State has not imposed a substantial obstacle on the right to an abortion.[72] And thus, the undue burden test proffered by the Court in *Casey* was encapsulated in abortion jurisprudence.[73]

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[60] *Gonzales*, 550 U.S. at 168.

[61] *Id*. at 156 (quoting *Casey*, 505 U.S. at 878).

[62] Transcript of Argument, Gonzales v. Carhart, No 05-380 (Nov 6, 2006), 20.

[63] *Gonzales*, 550 U.S. at 167.

[64] *Id*. at 167.

[65] *Id*. at 129.

[66] *See generally* Id.

[67] *Id*. at 157.

[68] *Id*. at 126-27.

[69] *Id*. at 126.

[70] The joint authors in *Casey* were Justice O'Conner, Justice Kennedy, and Justice Souter. *Casey*, 505 U.S. at 833.

[71] *Casey*, 505 U.S. at 879.

[72] C. Elaine Howard, *The Roe'd to Confusion: Planned Parenthood v. Casey*, 30 Hous. L. Rev. 1457, 1466 (1993).

[73] Desrouleaux *supra* note 59, at 571.

The holding in *Gonzales,* paired with the significant deference the Court gave to the states, fueled a steady stream of abortion regulations in order to limit the abortion right created in *Roe*.[74] *Roe* need not be overturned in order to uphold abortion-pill protocol legislation.[75] A court's holding must be consistent with *Gonzales* and utilize that standard of review most similar to rational basis. Under *Gonzales*, the states are given much more latitude to constitutionally regulate the right to an abortion.

G. Looking Ahead from Gonzales

In sum, the Court applied the undue burden test from *Casey* in upholding state laws that prohibited a specific method of abortion, but left safe, alternative methods available.[76] As such, the regulation was not held, on a facial challenge, to create an undue burden, and was therefore constitutional.[77] Thus, the Court provided an alternative for states attempting to regulate abortions by allowing states to respect the life of the unborn fetus if the regulation does not impose a substantial obstacle on most women's right to choose.[78] Since *Gonzales*, state and federal circuit courts have been inconsistently applying the undue burden test—with some using a rational-basis standard of review, while others use a more heightened scrutiny, and some examining both the purpose and effect of the legislation, while others only inquire into the effect.[79] This distinction is critical because the standard of review used by a court can easily determine the outcome of a case.[80] Nevertheless, it is clear that abortion, as a hot-button issue, has come roaring back to life in the wake of *Gonzales*.[81]

Consequently, the next major abortion-related issue could center on states' regulation of abortion-inducing drugs and how the *Casey-Gonzales* undue burden test should be applied. Given that multiple state laws regulating the use of abortion-inducing drugs have already been examined by circuit courts with differing results, this issue is ripe for

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[74] *Id*. at 571-72.

[75] *See infra* Section IV.

[76] *Gonzales*, 550 U.S. at 126.

[77] *Id*. at 126.

[78] *Id*. at 126.

[79] *Compare* Planned Parenthood of Wis., Inc. v. Van Hollen, 738 F.3d 786, 799 (7th Cir. 2013) (striking down a statute under heightened rationality review without reaching, but acknowledging, the purpose and effects tests), *with* Richmond Med. Ctr. for Women v. Herring, 570 F.3d 165, 179 (4th Cir. 2009) (upholding a statute criminalizing partial birth infanticide by applying a rational basis standard of review and only analyzing the effect, not the purpose of the statute in question). This split will be discussed at length in Part VI.

[80] *See* Eric Heinze, *The Logic of Standards of Review in Constitutional Cases: A Deontic Analysis*, 28 Vt. L. Rev. 121, 147 (2003). When strict scrutiny is triggered as the standard of review in cases involving a fundamental right, the government restriction will typically be struck down. However, rational basis review is very deferential and the government will almost always win. Even rational basis with bite–an intermediate standard–shows some deference to the government and provides that legislation will survive a challenge, as long as it serves a valid purpose and only incidentally infringes upon a protected liberty interest (e.g., abortion).

[81] Michael Valpy, *The abortion issue comes back to life*, The Globe and Mail (Mar. 26, 2010), http://www.theglobeandmail.com/globe-debate/the-abortion-issue-comes-back-to-life/article565366/.

consideration by the Court.[82] The Supreme Court is likely to apply the undue burden test in a way that comports with its most recent holding in *Gonzales*. The reasoning in *Gonzales* is critical to arguments supporting FDA-protocol legislation because the idea of restricting access to a certain type of abortion, while alternative methods remain, is the precise effect of protocol legislation. Upon recognizing the state's interest in the health of the mother and promoting fetal life, compared to the slight obstacle posed by restricting only one abortion method, the Court should rule in favor of the constitutionality of abortion-pill restrictions as consistent with both *Casey* and *Gonzales*.

III. The Problem with non-FDA Approved Abortion-Inducing Drug Regimens

In September of 2000, the FDA approved mifepristone, which is used alongside misoprostol, to terminate a pregnancy within 49 days of the start of a woman's last menstrual period.[83] The approved Mifeprex regimen for a medicinal abortion through 49 day's pregnancy involves the administration of 600 mg of Mifeprex on day one, 400 mcg misoprostol tablets on day three, and a post-treatment doctor's visit on day 14 to confirm the termination of the pregnancy.[84] However, Planned Parenthood and the Center for Reproductive Rights have argued that "the medical community has found that it is safe to use the two drugs in different quantities than recommended by the FDA and up to nine weeks in pregnancy."[85]

When Planned Parenthood is conducting a medicinal abortion, the organization dispenses Mifeprex in one-third the normal dose (200 mg), but then doubles the dose of the second drug, misoprostol, to 800 mcg.[86] The effect of the medicinal abortion on the user's body is described by Planned Parenthood as follows:

> The second medicine—misoprostol—will cause you to have cramps and bleed heavily. . . . It usually lasts a few hours. You may see large blood clots or tissue at the time of the abortion. More than half of women abort within four or five hours after taking the second medicine. For others, it takes longer. But most women abort within a few days.[87]

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[82] *Compare* Planned Parenthood Sw. Ohio Region v. DeWine, 696 F.3d 490 (6th Cir. 2012) (upholding legislation that banned abortion-inducing drugs for the time and dosage not outside of FDA-labeling guidelines), *with* Planned Parenthood Ariz., Inc. v. Humble, 753 F.3d 905 (9th Cir. 2014) (striking down a strikingly similar regulation on the use of abortion-inducing drugs).

[83] FDA, *Mifepristone U.S. Post-marketing Adverse Events Summary Through 04/30/2011* (July, 2011), *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf.

[84] *Id*.

[85] Dave Andrusko, *9th Circuit overturns Arizona RU-486 law, state vows to keep fighting* (Dec. 4, 2012), http://www.nationalrighttolifenews.org/news/2014/06/9th-circuit-overturns-arizona-ru-486-law-state-vows-to-keep-fighting/#.U9Xik3x0zIV.

[86] Joanne Moudy, *9th Circuit Court Trashes Arizona Law: Puts Women at Risk*, TOWNHALL MAGAZINE (June 5, 2014), http://townhall.com/columnists/joannemoudy/2014/06/05/9th-circuit-court-trashes-arizona-law-puts-women-at-risk-n1848137/page/full.

[87] *The Abortion Pill*, PLANNED PARENTHOOD (2014), http://www.plannedparenthood.org/health-info/abortion/the-abortion-pill.

Planned Parenthood uses this procedure, where allowed by law, through the first 63 days of pregnancy and claims it to be effective "97 out of every 100 times."[88]

Unfortunately, this expanded use of the abortion pill comes with great cost. Since approving the Mifeprex regimen in September of 2000, the FDA "has received reports of serious adverse events, including several deaths, in the United States following medicinal abortion with mifepristone and misoprostol."[89] According to a 2011 FDA report, there were 2,207 adverse events (complications) in the United States related to the use of mifepristone.[90] These adverse events included 14 deaths, 612 hospitalizations, 339 blood transfusions, and 256 infections (including 48 "severe infections") endangering women.[91] The primary cause of death for those suffering complications from the use of the drug combination is sepsis, which is caused by an infection of the bloodstream, and typically causes death approximately one week after the initiation of the medicinal abortion.[92]

The international community has also begun to take note of the dangers of off-label use: an Australian study reported that medicinal abortion complications are "much more frequent" than those due to surgical abortion, based upon a study involving 7,000 medicinal abortions.[93] The Italian government made a statement reiterating that patients should follow the approved guidelines for medicinal abortions to "better [ ] safeguard women's health."[94] Thus, a variety of different governmental entities are realizing the legitimate threat to women's health that off-label use of abortion-inducing medication may cause, signaling a need to further regulate the use of these dangerous drugs.

In spite of the harm to users of abortion-inducing drugs, the manufacturer of mifepristone insists that the drug, which has been used for medicinal abortions by over two million women in the United States, is "safe and effective" because there are bound to be some complications when any drug is used at such a high frequency.[95] This assertion is offered along with the admission that "5-8% of women [who use mifepristone] will need a surgical procedure to end the pregnancy or stop heavy bleeding."[96] Given the 98-99% surgical abortion 'success' rate, medicinal abortions are comparatively several times more risky than surgical abortions.[97] Although it is not certain that the timing and dosage of the medicinal abortion cocktail were the direct cause of injury, women have

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[88] *Id.*

[89] FDA, *supra* note 83.

[90] *Id.*

[91] *Id.*.

[92] *Id.*

[93] Steven Ertelt, *Abortion Drug Kills Girl in Portugal, Caused Deadly Infection*, LifeNews (May 16, 2011, 10:56 AM), http://www.lifenews.com/2011/05/16/abortion-drug-kills-girl-in-portugal-caused-deadly-infection/.

[94] *Id.*

[95] Renate Klein et al., *RU-486: Misconceptions, Myths, and Morals ix*, 31 (2nd ed. 2013); *see also More Facts About Mifeprex*, Danco Laboratories. http://earlyoptionpill.com/is-mifeprex-right-for-me/more-facts-about-mifeprex/.

[96] *More Facts About Mifeprex*, *supra* note 95; *see also* Klein, *supra* note 95, at xviii, xxxvii.

[97] Klein, *supra* note 95, at 111.

spoken up to encourage states to take action to restrict what they see as a dangerous medical practice.[98]

Many lives have been affected by the use of an unapproved medicinal abortion regimen.[99] For example, in 2003, Abby Johnson, at the time a 23-year-old Planned Parenthood volunteer, elected to undergo a medicinal abortion, using the off-label regimen.[100] Shortly after ingesting her prescribed medication, Abby experienced severe hemorrhaging. She contacted Planned Parenthood regarding why she was losing so much blood:

> [T]he Planned Parenthood nurse [] told Abby, that it "'is not abnormal.' I was shocked. She could not be serious. All of the bleeding, the clotting, the pain . . . that was NORMAL! 'Yes,' she said . . . I was angry. How could they not tell me the side effects? I felt so betrayed."[101]

Abby, was fortunate enough to survive this horrific experience after enduring eight weeks of blood clots, excruciating cramps, nausea, and heavy bleeding.[102] Upon returning to her post at Planned Parenthood, she shared her traumatic experience with patients, but, in her own words, "Planned Parenthood did not want [her] influencing women considering the RU-486 regimen."[103] Abby has since left Planned Parenthood and now spends her time sharing her experience with women, so that they can make fully informed decisions and be aware of the dangers caused by off-label use of a medicinal abortion regimen.[104]

Abby Johnson and Holly Patterson are not alone. There are other stories—like that of Manon Jones, an 18-year-old who died in London after taking the off-label regimen—or of a 16-year-old Portuguese girl who died from taking the same regimen from the same type of sepsis infection.[105] And, there are many others, both domestic and abroad, who have experienced the same deadly side effects from the off-label use of abortion-inducing medication.

In addition, the unapproved use of the Mifeprex regimen has also been tied to eight deaths arising from a severe bacterial infection.[106] No women have died from severe bacterial infection after using RU-486 in the way approved by the FDA.[107] Thus, state legislatures and the judicial system may feel compelled to protect women's health by restricting the use of the medicinal abortion regimen to only the FDA approved dosage.

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[98] *See Cline Amici Brief*, *supra* note 1, at *1.

[99] Ertelt, *supra* note 93.

[100] *Cline Amici Brief*, *supra* note 1, at app. 9-10.

[101] *Id*. at *27.

[102] *Id*. at app. 13.

[103] *Id*. at *25.

[104] *Id*.

[105] Monty L. Patterson, *Manon Jones' Story*, ABORTION PILL RISKS, http://abortionpillrisks.org/?doing_wp_cron=1413181968.6179850101470947265625.html (last updated Dec. 4, 2011); Ertelt, *supra* note 93.

[106] Jill Stanek, *The abortion industry's looming RU-486 legal crisis*, LIFESITENEWS, https://www.lifesitenews.com/pulse/the-abortion-industrys-looming-ru-486-legal-crisis (last updated Oct. 7, 2014).

[107] *Id*.

In this way, a state may be able to end the harm that the unapproved administration of abortion-inducing medication may cause to women, who are often already in a very vulnerable position. So far, five states have passed these types of restrictions on the use of abortion-inducing drugs in light of the safety concerns posed by off-label usage of Mifeprex.[108]

IV. State Legislatures Respond with Regulations

In passing comprehensive regulations of abortion-inducing drugs that limit their administration to the protocol approved by the FDA, five states—Arizona, North Dakota, Ohio, Oklahoma, and Texas—have responded to Planned Parenthood's expanded use of the abortion pill.[109] Each of those pieces of legislation has been challenged, resulting in the emergence of a circuit split within the federal courts.[110] While the legislation at issue has been upheld by the Sixth (Ohio) and Fifth Circuits (Texas), state courts in North Dakota and Oklahoma, as well as the Ninth Circuit (Arizona), have called it into question, illustrating the level of confusion in the court system.

A. Ohio

Ohio was the first state to pass FDA-protocol legislation in 2004.[111] The law, modeled after the Americans United for Life model legislation, provides that FDA (or other United States federal) regulations govern and limit the use of mifepristone for the purpose of inducing abortions.[112] The legislation was immediately challenged by Planned Parenthood, with the controversy eventually being decided by the U.S. Court of Appeals for the Sixth Circuit in 2012.[113] In that case, the law survived Planned Parenthood's claims that it was unconstitutionally vague, violated patients' right to bodily integrity, and posed an undue burden on women seeking an abortion within the state of Ohio.[114] This was because the Sixth Circuit concluded that a ban on a specific method of abortion would not impose an undue burden on "a woman's ability to make the decision to have an abortion;" in line with both *Casey* and *Gonzales*.[115] Here, the Sixth Circuit explicitly held that limiting the use of mifepristone to FDA regulations was consistent with the *Casey-Gonzales* standard.

B. North Dakota

In North Dakota, abortion-pill regulations are also modeled after the Americans United for Life model legislation. However, North Dakota's regulations are currently

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[108] Ams. United for Life, Abortion-inducing Drugs Safety Act (RU-486 & Response to "Telemed" Abortions) at 12 (2012), http://www.aul.org/wp-content/uploads/2012/11/Abortion-Inducing-Drugs-Safety-Act-2013-LG.pdf.

[109] *Id.* at 12.

[110] *Id.*

[111] Ohio Rev. Code Ann. § 2919.123 (West 2004).

[112] *Id.*

[113] *See DeWine*, 696 F.3d at 490.

[114] *Id.* at 494.

[115] *Id.*

enjoined by court order and are not in effect while the litigation is ongoing.[116] Judge Corwin of the North Dakota County of Cass District Court enjoined North Dakota's law using a standard of strict scrutiny, based upon his understanding that abortion is still considered by the Supreme Court to be a fundamental right.[117] Judge Corwin directly disputed the findings of the Sixth Circuit in holding that the North Dakota statute was not the most narrow alternative in satisfying the compelling state interest of citizen's health due to the low percentage rate of risk.[118] This holding does not comport with that from the Sixth Circuit due to the use of an inappropriate standard of review.

C. Texas

On the other hand, the Fifth Circuit supported Texas' regulations on medicinal abortions, concluding that the regulations do not facially require a court-imposed exception for the life and health of a woman.[119] The language of the Texas legislation is only slightly distinguishable from that of other states, because it allows abortion providers to use the dosages approved by FDA protocol or advocated for by the American College of Obstetricians and Gynecologists—however, the drugs must be administered according to FDA protocol, thus having the same effect.[120] The Fifth Circuit noted that Texas' regulations did not facially require a full, court-imposed health exception in light of *Gonzales*, nor did the regulations facially impose an undue burden on the life and health of the mother.[121] Although the result is the same as in the Sixth Circuit, the reasoning is slightly different. The Fifth Circuit came to its conclusion based on the reasoning that there is no longer a requirement for a health exception on the face of an abortion regulation that prohibits a particular method of abortion, whereas the Sixth Circuit focused its holding on the availability of alternative methods. The Fifth Circuit also specified that its holding did not detract from *Casey*, implying that it does not consider abortion to be a fundamental right deserving of strict scrutiny.[122] This level of scrutiny used is consistent with Supreme Court jurisprudence under *Gonzales*, but conflicts with North Dakota's adverse finding on similar legislation.[123]

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[116] MKB Mgmt. Corp. v. Burdick, No. 09-2011-CV-02205 (Cass Cnty. Ct. N.D. 2012), available at http:// reproductiverights.org/sites/crr.civicactions.net/files/documents/MKB%20v%C20Burdick%C200rder%C2021612%(2).pdf.; N.D. Cent. Code Ann. § 14-02.1-03.5 (West 2011); Lindsay D. Houser, *Hindering Webcam Outreach on the Women's Healthcare Frontier: Why Abortion-Specific Restrictions on Telemedicine Are Unconstitutional*, 42 Stetson L. Rev. 169, 205 (2012).

[117] *MKB Mgmt. Corp.*, No. 09-2011-CV-02205, at 60; *see also* Laurah J. Samuels, *Mifepristone Protocol Legislation-the Anti-Choice Movement's Disingenuous Method of Attack on the Reproductive Rights of Women and How Courts Should Respond*, 26 Colum. J. Gender & L. 316, 333 (2014).

[118] *MKB Mgmt. Corp.*, No. 09-2011-CV-02205, at 60; Samuels, *supra* note 117, at 333.

[119] Planned Parenthood of Tex. v. Abbott, 748 F.3d 583, 604 (5th Cir. 2014).

[120] Tex. Health & Safety Code Ann. § 171.063 (West); Samuels, *supra* note 117, at 330.

[121] *Abbott*, 748 F.3d at 603.

[122] *Id*. at 603.

[123] *Compare Abbott*, 748 F.3d at 603, *with* MKB Mgmt. Corp., No. 09-2011-CV-02205, at 60.

D. Oklahoma

In a case which never reached federal courts—a challenge to Oklahoma's medicinal abortion regulations—the initial legislative restrictions were ruled facially unconstitutional by the Oklahoma Supreme Court based upon an interpretation that the act attempted to ban the use of misoprostol in its entirety.[124] Thus, the court held that the possibility of an effective ban of all medicinal abortions failed the undue burden test under *Casey*.[125] After the Oklahoma Supreme Court's findings, the State of Oklahoma appealed to the United States Supreme Court to revive the law. Initially, the Court granted certiorari in the case;[126] however, the Court later removed the case from its docket in a one-sentence order declaring the petition of certiorari as "improvidently granted."[127] As a result, the Court put off the abortion-pill issue for at least one more term.[128]

E. Arizona

With Oklahoma no longer in a position to bring their case to the Supreme Court, it became unclear which state's regulations would next be challenged in order to confront the issue. However, when the Ninth Circuit struck down Arizona's medicinal abortion legislation, many anticipated that the Supreme Court would hear the case originating in Arizona and finally resolve the differing approaches in applying the undue burden test to abortion-pill regulations.[129]

The Ninth Circuit ruled on Arizona's abortion-pill restrictions in June of 2014.[130] Although the Arizona law was not substantially different from other versions of the model legislation authored by the Americans United for Life, the Ninth Circuit found that the law imposed an undue burden on women seeking an abortion.[131] This holding is in direct contradiction with the Fifth and Sixth Circuit's earlier findings that strikingly similar Ohio and Texas laws (respectively) are facially constitutional based upon the state's interest in protecting women's health and wide availability of alternatives to off-label medicinal abortions.[132] Upon examination of each of these cases, each state statute required that abortion-inducing drugs be prescribed or administered in compliance with

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[124] Okla. Coalition for Reproductive Justice v. Cline, 292 P.3d 27, 27 (Okla. 2012).

[125] *Id.* at 27.

[126] Casey Mattox, *Cline symposium: Another correction of the abortion distortion coming?*, SCOTUSBlog (Oct. 1, 2013), http://www.scotusblog.com/2013/10/cline-symposium-another-correction-of-the-abortion-distortion-coming/html.

[127] Lyle Denniston, *Court won't rule on RU-486 abortions*, SCOTUSblog (Nov. 4, 2013), http://www.scotusblog.com/2013/11/court-wont-rule-on-ru-486-abortion/.

[128] *Id.* Oklahoma since amended its law and approved the legislation, with an effective date of November 1, 2014. As amended, the law includes a stated purpose to limit the use of misoprostol to FDA guidelines, but not to ban the drug entirely, which was the main reason it was initially declared unconstitutional. 2014 Okla. Sess. Laws Ch. 121 (H.B. 2684).

[129] *Humble*, 753 F.3d at 907.

[130] *Id.* at 907.

[131] *Id.*

[132] *Compare Humble*, 753 F.3d at 907 (9th Cir. 2014), *with DeWine*, 696 F.3d at 490 (6th Cir. 2012).

federal law, as outlined by the FDA.[133] Therefore, the difference in the outcomes of these cases was not due to any discrepancies between the two state's laws, but rather due to an inconsistent application of the *Casey-Gonzales* undue burden test. This inconsistent application created the current circuit split.

F. The Need for Clarification

Courts are inconsistently applying the undue burden test by using varying standards of judicial scrutiny, which results in differing outcomes. The Fifth and Sixth Circuits correctly decided the issue under the *Casey-Gonzales* undue burden test, which allows for regulation when it does not place a substantial obstacle in the way of a women's ultimate decision to get an abortion.[134]

However, in North Dakota, the court incorrectly applied strict scrutiny to enjoin FDA-protocol legislation.[135] The Court has long since abandoned strict scrutiny as the standard of review in abortion cases, so as long as legislation is advancing a legitimate government interest and does not serve as a complete bar to access to abortions—either in purpose or effect—the Court should uphold the legislation.[136] Even if some form of heightened scrutiny is merited, abortion no longer receives strict scrutiny after *Casey*.[137] It is instead considered a protected liberty interest, which may fall short of a fundamental right, but is still subject to significant state limitations.[138] Furthermore, the Ninth Circuit decision striking down Arizona's protocol legislation inconsistently applied their interpretation of the *Casey-Gonzales* undue burden test, which desperately requires the Supreme Court to provide a remedy on appeal.[139] However, the Supreme Court once again skirted the issue by denying certiorari in December of 2014.[140]

V. At an Impasse and Ripe for Supreme Court Review

Abortion jurisprudence is now at a stand-still. However, the abortion-pill predicament adds a new twist to the abortion debate.[141] In an effort to boost its case, the Arizona legislature specifically adopted and enumerated several women's-health interests as rea-

[133] *Compare* Ariz. Rev. Stat. § 36-449.03(E)(6) (2012) *with* Ohio Rev. Code Ann. § 2919.123 (West). However, the Arizona statute is slightly broader because it applies to any abortion-inducing medication, which could include drugs beyond the currently used mifepristone, whereas mifepristone is singled out by the Ohio law.

[134] *Abbott*, 748 F.3d at 593-95; *DeWine*, 696 F.3d at 513-18.

[135] *MKB Mgmt. Corp.*, No. 09-2011-CV-02205, at 60.

[136] The strict scrutiny standard of review is applied when legislation will infringe upon a fundamental right; such legislation will be upheld only if the law furthers a "compelling governmental interest" and is necessary or "narrowly tailored" to achieve that interest. *See* Richard H. Fallon, Jr., *Strict Judicial Scrutiny*, 54 UCLA L. Rev. 1267, 1268-69 (2007) (citing Johnson v. California, 543 U.S. 499, 505 (2005)).

[137] *Casey*, 505 U.S. at 859.

[138] *Id.*

[139] *See* Mailee Smith, *Why the Supreme Court Could Soon Review Regulations on Chemical Abortion*, Nat'l Review Online (June 9, 2014), http://www.nationalreview.com/corner/379901/why-supreme-court-could-soon-review-regulations-chemical-abortion-mailee-smith.

[140] *Humble*, 753 F.3d at 905 (9th Cir. 2014), *cert. denied*, 135 S.Ct. 870 (2014).

[141] *See Patterson*, *supra* note 2.

sons to regulate these drugs.[142] In focusing on women's health as one of the underlying purposes of the regulations, instead of only relying on the State's interest in protecting the unborn, Arizona and similarly situated states are attempting to shift the dynamics in abortion litigation and improve their chances of litigation success.[143] Typically, protecting fetal life has been the government's primary motivation for abortion restrictions.[144] Even in states where fetal life is not protected by law, *Gonzales* dictates that "the State has legitimate interests from the outset of the pregnancy in protecting the health of the woman."[145] When the health of the mother interest is sincere, abortion *regulations*—if not effective bans—that promote the legitimate state interest in women's health should satisfy *Gonzales*.[146] Still, the State is faced with serious opposition from those who argue that the restrictions are outdated, restrictive, and simply mask an unstated purpose to discourage women from having an abortion.[147]

Opponents of the Arizona law also question the necessity of the regulations on the grounds that scientific advancements make the dangers posed by the use outside of FDA protocol moot. For example, opponents argue that it is only "marginally possible" that vaginal use of misoprostol contributed to deaths following medicinal abortions and that providers now found a way to avoid this risk by giving women misoprostol buccally (by mouth) instead of vaginally.[148] Furthermore, opponents argue that the legislation does not protect the unborn fetus because it does not necessarily prevent an abortion from occurring.[149] Surgical abortions are still readily available to women past 49 days of gestation (the end of the FDA approved timeframe). Therefore, protocol legislation does not stop abortions; it just makes them "less convenient."[150]

Proponents of the law respond that that there is mounting evidence that the heightened risk to women remains after 49 days of gestation, even when the drugs are taken through different methods.[151] Personhood arguments also may come into play as proponents of the law defend the protocol legislation. However, the persuasiveness of each factor for the Court will likely be determined by its application of the undue burden test.

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[142] Smith, *supra* note 139.

[143] Erica A. Phillips, *Arizona's Limits on 'Abortion Pills' Struck Down by Court*, Wall St. J. (June 3, 2014), http://online.wsj.com/articles/arizona-limits-on-so-called-abortion-pills-overturned-1401827960.

[144] *See* Khiara M. Bridges, *"Life" in the Balance: Judicial Review of Abortion Regulations*, 46 U.C. Davis L. Rev. 1285, 1335-36 (2013).

[145] *Gonzales*, 550 U.S. at 145 (citing *Casey*, 505 U.S. at 846).

[146] Morgan Arnett, *Update: Phasing Out Abortion: One Step Closer to Terminating a Woman's Constitutional Right, in Gonzales v. Carhart*, 24 T.M. Cooley L. Rev. 597, 613 (2007).

[147] Phillips, *supra* note 143.

[148] Samuels, *supra* note 117, at 330.

[149] *Id.* at 340.

[150] *Id.*

[151] *Know the Risks of the Abortion Pill*, AbortionPill.CA, http://www.abortionpills.ca/risks1.html (last visited Nov. 11, 2014).

VI. The Weight of the Undue Burden Test

Ultimately, the Court must reconcile inconsistent applications of the undue burden test to resolve the circuit split on the regulation of abortion-inducing drugs. Currently, the test is being applied in two ways: (1) the "Traditional Approach" in which a court first ensures that legislation has a rational basis and then assesses whether it creates a substantial obstacle to an abortion for a large fraction of the women; and (2) the "Balancing Test" method where a court looks at the purpose and effect of legislation separately to balance the State's interests against the burden levied on women seeking an abortion.[152] While the Traditional Approach finds its origins in *Casey* and was cemented in *Gonzales*, the Balancing Test is a new invention of lower courts, which has no basis in Supreme Court precedent, and is therefore incorrect.[153]

A. The Flaws of the Balancing Test

Before weighing the considerations in protocol-legislation, the Court will first have to clarify the proper use of the undue burden test. Judge Posner of the Seventh Circuit recently introduced a two-part test requiring that "legislation regulating abortions must pas[s] muster under rational basis review and must not have the 'practical effect of imposing an undue burden' on the ability of women to obtain abortions."[154] This interpretation separates the test into two parts, examining both the legislative purpose and practical effect of the law.[155] Then, under this framework, a court should strike down a regulation when "the extent of the burden a law imposes on a woman's right to abortion outweighs the strength of the state's justification for the law."[156] Although this test still should not pose any additional barriers to upholding abortion protocol-legislation, it was relied upon to do just that by the Ninth Circuit and is not the appropriate standard under *Gonzales*.[157]

Under this test, legislation is often assumed to pass rational basis.[158] However, in weighing the State interest with the resulting burden, the test encourages some courts to improperly scrutinize the medical evidence and legislative intent behind abortion regulations.[159] This comes from the notion that undue burden analysis is context-specific and that the severity of a burden and the strength of the state's justification can vary depending on the circumstances.[160] The Balancing Test argument follows that the

[152] *Compare Van Hollen*, 738 F.3d at 799 *with DeWine*, 696 F.3d at 514; *Abbott*, 748 F.3d at 590.

[153] Karen A. Jordan, *The Emerging Use of a Balancing Approach in Casey's Undue Burden Analysis* (forthcoming 2016) (manuscript at 10) (on file with author).

[154] *Van Hollen*, 738 F.3d at 799 (7th Cir. 2013) (quoting Karlin v. Foust, 188 F.3d 446, 481 (7th Cir.1999)).

[155] *Van Hollen*, 738 F.3d at 799.

[156] *Humble*, 753 F.3d 905, *petition for cert. filed*, 2014 WL 4467076 (U.S. Sept. 2, 2014) (No. 14-284), 20-21.

[157] *Humble*, 753 F.3d at 912.

[158] *Id*.

[159] *Van Hollen*, 738 F.3d at 800.

[160] *Humble*, 753 F.3d 905, *petition for cert. filed*, 2014 WL 4467076 (U.S. Sept. 2, 2014) (No. 14-284), 16.

stronger the state's justification for the legislation, the greater the burden imposed must be before it is found to be "undue"; and, the more substantial the burden imposed, the stronger the state's justification for the law must be for the legislation to pass the undue burden test.[161]

This context-specific approach does not give proper deference to the state and results in valid laws being struck down after an improper inquiry into the medical evidence that legislatures rely upon to form the intent of the law.[162] The Seventh Circuit addressed this specific issue and concluded that the notion that abortion legislation is unconstitutional because some medical evidence contradicts the state's claim that an abortion restriction furthers women's health is a "misguided argument."[163] As a result, an abortion restriction that is rationally related to a state's legitimate interests should be considered valid, regardless of medical evidence presented to undermine that state's medical justification for the law, in so far as it does not impose a substantial obstacle to an abortion.[164]

On the other hand, even when examining the purpose of a law, "states have 'broad latitude' to regulate abortion doctors, 'even if an objective assessment might suggest that' the regulation is not medically necessary."[165] Thus, an abortion regulation that simply "may be helpful" or "can be useful" still should pass the requirement that it have a legitimate purpose and be upheld as long as it does not create a substantial obstacle for a large fraction of women.[166]

This interpretation is consistent with the Supreme Court's reasoning in *Mazurek v. Armstrong*, which held that an impermissible purpose will only be found if the law succeeds in achieving an impermissible effect; therefore, there need not be an analysis of the legislative purpose before examining the effect of the law.[167] Even the fact that a law was drafted by an anti-abortion group, "says nothing significant" about the state's purpose in passing the abortion restriction.[168] Therefore, the relational inquiry in the *Casey* analysis should be deferential to state legislatures and the Balancing Approach is an inappropriate dilution of the Traditional Approach.[169] The undue burden test does not allow courts to balance the burden imposed by a law against its medical justification.[170]

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[161] *Id*. at 48.

[162] *Id*. at 16.

[163] *Van Hollen*, 738 F.3d at 800 (citing *Mazurek*, 520 U.S. at 971-75).

[164] *Id*. at 807.

[165] *Id*. at 800 (quoting Mazurek v. Armstrong, 520 U.S. 968, 973 (1997)).

[166] *Van Hollen*, 738 F.3d at 800 (quoting Planned Parenthood of Cent. Mo. v. Danforth, 428 U.S. 52, (1976)).

[167] Ctr. for Reproductive Rights, The Undue Burden Standard: Abortion Jurisprudence after Casey at 164, http://reproductiverights.org/sites/crr.civicactions.net/files/documents/crr_Updated_UB_Module.pdf.

[168] *Id*. at 164 (citing Mazurek v. Armstrong, 520 U.S. 968, 973, (1997)).

[169] Jordan, *supra* note 153.

[170] Brief for Appellants at 13-14, Whole Women's Health v. Lakey, 135 S. Ct. 399 (2014) (No. 14-50928), 2014 WL 5802849, at *1-2 (citing *Abbott*, 748 F.3d at 597).

Instead, "once a law passes rational-basis review, the sole remaining question is whether it imposes a 'substantial obstacle' in the path of abortion patients."[171]

B. The Traditional Approach Controls

Although the Court has indicated that legislative intent need not be heavily scrutinized in abortion regulations, such scrutiny is not likely to invalidate a law. Still, the simplicity of the Traditional Approach, taken from *Casey*, is the predominant test used in operation.[172] Following rational basis review, the traditional test simply asks whether the requirement is "likely to prevent a significant number of women [affected by the regulation] from obtaining an abortion."[173] It does not suggest that a court should weigh the state interest with the burden imposed by the legislation.[174] This assertion is validated by recent cases, including *Mazurek* and *Gonzales*, which hold that only when a regulation creates a substantial obstacle to obtaining an abortion is an undue burden imposed by the legislation.[175]

Furthermore, a regulation only imposes an undue burden on women under *Casey* when it prohibits a woman from making the ultimate decision to terminate her pregnancy; an incidental interference with that decision will not suffice.[176] *Gonzales* further clarified that even the elimination of a popular abortion method is not enough to constitute an undue burden when a safe, alternative method exists.[177] A health exception is also not a constitutional requirement either, following *Gonzales*.[178] There must be a substantial obstacle hindering the right to choose that will prevent a large fraction of women from obtaining an abortion before striking down an abortion restriction on a facial challenge. Such an obstacle is not present in FDA-protocol legislation.[179]

C. As Applied

An abortion restriction which simply regulates the means by which a woman can have an abortion is not an undue burden in and of itself.[180] There is a legitimate interest in women's health being protected by greater regulation of mifepristone, following the 2,207 complications, 612 hospitalizations, and 14 deaths resulting from its use.[181] FDA-protocol legislation could—although not certainly would—have prevented eight of those 14 deaths from occurring from a severe bacterial infection after unapproved

[171] *Id.* at *2.
[172] *Humble*, 753 F.3d at 911.
[173] *Casey*, 505 U.S. at 893.
[174] *Humble*, 753 F.3d 905, *petition for cert. filed*, 2014 WL 4467076 (U.S. Sept. 2, 2014) (No. 14-284), 20-21.
[175] *Id.* at 21.
[176] *Casey*, 505 U.S. at 879.
[177] Transcript of Argument, Gonzales v, Carhart, No 05-380 (Nov 6, 2006), 20.
[178] *Gonzales*, 550 U.S. at 167.
[179] *Humble*, 753 F.3d 905, *petition for cert. filed*, 2014 WL 4467076 (U.S. Sept. 2, 2014) (No. 14-284), 12.
[180] Transcript of Argument, Gonzales v. Carhart, No 05-380 (Nov 6, 2006), 20.
[181] FDA, *supra* note 83.

mifepristone use.[182] Even though the precise cause of death in those cases is unknown, the state is allowed to use its "broad latitude" in regulating drug use.[183] This is because protecting women's health through FDA-protocol legislation "may be helpful," but need not be proven medically necessary in order to be upheld as constitutional.[184] This justification is clearly enough to satisfy rational basis review because the state has a legitimate interest (if not a duty) to neutralize this threat to women's health, but the effect of the regulation should also be scrutinized under the *Casey-Gonzales* test.

Here, the state has an interest in protecting women's health and legitimate concerns provide a legitimate purpose for upholding FDA-protocol legislation; thus satisfying the rational basis requirement. Next, the restrictions still must not effectively place a substantial obstacle in the path of a woman seeking an abortion to be valid.[185] The court in *Gonzales* described such an obstacle as one that imposes an undue burden on a woman's ultimate decision to have an abortion.[186] Just as a ban on D&E abortions in *Gonzales* did not substantially interfere with a woman's right, the narrow restrictions placed on medicinal abortions here also do not interfere with a woman's ultimate right.[187]

The legislation in *Gonzales* even banned a specific procedure in its entirety, whereas FDA-protocol legislation only restricts the dosage and timeframe of an otherwise legal procedure.[188] If the regulation of medicinal abortion means a woman cannot have one because she's past gestational dates, she still has the option of surgical abortion; which is the most commonly used abortion method.[189] According to the most recently available reports, 76.9% of all abortions are of the surgical variety (whereas 23.1% are medicinal)[190] and there is peer-reviewed evidence that surgical abortions are safer than medicinal abortions.[191] As a result, FDA-protocol legislation should be upheld, in line with the Fifth and Sixth Circuits' reasoning. This legislation leaves a more popular, safer alternative for women and is by no means a de facto ban on abortion, making such legislation consistent with both *Casey* and *Gonzales*.[192] Nowhere has the Supreme Court

[182] Stanek, *supra* note 106.

[183] *Van Hollen*, 738 F.3d at 800 (quoting *Mazurek*, 520 U.S. at 973).

[184] *Id*. at 800 (quoting *Danforth*, 428 U.S. at 52).

[185] *Gonzales*, 550 U.S. at 156 (quoting *Casey*, 505 U.S. at 878).

[186] *Id*. at 146.

[187] *Id*.

[188] *Id. at* 128.

[189] Stanek, *supra* note 106.

[190] CDC, *Abortion Surveillance — United States, 2012* (November 27, 2015), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6410a1.htm?s_cid=ss6410a1_e.

[191] Reply Brief for Petitioners, Cline v. Okla. Coalition for Reproductive Justice, 133 S. Ct. 2887 (2013) (No. 12–1094), 2013 WL 2428978, at *11 (citing M. Niinimaki et al., *Immediate Complications after Medical compared with Surgical Termination of Pregnancy*, Obstet. Gynecol. 114:795 (Oct. 2009)); *see also Comparison of Medical and Surgical Abortion*, Feminist Women's Health Center, http://www.fwhc.org/abortion/abpill-compare-surgical.htm (last updated Oct. 5, 2010); *Medical Versus Surgical Abortion*, UCSF Medical Center, http://www.ucsfhealth.org/education/medical_versus_surgical_abortion/ (last updated 2015).

[192] *DeWine*, 696 F.3d at 494.

found a fundamental right to medicinal abortions—only to an accessible abortion option; a right which remains viable, even with FDA-protocol legislation in place.

Opponents of abortion regulations will argue that the special autonomy enjoyed within the doctor-patient relationship should serve as a stronger shield to the abortion right.[193] If autonomy is the paramount value when preserving both a woman's and her doctor's right to control medical decisions, then how can the state encroach upon that autonomy by denying a woman the right to a certain means of abortion that a doctor is willing to perform? But, even in *Roe*, the Court rejected autonomy as the primary value at stake in abortion cases by adopting rules that limit a woman's abortion options.[194] Justice Blackmun himself, the author of *Roe*, later reiterated his support for regulating abortion after the first trimester in the interest of maternal health; thus illuminating that the autonomy of the mother is not the supreme value in abortion jurisprudence.[195] Instead, the interest of public health allows for the state to hold a legitimate interest from the onset of a pregnancy in the health of the mother and pass restrictions to preserve that interest.[196]

However, states are now more than ever promoting patient autonomy and limiting barriers to treatment posed by FDA regulations. Arizona recently became the fifth state to pass a "right-to-try" statute, which allows terminally ill patients to request access to treatment that has not yet been approved by the FDA.[197] It is understood that the requested treatment might not be safe or effective, but access is granted based on the value of patient autonomy.[198] On a philosophical level, the promotion of a right-to-try statute might seem to conflict with FDA-protocol legislation in the abortion context, which restricts patient autonomy, but the aims of the two types of legislation are vastly different.

On one hand, right-to-try legislation builds off the FDA's compassionate use program, which expands access to unapproved treatments only *after* a patient has exhausted all available alternatives.[199] Consequently, the right-to-try is based on the assumption that there are no known, safe alternatives that can accomplish the desired health outcome. FDA-protocol legislation is supported by the exact opposite reasoning because surgical abortion remains the safe, popular alternative that accomplishes the same outcome as a medicinal abortion without heightened risk. Therefore, state legislatures (including

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[193] Peter M. Ladwein, *Discerning the Meaning of Gonzales v. Carhart: The End of the Physician Veto and the Resulting Change in Abortion Jurisprudence*, 83 Notre Dame L. Rev. 1847, 1853 (2008).

[194] Roger B. Dworkin, *Getting What We Should from Doctors: Rethinking Patient Autonomy and the Doctor-Patient Relationship*, 13 Health Matrix 235, 255-56 (2003) (citing *Roe*, 410 U.S. at 154).

[195] *Id.* at 256 (citing Webster v. Reprod. Health Servs., 492 U.S. 490, 538 (1989) (Blackmun, J., concurring in part and dissenting in part)).

[196] *Id.* (citing *Casey*, 505 U.S. at 846).

[197] Kimberly Leonard, *Seeking the Right to Try,* U.S. News (Nov. 18, 2014), http://www.usnews.com/news/articles/2014/11/18/right-to-try-laws-allowing-patients-to-try-experimental-drugs-bypass-fda.

[198] *Id.*

[199] *Id.; Expanded Access: Information for Patients*, U.S. Food & Drug Admin. (April 17, 2015), http://www.fda.gov/ForPatients/Other/ExpandedAccess/ucm20041768.htm.

Arizona) that pass both right-to-try and FDA-protocol legislation are not promoting contradictory messages, but a unified policy position in favor of promoting patient health. After all, right-to-try legislation gives patients the opportunity to take a risk for the goal of preserving life. The off-label medicinal abortions put the life of the mother in unnecessary danger and, deliberately, end the life of another, which should not be overlooked.

With the interest of promoting life in mind, the Court previously held that the State may use its regulatory authority to show profound respect for the life of the unborn.[200] The government's "legitimate, substantial interest in preserving and promoting fetal life," is still outweighed by a woman's right to privacy and personal autonomy, but should not be discounted as irrelevant.[201] Prenatal life is recognized in criminal statutes providing that wrongdoers stand trial for crimes which prevent the unborn from reaching their full potential—including mothers who use drugs while pregnant.[202] Although not enough in its own right, when combined with an interest in women's health, the State's interest in protecting the unborn weighs heavily in favor of legislation restricting, but not eliminating, access to certain abortion procedures.[203] Ultimately, a woman's autonomy is not overburdened by specific procedural restrictions on abortion that advance legitimate state interests in both women's health and the life of the unborn.

Conclusion

Although the State of Arizona's petition asking the Supreme Court to make the final determination on the validity of abortion-inducing drug restrictions was denied, this issue is far from resolved. In fact, the issue is ripe for Supreme Court consideration in light of the recent circuit split. States need further clarification on the proper test for abortion regulations and a specific resolution on FDA-protocol legislation.

While the Supreme Court first recognized a woman's right to an abortion 43 years ago, the Court significantly modified the way in which that right was recognized over time.[204] What was once identified as a fundamental right has since been downgraded to a protected liberty interest, which may be regulated.[205] *Casey* remains valid law—providing the framework through which the Court may interpret abortion restrictions—while indicating that the State may show profound respect for the life of a pre-viability fetus and even attempt to discourage a woman from exercising her right to abortion.[206]

Casey is most efficiently interpreted to proffer a simple requirement that a law, having rational basis, must not impose a substantial obstacle to a woman's right to an

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[200] *Gonzales*, 550 U.S. at 157.

[201] *Id.* at 126-27.

[202] Amy Lotierzo, *The Unborn Child, A Forgotten Interest: Reexamining Roe in Light of Increased Recognition of Fetal Rights*, 79 Temp. L. Rev. 279, 291 (2006).

[203] *Id.* at 310.

[204] *Roe*, 410 U.S. at 170.

[205] *Casey*, 505 U.S. at 859.

[206] *Id.* at 867.

abortion in a large fraction of relevant cases.[207] The Court need not conduct an ad hoc balancing test to weigh a woman's right to privacy and autonomy against the purposes behind State regulation; but regardless of how one interprets *Casey*, it offers a standard of review more lenient than *Roe*.[208] Furthermore, the nearly unfettered right to abortion created by the discretion shown to doctors through the health exception requirement in *Doe* has been rendered impotent through the upholding of an abortion method ban without a health exception in *Gonzales*.[209] Thus, *Gonzales* remains the controlling case for abortion regulations and indicates that the undue burden test is much more similar to traditional rational basis than strict scrutiny.

Finally, *Gonzales* turns *Roe* on its head, while providing a specific example of a constitutional burden on the right to an abortion.[210] *Gonzalez* supports the idea that the abortion right does not mean that every method must go unrestricted.[211] So long as there is "a commonly used and generally accepted method," a restriction does not present a substantial obstacle.[212] Therefore, under *Gonzales*, the Ninth Circuit erred in finding FDA-protocol legislation unconstitutional. To the extent that it might restrict some women from obtaining a medicinal abortion, FDA-protocol legislation does not pose *any* obstacle to prevent a woman from obtaining a surgical abortion.[213] As such, FDA-protocol legislation is constitutional and consistent with the holdings of the Fifth and Sixth Circuits.

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207 *Id*. at 837; *Gonzales*, 550 U.S. at 168.

208 *Id*. at 855.

209 *Gonzales*, 550 U.S. at 161.

210 *Id*. at 164-65.

211 *Id*. at 165.

212 *Id*.

213 *Humble*, 753 F.3d 905, *petition for cert. filed*, 2014 WL 4467076 (U.S. Sept. 2, 2014) (No. 14-284), 30.