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Benjamin A. Hooper
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THE NEGATIVE EFFECTS OF CUMULATIVE ABORTION REGULATIONS: WHY THE 5TH CIRCUIT WAS WRONG IN UPHOLDING REGULATIONS ON MEDICATION ABORTIONS (PLANNED PARENTHOOD OF GREATER TEXAS SURGICAL HEALTH SERVICES V. ABBOTT)[1]

*Benjamin A. Hooper**

I. INTRODUCTION

Imagine having a sixteen year-old daughter who is pregnant and wishes to terminate the pregnancy. The closest abortion clinic is seventy-five miles away and the state you live in requires a mandatory 24-hour waiting period. On top of that you have no health insurance and cannot afford to take off work. This is the exact situation in which Jennifer Whalen found herself, and as a result of her actions she is now currently serving a nine to eighteen month prison sentence.[2]

Whalen was faced with the above scenario and decided to purchase abortion pills online for her daughter.[3] When her daughter began to show symptoms of bleeding, Whalen took her to the hospital.[4] Though the bleeding was the result of a miscarriage, and no serious health issues were present, Whalen was charged with a felony for offering medical consultation without a license along with three misdemeanors.[5] With increasing regulations being passed by a number of states, abortion clinics have been forced to shut down. This has caused many women to find themselves in similar situations to Whalen's with no affordable or practical access to abortion providers.[6]

Since the United States Supreme Court's decision in *Roe v. Wade*, holding that a woman's right to abortion is protected under the Constitution, the topic of abortion has been a highly contested and

* Associate Member, 2014–2015 *University of Cincinnati Law Review.*

1. 748 F.3d 583 (5th Cir. 2014).

2. Emily Bazelon, *A Mother in Jail for Helping Her Daughter Have an Abortion*, N.Y. TIMES (Sept. 22, 2014), http://www.nytimes.com/2014/09/22/magazine/a-mother-in-jail-for-helping-her-daughter-have-an-abortion.html/.

3. *Id*.

4. *Id*.

5. *Id*.

6. Esmé E. Deprez, *The Vanishing Abortion Clinic*, BLOOMBERG BUSINESSWEEK (Nov. 27, 2013), http://www.businessweek.com/articles/2013-11-27/abortion-clinics-face-shutdown-spiral-as-republicans-push-restrictions/. "Since 2011, legislatures in 30 mostly Republican-controlled states have passed 203 abortion restrictions, about as many as in all of the prior decade. At least 73 clinics have closed or stopped performing abortions." *Id*.

controversial issue throughout the United States. The current political climate in the United States has helped reignite the fight over abortion with many politicians taking hardline views on the issue. For example, former Texas Governor Rick Perry stated that "he hopes to make abortion a thing of the past."[7]

Though abortion is legal in the United States, "in practice 87% of counties in the United States do not have a single abortion provider."[8] This lack of providers can be attributed to a number of different laws and regulations that states have put in place related to abortion over the years. For example, almost half of all states now have a 24-hour waiting period for abortions.[9] The most stringent states, South Dakota, Utah and Missouri, have implemented a 72-hour waiting period.[10] This fierce debate over abortion has caused a "lattice work of abortion law."[11] Some additional types of abortion regulations that are notable include: licensing requirements for physicians, requirements for abortion procedures to be performed in a hospital, gestational limits, insurance coverage, requirements of parental involvement, and regulations requiring state-mandated counseling.[12]

While abortion remains legal in the United States, the intricate web of regulations enacted by various states have resulted in the closure of a large number of abortion clinics and have restricted women's access to abortion providers, particularly impacting women who live in rural areas.[13] Some of the more recent fights over the constitutionality of abortion laws have arisen with the passing of new laws requiring physicians to have hospital admitting privileges,[14] as well as laws requiring abortion providers to follow the on-label regimen of certain abortion medications.[15]

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7. Erik Eckholm, *Judge in Texas Partly Rejects Abortion Law*, N.Y. TIMES (October 28, 2013), http://www.nytimes.com/2013/10/29/us/judge-blocks-part-of-texas-abortion-law.html/.

8. Quinn Cummings, *Making Abortions Illegal Doesn't Make Them Go Away*, TIME (Sept. 24, 2014), http://www.time.com/3423785/illegal-abortions/.

9. Kate Pickert, *What Missouri's New Abortion Law Means for Women,* TIME (Sept. 11, 2014), http://www.time.com/3323608/missouri-lawmakers-enact-72-hour-abortion-wait/.

10. *Id*.

11. Guttmacher INT., *State Policies in Brief: An Overview of Abortion Laws* (2013), *available at* http://www.guttmacher.org/statecenter/spibs/spib_OAL.pdf/.

12. *Id*.

13. Manny Fernandez & Erik Eckholm, *Abortion Providers in Texas Press Judge to Block Portions of New Law*, N.Y. TIMES (Aug. 4 2014), http://www.nytimes.com/2014/08/05/us/texas-abortion-providers-press-judge-to-block-curbs-in-new-law.html/.

14. Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott, 748 F.3d 583 (5th Cir. 2014); Planned Parenthood of Wis., Inc. v. Van Hollen, 738 F.3d 786 (7th Cir. 2013) (holding that requiring abortion providers to have hospital admitting privileges was unconstitutional).

15. Planned Parenthood Ariz., Inc. v. Humble, 753 F.3d 905, 907, 911 (9th Cir. 2014); Planned Parenthood Sw. Ohio Region v. Dewine, 696 F.3d 490, 493–94 (6th Cir. 2012); Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott, 748 F.3d 583 (5th Cir. 2014). *See also Humble*, 753 F.3d

This Casenote examines the circuit split surrounding the constitutionality of these "medication abortion" laws, while focusing on the Fifth Circuit's decision in *Planned Parenthood of Greater Texas Surgical Health Services v. Abbott*. In *Abbott*, the Fifth Circuit upheld a law requiring physicians to follow the Food and Drug Administration (FDA) approved "on-label" regimen for medication abortions.[16] Part II of this Casenote provides an overview of the background on how medication abortions emerged as an option and, the two different regimens in question, and it explains the legal precedent governing abortion and abortion regulations. Part III examines the procedural history and decisions of the Fifth Circuit case, as well as decisions by the Sixth and Ninth Circuit on this issue. Part IV analyzes the Fifth Circuit's decision and illustrates where the Fifth Circuit went wrong. Finally, Part V concludes that to adequately determine whether regulations that require physicians to follow the on-label regimen for medication abortions place an undue burden on women's ability to receive appropriate healthcare, courts need to take a broader look at the cumulative effect of regulations already in place.

II. BACKGROUND

A. The Supreme Court Jurisprudence on Abortion Law

The Supreme Court first established a woman's right to have an abortion in *Roe v. Wade*.[17] In *Roe*, the Court held that a Texas statute outlawing abortion except in cases where the mother's health was at risk violated the Constitution.[18] The Court held that the statute was in violation of the Fourteenth Amendment's guarantee of liberty and that a woman's right to choose to have an abortion fell within the Fourteenth Amendment's protection.[19] In particular, the Court found that the Fourteenth Amendment establishes a right of personal privacy and that a woman's right to abortion falls into this category.[20] Though the Court did establish the right to abortions, it did not establish an absolute right to the procedure.[21]

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at 909 (explaining that the "on label" protocols for drugs are those which are submitted by manufacturers and subsequently approved by the FDA).

16. *See generally Abbott*, 748 F.3d.

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

18. *Id*. at 166.

19. *Id*. at 153.

20. *Id*. at 154.

21. *Id*. at 155.

The Court held that "this right is not unqualified and must be considered against important state interests in regulation."[22] To address a state's interests in regulating abortions at different stages of a woman's pregnancy, the Court established a trimester framework.[23] The Court noted that when regulating rights that are "fundamental", such regulations are subject to strict scrutiny and must serve a compelling state interest.[24]

Following this approach, the Court held that, during the first trimester, the decision should be left up to the woman and the medical judgment of her physician.[25] The Court further explained that a state may introduce minor regulations on abortion, but the regulations must not restrict a woman's choice to have an abortion.[26] However, the Court held, that during the second trimester, a state's interest is greater and therefore, "a State may regulate the abortion procedure to the extent that the regulation reasonably relates to the preservation and protection of maternal health."[27] Finally, the Court held that during the third trimester, a state has a compelling interest, and, therefore can "go so far as to proscribe abortion," except in cases where abortion is necessary to preserve the health or life of the mother.[28]

The Court's trimester analysis remained good law for 19 years until the Supreme Court ruled on yet another abortion case in *Planned Parenthood v. Casey*.[29] *Casey* centered on a Pennsylvania statute which required that a woman seeking an abortion (1) be provided with certain medical information twenty-four hours prior to an abortion procedure; (2) if a minor, have the informed consent of one parent; and (3) if married, have a signed statement from her husband consenting to the abortion.[30] In its analysis, the Court abandoned the trimester approach but maintained the central holding set forth in *Roe*.[31] In reaffirming the central holding of *Roe*, the Court outlined three essential takeaways: (1) women have a right to choose to have an abortion before viability without undue interference from the state; (2) states have power to impose regulations after viability; and (3) states have a legitimate interest in

22. *Id* at 154.
23. *Id*. at 163.
24. *Id*. at 155.
25. *Id.* at 163.
26. *Id*.
27. *Id*.
28. *Id*. at 164–65.
29. Planned Parenthood v. Casey, 505 U.S. 833 (1992).
30. *Id*. at 844.
31. *Id*. at 846.

protecting the health of the mother and child from the onset of pregnancy.[32]

While striking down the previous trimester analysis set forth in *Roe*, the Court established an undue burden standard for abortion regulations imposed before the point of viability.[33] The Court held that a regulation or law is an undue burden when "its purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability."[34] The Court emphasized that states have a "profound interest" in protecting potential life and therefore, the "rigid trimester approach" needed to be replaced to give states the opportunity to take measures that would inform and potentially persuade women to choose childbirth over abortion.[35] The Court's adoption of the undue burden standard paved the way for new abortion laws to be passed and for states to test the waters regarding what actually constituted an undue burden under this new standard.

The next piece of Supreme Court jurisprudence on this issue arose in 2007 with *Gonzales v. Carhart* where the Court reversed the decisions of the Courts of Appeals for the Eighth and Ninth Circuits and upheld the Partial-Birth Abortion Ban Act of 2003 (the Act).[36] The Act prohibited a particular type of abortion, namely the surgical procedure known as "Dilation and Evacuation" or "D&E."[37] This type of abortion is most commonly used for second trimester abortions.[38] The Court held that the Act did not place an undue burden on women who were seeking abortion as there were other alternatives available to them.[39] Specifically, the Court noted that "physicians are not entitled to ignore regulations that direct them to use reasonable alternatives."[40]

In addition to upholding the Act, the Court also reshaped the undue burden analysis by stating that "where [a State] has a rational basis to act, and it does not impose an undue burden, the State may bar certain procedures, and substitute others, all in furtherance of its legitimate interests in regulating the medical profession."[41] In

32. *Id*.

33. *Id*. at 878.

34. *Id*.

35. *Id*.

36. Gonzales v. Carhart, 550 U.S. 124, 168 (2007).

37. *Id*. at 136.

38. *Id* at 135. The procedure is performed by first dilating a woman's cervix to allow for a doctor to then insert surgical instruments into the uterus and to then evacuate the fetus.

39. *Id*. at 164.

40. *Id* at 163.

41. *Id*. at 158.

essence, a state can put in place a regulation as long as that regulation has a rational basis and does not place a substantial obstacle in the way of women seeking abortions.[42]

Further, the Court upheld the Act even though it did not have an exception in place for when a mother's health or life is at risk.[43] Again, the Court relied on the availability of alternatives in holding that the exclusion of this exception did not make the Act invalid on its face.[44] Additionally, the Court held that there was not enough medical evidence to demonstrate that the prohibition of this specific type of abortion would place a significant health risk upon women.[45] Instead, the Court held that state and federal legislatures should be given wide discretion in passing legislation regarding medical uncertainty over potential health risks.[46]

The evolution of abortion jurisprudence over the years has worn away many of the protections originally afforded to women. The holding in *Casey* whittled down the strict scrutiny imposed by the holding in *Roe*,[47] and the holding in *Gonzales* opened the door for many states to begin passing piecemeal regulations that have begun to disrupt the availability of abortion providers.[48]

B. The FDA's Process for Approving Drugs

When a drug is submitted to the FDA for approval, the FDA does not independently test the drug.[49] Instead, the pharmaceutical company who is manufacturing the drug will perform its own tests and determine an on-label regimen that it believes is safe for use.[50] The manufacturer then sends those results to the FDA for approval[51] and the FDA independently reviews the results of such tests and

42. *Id*.

43. *Id*. at 166–67.

44. *Id*. at 166.

45. *Id*.

46. *Id*. at 163.

47. Planned Parenthood v. Casey, 505 U.S. 833, 846 (1992).

48. David Masci, *A History of Key Abortion Rulings of the U.S. Supreme Court*, PEW RES. CENTER (Jan. 16, 2013) http://www.pewforum.org/2013/01/16/a-history-of-key-abortion-rulings-of-the-us-supreme-court/. After the Supreme Court's decision in Carhart a number of states stepped up regulations including 10 states which passed laws requiring the performance of ultrasounds procedures prior to an abortion.

49. *Development & Approval Process (Drugs)*, U.S. FED. DRUG ADMIN., http://www.fda.gov/Drugs/DevelopmentApprovalProcess/http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ (last visited October 26, 2014).

50. *Id*.

51. *Id*.

decides whether the drug should be approved.[52] The manufacturer will send a proposed label to the FDA which indicates how physicians should use the drug in accordance with the tests sent to the FDA.[53] Though the FDA approves only the on-label use of drugs, it is commonly expected that many drugs will be used off-label at the discretion of medical doctors.[54] Estimates suggest that of all the drug products prescribed each year, over 25 percent are off-label uses with some estimates reaching as high as 60 percent.[55] The FDA has gone as far as explicitly recognizing the importance off-label use of drugs stating, "once a product has been approved . . . a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling."[56] Further, Congress has exempted the practice of medicine from the Federal Food, Drug, and Cosmetic Act, which oversees the safety of food and drugs, in order to avoid limiting a physician's ability to treat patients.[57] Similarly, the United States Supreme Court has recognized that off-label use of drugs and devices approved by the FDA are generally left to the discretion of medical doctors.[58]

C. The Rise of Medication Abortions

In 2000, the FDA approved the drug Mifepristone for use in medication abortions under the brand name Mifeprex.[59] Prior to the FDA's approval of Mifepristone, most first-trimester abortions were surgical and were performed by a procedure commonly known as vacuum aspiration or suction curettage.[60] Over the past fourteen years, however, medication abortions have become a more common choice for doctors performing first-trimester abortions. Planned Parenthood has reported that medication abortions now account for 41 percent of all first-trimester abortions nationwide.[61] When the FDA approved the use of Mifepristone in medication abortions they

52. *Id*.

53. Planned Parenthood Ariz., Inc. v. Humble, 753 F.3d 905, 909 (9th Cir. 2014).

54. James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food Drug L.J. 71, 76–80 (1998).

55. *Id*. at 80.

56. *Id*. at 77.

57. *Id*. at 79.

58. See generally Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, (2001). The Supreme Court noted that the FDA's mission is to regulate without interfering with the practice of medicine. The use of off-label regimens and devices is a necessary corollary of this mission.

59. Planned Parenthood Ariz., Inc. v. Humble, 753 F.3d 905, 907 (9th Cir. 2014).

60. Planned Parenthood Sw. Ohio Region v. Dewine, 696 F.3d 490, 494 (6th Cir. 2012).

61. *Humble*, 753 F.3d at 908.

also established a drug label that described an "on-label" regimen that the manufacturers of the drug recommended.[62] Though the FDA approved the "on-label" regimen, many studies had already shown that a different regimen is also safe and effective to use for performing medication abortions.[63] In response to these two different regimens, state legislatures have begun to pass laws requiring abortion providers to follow the "on-label" regimen as approved by the FDA.[64]

D. Mifepristone and the Differing Protocols

The most common method of medication abortion employs a combination of two prescription drugs, Mifepristone and Misoprostol.[65] Mifepristone is taken first and "terminates the pregnancy by detaching the gestational sac from the uterine wall."[66] Misoprostol is then taken twenty-four to forty-eight hours later and causes the uterus to "contract and expel its contents."[67] The "on-label" procedure for this combination of drugs indicates that a woman should first take 600 milligrams of Mifepristone orally at a clinic, return two days later to take an additional 400 micrograms of Misoprostol, and then return again for a follow-up visit.[68] The FDA procedure also states that the medication should only be given to women who are up to seven weeks pregnant, or forty-nine days from the woman's last menstrual period (LMP).[69]

In contrast to this protocol, a second protocol was established through additional clinical trials of the drugs. This second protocol is commonly referred to as the "evidence-based regimen" or the "off-label regimen" and varies from the "on-label" protocol approved by the FDA.[70] The off-label regimen calls for 200 milligrams of Mifepristone to be administered orally at a clinic followed by 800 micrograms of Misoprostol to be administered orally two days later

62. *Id*. at 907.

63. *Id.*

64. *Id*. at 909; See also Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott 748 F.3d 583, 586 (5th Cir. 2014) (discussing H.B.2 which mandates that the administration of abortion inducing drugs comply with the protocol authorized by the FDA); *See also Dewine*, 696 F.3d at 495 (discussing Ohio's ban on off-label use of mifepristone).

65. *Humble*, 753 F.3d at 907.

66. *Dewine*, 696 F.3d at 494.

67. Humble, 753 F.3d at 907.

68. *Id*.

69. *Id*.

70. *Id*.

through dissolving of the drug between the cheek and gum.[71] Under this regimen, the Misoprostol can be taken at home instead of at a clinic and a patient then has a follow-up visit to a clinic after the treatment has been completed.[72] This regimen has been found to be safe and effective through nine weeks of pregnancy, or sixty-three days LMP, allowing for more women to have access to this method of abortion.[73]

A 2013 study examining the previous six years of data, found that out of 711,566 medication abortions following the evidence-based regimen, there were no infection-related deaths resulting from the combination of drugs.[74] Additionally, the failure rate for termination of pregnancy for the on-label regimen was found to be 1 percent, while the failure rate for the evidence-based regimen was around 0.5 percent.[75] The on-label regimen also results in the need for subsequent surgical abortions in about eight percent of women, while fewer than two percent of women who have followed the evidence-based regimen have required subsequent surgical abortions.[76] Finally, the additional required visit to administer the Misoprostol in accordance with the on-label regimen, as well as the higher doses that are required, raises the overall cost of the procedure in comparison to the evidence-based regimen.[77]

III. THE CIRCUIT SPLIT

A. Planned Parenthood of Southwest Ohio Region v. Dewine

1. The District Court Decision

In 2004, Ohio passed a law that criminalized the prescription and distribution of Mifepristone and Misoprostol for use in abortion procedures unless the distribution was done in accordance with certain protocols and time limits approved by the FDA.[78] In response

71. *Id*.

72. *Id*.

73. *Id*.

74. *Id*. at 908. *See* James Trussell et al., *Reduction in Infection-Related Mortality Since Modifications in the Regimen of Medical Abortion*, 89 Contraception 193, 195 (2014). This study consisted of data gathered from Planned Parenthood centers across the United States and tracked the complications arising from medication abortions after the procedure had changed from vaginal administration of Misoprostol to oral administration.

75. *Id*.

76. *Id*.

77. *Id*.

78. Planned Parenthood Sw. Ohio Region v. Dewine, 696 F.3d 490, 493 (6th Cir. 2012).

to this legislation, Planned Parenthood's Ohio regional clinics and two of its doctors brought suit challenging the constitutionality of the law.[79] Planned Parenthood made four separate constitutional arguments, three of which the district court granted summary judgment in favor of the defendants.[80] These three constitutional challenges were then appealed to the Sixth Circuit to determine: (1) whether the Act was unconstitutionally vague; (2) whether the Act violated a woman's right to bodily integrity under the Fourteenth Amendment; and (3) whether the Act imposed an undue burden on a woman's Fourteenth Amendment right to choose to have an abortion.[81]

2. The Sixth Circuit's Decision

On appeal, The United States Court of Appeals for the Sixth Circuit reviewed the district court's grant of summary judgment de novo.[82] Based on its review, the Sixth Circuit affirmed the district court's finding of summary judgment that the Act was not unconstitutionally vague.[83] Planned Parenthood argued that physicians would be confused by the language included within the Act, as well as the four documents contained within the "final printing label," and, therefore, physicians would be unable to understand what the Act was prohibiting.[84] The court, ultimately, rejected this view because the Ohio Supreme Court had previously interpreted the statute and specified what it prohibited.[85] This interpretation was then subsumed within the Act because "when a state's highest court interprets a statute, its construction is considered part of the statute itself."[86]

The Sixth Circuit also affirmed the district court's ruling of summary judgment on Planned Parenthood's bodily integrity claim.[87] Creatively, Planned Parenthood argued that the Act was parallel to a forcible physical intrusion because women who wish to have a medication abortion between fifty and sixty-three days after their LMP are forced to undergo surgery under this Act.[88] This type of

79. *Id.*
80. *Id.*
81. *Id.*
82. *Id.* at 503.
83. *Id.* at 506.
84. *Id.* at 504–05.
85. *Id.* at 505.
86. *Id.*
87. *Id.* at 507.
88. *Id.* at 506.

forcible intrusion would therefore require a compelling state interest, which Planned Parenthood argued was not present.[89] The Sixth Circuit dismissed this argument stating that "strict scrutiny, of course, no longer applies to abortion legislation"[90] and that the Supreme Court has made clear that these types of questions are analyzed under the undue-burden framework rather than a return to a stricter balancing standard.[91]

In regard to the undue burden claim put forward by Planned Parenthood, the Sixth Circuit affirmed the district court's finding on summary judgment that the Act does not place an undue burden on a woman's ability to receive an abortion.[92] The court relied, in part, on the fact that medication abortions are preferred by only 31 percent of women to whom it is available and, therefore, is less likely to pose an issue. In support of this notion, the court referenced *Gonzales v. Carhart*, stating "that state action is likely to constitute an undue burden where the most common abortion technique . . . is prohibited."[93] The court concluded that the Constitution protects a woman's right to choose to terminate her pregnancy but does not protect her preferred method of choice.[94] Accordingly, the court focused on the amount of women who choose this procedure and determined that the Act does not place a substantial obstacle in the way of a woman's ultimate choice to terminate her pregnancy.[95]

B. Planned Parenthood of Arizona v. Humble

1. The District Court Decision

Two years after the Sixth Circuit's decision in *Dewine*, the Ninth Circuit addressed the constitutionality of a similar type of legislation.[96] Parallel to the Ohio law, Arizona's legislation regulated medication abortions by requiring doctors to follow the protocol approved by the FDA and outlined in the final printing label.[97] This legislation was challenged by Planned Parenthood of Arizona, who

89. *Id*.
90. *Id*.
91. *Id*. at 506–07.
92. *Id*. at 518.
93. *Id*. at 514.
94. *Id*. at 516.
95. *Id*.
96. *See generally* Planned Parenthood Ariz., Inc. v. Humble, 753 F.3d 905 (9th Cir. 2014).
97. *Id*. at 909.

sought a preliminary injunction against the law.[98] Following in the Sixth Circuit's footsteps, the district court denied the preliminary injunction and relied on the availability of surgical abortions as grounds for dismissing the possibility of any undue burden caused by the legislation.[99] The district court concluded that Planned Parenthood was not entitled to a preliminary injunction because it had failed to establish any question that was likely to succeed on the merits.[100]

2. The Ninth Circuit's Decision

On appeal, the Ninth Circuit reviewed the denial of a preliminary injunction for abuse of discretion.[101] Planned Parenthood's main argument was that the legislation imposes an undue burden upon a woman's right to abortion.[102] In addressing this argument, the Ninth Circuit criticized the Fifth and Sixth Circuits' analyses in holding that legislation requiring doctors to follow the FDA protocol did not place an undue burden upon women.[103] The Ninth Circuit emphasized, that in making this determination, both Circuit's applied rational basis review but then failed to pay attention to whether the regulation actually advanced the state interest the legislation was allegedly created for.[104] Specifically, the court noted that the burden that an abortion regulation imposes on a woman needs to be compared with the strength of the state justification for which the law is being claimed to serve.[105]

The Ninth Circuit focused on this reasoning, maintaining that "the more substantial the burden, the stronger the state's justification for the law must be to satisfy the undue burden test."[106] Arizona's purported justification for this legislation was to protect a mother's life.[107] The main factors considered were the increased dosages that the final printing label required,[108] the increased cost and travel time

98. *Id*. at 910.

99. Planned Parenthood Ariz., Inc. v. Humble, 13 F. Supp. 3d 1017, 1025 (D. Ariz. Mar. 31, 2014).

100. *Id*. at 1026.

101. *Humble*, 753 F.3d at 910.

102. *Id*. at 911.

103. *Id*. at 914.

104. *Id*.

105. *Id*. at 912.

106. *Id*.

107. *Id*. at 909.

108. *Id*. at 915.

associated with the on-label regimen,[109] evidence demonstrating that clinics would likely close as a result of the law,[110] and evidence that the legislation may delay abortions which would result in increased health risks for women.[111] Ultimately, the Ninth Circuit determined that Planned Parenthood was likely to succeed on the merits of the undue burden claim as a result of these factors and, therefore, reversed the district court's ruling and remanded the case back to the district court with instructions to issue the preliminary injunction.[112]

C. Main Case: Planned Parenthood of Greater Texas Surgical Services v. Abbott

1. The District Court Decision

Shortly before the Ninth Circuit's decision, legislation was passed in Texas that restricted the use of abortion inducing drugs.[113] Similar to the Ohio and Arizona laws, the Texas law, House Bill 2 (H.B. 2), required that abortion-inducing drugs comply with the protocol authorized by the FDA.[114] The district court held that the law placed an undue burden on women who will seek an abortion after forty-nine days from their LMP where, in the medical opinion of a doctor, a medical abortion is the safest option and would therefore require a doctor to follow the off-label regimen.[115] The district court reasoned that this law could interfere with the safety of a mother's life because certain health conditions or physical abnormalities prevent women from safely undergoing surgical abortions.[116] The court stated that for women who suffer from these conditions, the restrictions on medical abortions serve as a complete ban after forty-nine days from their LMP because of the significant health risks that would be associated with a surgical abortion.[117] The district court granted an injunction against enforcement of the legislation on medical providers who chose to follow the off-label regimen for women who

109. *Id* at 916.

110. *Id*.

111. *Id*.

112. *Id*. at 918.

113. Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott 748 F.3d 583, 587 (5th Cir. 2014)

114. *Id*.

115. Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott, 951 F. Supp. 2d 891, 908 (W.D. Tex. 2013).

116. *Id*. at 907.

117. *Id* at 908.

are between fifty to sixty-three days from their LMP.[118]

2. The Fifth Circuit's Decision

On appeal, the Fifth Circuit reviewed the district court's holding to determine whether the district court erred in finding that the H.B. 2 placed an undue burden on the abortion rights of women seeking an abortion from fifty to sixty-three days from their LMP and, in the opinion of a doctor, could not safely undergo a surgical abortion.[119] In its description of the off-label protocol, the court seemed to be surprised by the notion that many medical professionals across the country preferred the off-label regimen rather than the FDA approved on-label regimen.[120] The court appeared to give strong deference to the FDA protocol and failed to mention the *Humble* court's findings that off-label uses of medication are extremely common and have even been acknowledged by the FDA as "sometimes required by good medical practice."[121] The Fifth Circuit went on to hone in on, what it described as, the "hypotheses and speculation" of the district court to determine that restrictions on medical abortions do not facially impose an undue burden on women seeking an abortion.[122] Specifically, the Fifth Circuit concluded that a facial attack on the constitutionality of the provision was untenable and that the argument would need to be brought in an as applied challenge.[123]

In reaching this conclusion, the Fifth Circuit relied heavily on the Supreme Court's ruling in *Gonzales*.[124] In particular, the court reasoned that the restrictions placed upon medication abortion did not restrict an entire type of abortion but, rather, just a specific time period allowing women the opportunity to pursue alternative abortion procedures.[125] Though the Fifth Circuit reversed the district court's decision, it failed to make an actual determination as to whether the Texas law would place an undue burden on women who suffer from certain conditions and whom doctors believe cannot safely undergo surgical abortions.[126]

118. *Id.* at 909.

119. Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott 748 F.3d 583, 586 (5th Cir. 2014)

120. *Id*. at 600.

121. Planned Parenthood Ariz., Inc. v. Humble, 753 F.3d 905, 909 (9th Cir. 2014).

122. Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott, 748 F.3d 583, 604 (5th Cir. 2014).

123. *Id*.

124. *Id*.

125. *Id*.

126. *Id*. at 605.

IV. DISCUSSION: WHY THE FIFTH CIRCUIT REACHED THE WRONG CONCLUSION

The Fifth Circuit's determination that H.B. 2 does not facially impose an undue burden on the abortion rights of some women was inherently flawed. In reaching this conclusion, the court misconstrued the proper standard required for such a finding and also failed to take into consideration all relevant factors. The court's approach to this analysis was problematic in a number of ways. First, the court failed to utilize the undue burden standard correctly. Second, the court overlooked the cumulative effects of abortion regulations were placing upon women. Finally, the court failed to recognize the true role of the FDA in approving drugs and the discretion that is still awarded to medical professionals. All of these shortfalls suggest that a new approach may be needed when analyzing abortion regulations.

A. The Fifth Circuit Failed to Utilize the Undue Burden Standard Correctly

1. The Court Failed to Consider the Strength of the State Interest Being Pursued

One of the largest concerns with the Fifth Circuit's determination is the failure of the court to take into account the balancing test required under the undue burden standard set forth by the Supreme Court. Instead of comparing the burden created by H.B. 2 against the state interest the law was allegedly created to protect, the Fifth Circuit focused merely on whether there was a rational basis for the legislation and went no further. This approach fails to consider one of the most important aspects of the undue burden analysis: whether the burden placed upon women's access to abortions is greater than the state interest being protected.

In its opinion, the Fifth Circuit noted that the alleged purpose of the Texas law was the protection of maternal health, rather than the health of potential fetal life.[127] This is supported by the State's inclusion of evidence from Dr. Harrison, which focused on the mother's health.[128] Nonetheless, the court focused purely on *Gonzales* in drawing a supposed parallel when asserting that the legislation passes a rational-basis review. Texas purports that the

127. *Id*. at 590.

128. *Id.* at 602.

legislation is meant to protect the life of the mother but then fails to take into consideration whether placing limits on the availability of medication abortions really does protect a woman's health. The court relies on the assertion that there was a lack of evidence presented by Planned Parenthood to allow for the district court to come to the conclusion that women would be unable to receive a medication abortion before the 49-day LMP window closes.[129] Though the Fifth Circuit focuses on a supposed lack of evidence, it then fails to present any evidence itself. The Fifth Circuit stressed that decisions must be based on "facts, not hypothesis and speculation," but then went on to speculate about the strength of the legislation. Instead, the court avoids having to make any sort of real determination by simply stating that an as applied challenge is necessary before an actual determination can be made about the burden the law places upon women.[130]

The Fifth Circuit's avoidance of this issue was clearly flawed. The Fifth Circuit should have followed the same reasoning applied by the Ninth Circuit and focused on balancing the strength of the state interest against the burden being placed upon women.[131] There is no question that H.B. 2 places an obstacle in the path of women seeking abortions. The question is whether that burden outweighs the purported health benefits the bill was created to protect. The Fifth Circuit missed the mark in this case by avoiding this question altogether and relying solely on *Gonzales* to find that because the law was only placing a burden on the choice of preferred procedure, rather than a blanket burden on all types of abortion, it was not facially unconstitutional.[132]

The Fifth Circuit failed to analyze whether this restriction on medication abortions would really have the effect of protecting the health of mothers. The court relied on the lack of concrete evidence regarding medical conditions or abnormalities that would put women at risk for surgical abortions[133] but failed to consider that doctors should have the ultimate choice in determining what they believe is the safest procedure for their patients. In its opinion, the court noted that there is "disagreement over whether medication abortions are safer [for at-risk women], at least when subsequent emergency

129. *Id*. at 604.

130. *Id*.

131. Planned Parenthood Ariz., Inc. v. Humble, 753 F.3d 905, 912–13 (9th Cir. 2014).

132. Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott, 748 F.3d 583, 604 (5th Cir. 2014).

133. *Id*.

surgical abortions are necessary."[134] This type of decision-making about the correct procedure for individual patients needs to be left to the discretion of doctors, not legislators. By limiting the window of availability for medication abortions the Fifth Circuit is putting this discretion in the hands of lawmakers rather than trained medical professionals who can better determine the best treatment for their patients on a case-by-case basis.

2. The Court's Analysis Failed to Examine the Effectiveness of the Law

The Fifth Circuit's failure to apply the correct balancing test was coupled with the omission of any real look into the effectiveness the Texas law had towards reaching its stated purpose. Current medical statistics show that medication abortions rarely result in complications[135] and are often preferred by women because, following the off-label protocol, the second dose of medication can be taken in the privacy of one's own home. In fact, medication abortions now account for forty-one percent of all first-trimester abortions nationwide.[136] Further, a study conducted in 2009 found that medication abortions present little to no risk to the health of women when the combination of Misoprostol-Mifepristone drugs are used between fifty to sixty-three days from a woman's LMP.[137] The study also found that the chance of successful terminations was found to be 98.3 percent when the combination of drugs was used within sixty days or less from a woman's LMP, while it was found that the procedure was 96.8 percent effective for all procedures performed on women below fifty days from their LMP.[138] Additionally, new changes in the administration of the second drug, Misoprostol, has reduced the risk of serious infections related to the procedure to as low as .0025 percent.[139] Coupled with antibiotics, this risk can be lowered by another seventy-six percent,[140] making medication

134. *Id*.

135. *See generally* James Trussell et al., *Reduction in Infection-Related Mortality Since Modifications in the Regimen of Medical Abortion*, 89 Contraception 193, 195 (2014).

136. *Humble*, 753 F.3d at 908.

137. Mary Fjerstad et al., *Effectiveness of medical abortion with mifepristone and buccal misoprostol through 59 gestational days*, 80"Effectiveness of medical abortion with mifepristone and buccal misoprostol through 59 gestational days." *Contraception* 282, 282–86 (2009) (finding that complications arose in less than 1% of the procedures).

138. *Id*.

139. Amanda Garner, *Changes Reduced Infections from Medical Abortions*, ABC NEWS (July 8, 2009), http://abcnews.go.com/Health/Healthday/story?id=8037060.

140. *Id*.

abortions arguably safer than the alternative surgical procedures.

The Fifth Circuit's failure to take this information into account was egregious. The court stated that there was a lack of sufficient evidence to support such claims, discrediting the expert testimony presented by Planned Parenthood and finding that it was not sufficient to show that an undue burden was placed upon women as a result of these restrictions.[141] In doing so, the court ignored the multitude of other evidence that was submitted in the plaintiff's original motion.[142] This failure by the court resulted in the merits of Planned Parenthood's argument to not be truly examined under the undue burden standard set forth by the Supreme Court. Ultimately, this error led the Fifth Circuit to erroneously decide this case against Planned Parenthood.

B. The Effect of Additional Abortion Regulations Were Not Taken into Consideration

In ruling against the appellees, the Fifth Circuit failed to consider and weigh the effects of other abortion regulations that were already in place within Texas. The myriad of existing abortion regulations play a large role in the ability of a majority of women to access abortion procedures. In determining whether a new piece of legislation places an undue burden on a woman's access to abortion, not only do the effects of that specific law need to be taken into consideration, the effects of existing regulations need to be weighed and examined alongside the new restriction.

As of July 1, 2014, Texas had the following restrictions on abortion in effect: (1) a woman must receive state-directed counseling, including information designed to dissuade her decision, and then wait twenty-four hours prior to procedure; (2) minors must receive parental consent and notify their parents prior to procedure; (3) public funding is available only in cases of life endangerment, rape, or incest; and (4) a woman must undergo an ultrasound before obtaining an abortion and be shown the ultrasound prior to procedure.[143] H.B. 2 adds two separate restrictions to this list: (1) that abortion providers must have hospital admitting privileges for a

141. Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott, 748 F.3d 583, 604 (5th Cir. 2014).

142. *See generally* Plaintiff's Motion for Preliminary Injunction and Memorandum of Law in Support Thereof, Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott, 748 F.3d 583 (2013) (No. 1:13-cv-00862-LY).

143. *State Facts About Abortion: Texas*, GUTTMACHER INST., http://www.guttmacher.org/pubs/sfaa/texas.html (last visited June 1, 2015).

hospital within thirty miles from the place of procedure; and (2) doctors who wish to utilize medication abortions must adhere only to the final printing label regimen as approved by the FDA for the administration of Misoprostol and Mifepristone.[144]

Instead of focusing on the impact that would result only from the prohibitions related to medication abortions, the Fifth Circuit should have considered that impact along with the other restrictions on abortion that were already in place. The appearance of piecemeal legislation adding restrictions to abortion has become very popular amongst states who wish to add layers of red-tape and regulations which ultimately result in the closing of abortion clinics.[145] Today, almost half of the United States has a 24-hour waiting requirement with some states requiring as much as a 72-hour wait period.[146] A more recent wave of legislation has begun to require that doctors perform an ultrasound on all women who seek an abortion even though ultrasounds are not medically necessary for the procedure.[147]

When analyzing the constitutionality of H.B. 2, the Fifth Circuit failed to consider the true purpose and motivation behind the law. It is important for courts to not only take into consideration the current restriction being challenged but to also be aware of the overlying atmosphere of abortion regulation within the state itself. The Fifth Circuit blindly accepted Texas's argument that the regulation was for the purpose of protecting maternal health without doing any empirical analysis or further thought. Indeed, the court explicitly stated "there is never a role for evidentiary proceedings under rational basis review."[148] The court's attempt to dismiss the need for empirical evidence fails common sense. Though the burden remains on the plaintiffs to show that the purpose of the regulation is to place a substantial obstacle in the way of a woman seeking an abortion, the court should not blindly accept the state's purported rationale for the legislation and then not permit any type of empirical analysis into whether the legislation actually meets that purpose.

144. *Abbott*, 748 F.3d at 587.

145. Tara Culp-Ressler, *Seven States Working Hard to Shut Down Abortion Clinics*, THINK PROGRESS (April 3, 2013), http://thinkprogress.org/health/2013/04/03/1815111/states-advancing-trap-laws/.

146. Kate Pickert, *What Missouri's New Abortion Law Means for Women,* TIME (Sept. 11, 2014), http://www.time.com/3323608/missouri-lawmakers-enact-72-hour-abortion-wait/.

147. *State Policies in Brief: Requirements for Ultrasound*, GUTTMACHER INST. (October 1, 2014), http://www.guttmacher.org/statecenter/spibs/spib_RFU.pdf. Twenty-three states have regulated ultrasound requirements prior to abortion procedures.

148. Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott, 748 F.3d 583, 596 (5th Cir. 2014).

This interpretation of rational-basis review fails to protect a woman's right to abortion and allows for states to pass these regulations with false motives. The Fifth Circuit's reading fell directly into this line of thinking and failed to afford the appropriate constitutional protection that the Supreme Court intended to extend to women since its holding in *Roe*. Instead, the Fifth Circuit should have taken an approach similar to the Ninth Circuit's analysis in *Humble*. In particular, the Ninth Circuit noted that the constitutional analysis of an abortion regulation cannot end once it is found that the regulation has been supported by only "rational speculation."[149] It is also necessary to consider whether the regulation has actually been shown to advance the purported state interest.[150]

C. The Fifth Circuit Misunderstood the Roles of FDA Approvals

In its opinion, the Fifth Circuit demonstrates that it does not fully understand the FDA's approval process or the role that the FDA plays in determining what appears on the final printing label of a drug. This misunderstanding likely played a significant role in the court's decision because of the apparent credibility they gave the on-label regimen of Misoprostol and Mifepristone while showing clear disdain for the off-label regimen being used by doctors across the nation.

The Fifth Circuit appeared wholly unaware of the FDA's regulatory authority and seemed to be taken by surprise when learning that doctors across the nation were following an off-label regimen in medication abortions. The court explained this usage by stating "doctors performing such abortions in Texas, *and apparently across the country*, have developed an off-label protocol that differs from the FDA-approved version[.]"[151] The ultimate result was clearly effected by the Fifth Circuit's lack of knowledge on this matter. One of the main factors in the court's rationale was that there was a lack of evidence to show that medical abortions were actually a safe alternative to surgical abortions. The court should have given credibility to the off-label regimen that had been implemented across the country and chosen as the preferred method by numerous medical professionals. The Fifth Circuit's apparent lack of knowledge on the process of FDA approval of drugs led to an erroneous decision that

149. Planned Parenthood Ariz., Inc. v. Humble, 753 F.3d 905, 914 (9th Cir. 2014).

150. *Id*. *See also* Planned Parenthood of Wisconsin, Inc. v. Van Hollen, 738 F.3d (7th Cir. 2013) (the Seventh Circuit took a similar approach by weighing the extent of the burden against the state's justification for the regulation).

151. *Abbott*, 748 F.3d at 600.

took away the power of discretion and choice from medical professionals and women.

D. The Current Constitutional Framework Falls Short in Protecting a Woman's Right to Abortion

The changing landscape of abortion regulation in the United States calls for a change in the constitutional framework that governs these new restrictions. More protection needs to be afforded to women who seek abortion. To accomplish this task, courts need to begin taking a comprehensive approach towards interpreting abortion regulations, rather than the narrow approach seen in *Abbott*. As more states continue to pass laws targeting abortion clinics with supposed goals of protecting maternal or fetal health, courts need to increase the amount of time and effort spent determining the true purpose of the regulations.

The optimal approach is similar to the Ninth Circuit's analysis in *Humble*. No longer should an abortion regulation be able to pass constitutional muster simply because it can be tied to some rational basis. Instead, the state's justification needs to be weighed against the burden that it creates. Additionally, courts need to actually examine the effectiveness the law will have towards reaching that justification. Taking a lenient approach to these regulations has resulted in a buildup of cumulative regulations that have resulted in the closures of more and more clinics and have placed a substantial obstacle in the path of women who seek abortion procedures. A better method for determining the constitutionality of new abortion regulations would not only consider the burden that results from the specific piece of legislation in question, but also the cumulative effect that other abortion regulations within the state also have on a woman's ability to seek out an abortion.

These targeted abortion regulations have become far too common. It can be argued that the overall goal of states in enacting this type of legislation is not to protect the health of its citizens, but instead, to restrict access to a procedure that the state's legislators do not personally believe in. This motive flies directly against the Supreme Court's finding that a woman's right to abortion is constitutionally protected. The courts only option is to react to these regulations by changing the framework in which they are interpreted within.

V. CONCLUSION

With the continual emergence of abortion regulations across the

United States, it is time for courts to begin examining these regulations with a stricter constitutional interpretation. The effects of these regulations are already affecting women in a number of states and are undermining the constitutional protections afforded by the Supreme Court in *Roe v. Wade*. Rather than focusing strictly on each regulation as they are individually introduced, courts need to begin examining the burden placed upon women from the cumulative effects of both existing abortion regulations and the new regulations that they are reviewing.

In addition to this need, another troubling aspect of interpretation has begun to be demonstrated. As the Fifth Circuit made clear in its holding, the discretion and determination of what types of procedures are safest for women should be awarded to legislators rather than medical professionals. This troubling notion is untenable in modern society. Medical professionals are much better equipped to make medical decisions on a case-by-case basis rather than an outright ban on off-label use of medication abortions. The Fifth Circuit's acceptance of a ban on off-label use for a particular combination of drugs goes against a line of thinking that the FDA themselves has said was necessary. It offends common sense to disallow doctors the discretion to administer these two drugs while allowing them to continue with off-label use for almost all other drugs. The decision of whether medication abortions are the safest option for a woman should be left up to the medical professionals not legislators. The Fifth Circuit failed to grasp this concept and as a result struck a blow to the constitutional protections long afforded to women.