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# Miss-Conceptions: Abortifacients, Regulatory Failure, and Political Opportunity

**ABSTRACT.** Scientific evidence overwhelmingly shows that the categorization of Plan B and other emergency contraceptives as "abortifacient," or abortion-inducing, is incorrect. The FDA, federal courts, and the executive branch compound and entrench this misunderstanding by relying on it as a foundation for contraceptive law and policy. This Note traces the development and consequences of this collective error and proposes solutions. It then considers the role of emergency contraception in two worrying legal developments. First, the mistaken categorization of emergency contraception blurs the distinction between contraception and abortion, shifting contraception and ground by stretching the deference usually reserved for litigants' moral claims to factual assertions.

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# NOTE CONTENTS

INTRODUCTION	210
<ul> <li>THE MECHANISM OF EMERGENCY CONTRACEPTION: FACT &amp; FICTION</li> <li>A. The Process of Conception and the Physical Functioning of Emergency Contraceptives</li> </ul>	213 214
B. The Myth of Abortifacients	220
<ul> <li>II. MISSTEPS ACROSS THE BRANCHES OF GOVERNMENT</li> <li>A. Fumbles at the FDA</li> <li>B. The Trojan Horse Contraceptive Mandate Rollback</li> <li>C. The Courts <ol> <li>Stormans</li> <li>Hobby Lobby</li> </ol> </li> </ul>	224 224 227 230 230 232
III. REALIGNING SCIENTIFIC AND LEGAL UNDERSTANDINGS	234
<ul><li>A. Agencies</li><li>B. Courts</li><li>C. Politics and Public Education</li></ul>	234 235 239
IV. CULTURAL AND LEGAL IMPLICATIONS	240
A. Merging Contraception and Abortion	241
<ul><li>B. Conflating Moral and Factual Deference Under <i>Roe</i></li><li>C. The Broader Context of Fact Versus Belief</li></ul>	244 246
CONCLUSION	249

## INTRODUCTION

The battle over women's right to contraception has been long fought and yet seems to approach no end. The Supreme Court decriminalized contraception in 1965,<sup>1</sup> but Americans remain bitterly divided over whether contraception is a basic component of health care<sup>2</sup> or a means by which innocent third parties become complicit in abortions and nonprocreative sex.<sup>3</sup>

These debates play out in numerous spheres and have become increasingly salient in recent years. For example, changes to the Affordable Care Act's "contraceptive mandate" that previously required all insurers to provide free contraception to women now permit employers and other insurance providers to cite spiritual or moral opposition to contraception in order to avoid coverage, leaving female users to cover the costs.<sup>4</sup> Religious exemptions from mandatory contraception coverage have been litigated in courts at every level, including the Supreme Court in the seminal case *Hobby Lobby*.<sup>5</sup> State governments have also intervened by passing their own contraceptive mandates.<sup>6</sup>

Political objections to government- or employer-funded contraception range from objections to requiring men to support female-only health care<sup>7</sup> to concerns about promoting sex outside of marriage.<sup>8</sup> In recent years, social conserva-

<sup>1.</sup> Griswold v. Connecticut, 381 U.S. 479, 485-86 (1965).

<sup>2.</sup> See, e.g., Douglas NeJaime & Reva B. Siegel, Conscience Wars: Complicity-Based Conscience Claims in Religion and Politics, 124 YALE L.J. 2516, 2529-31 (2015).

<sup>3.</sup> See, e.g., id. at 2522-23.

Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792 (Oct. 13, 2017) (to be codified at 26 C.F.R. pt. 54; 27 C.F.R. pt. 2590; 45 C.F.R. pt. 147); Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,838 (Oct. 13, 2017) (to be codified at 26 C.F.R. pt. 54; 27 C.F.R. pt. 2590; 45 C.F.R. pt. 147).

Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751 (2014). Lower courts have also decided contentious cases. See, e.g., Stormans, Inc. v. Selecky, 854 F. Supp. 2d 925, 932-33 (W.D. Wash. 2012); Menges v. Blagojevich, 451 F. Supp. 2d 992, 995 (C.D. Ill. 2006).

See Insurance Coverage of Contraceptives, GUTTMACHER INST. (Sept. 1, 2019), https:// www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives [https:// perma.cc/CC2C-BDNZ].

<sup>7.</sup> See, e.g., Avi Selk, A Congressman Said Making a Man Get Maternity Insurance Was 'Crazy.' A Woman's Reply Went Viral, WASH. POST (May 15, 2017), https://www.washingtonpost.com /news/the-fix/wp/2017/05/15/a-congressman-said-making-a-man-get-maternity-insurance -was-crazy-a-womans-reply-went-viral [https://perma.cc/YH7T-E6PR].

<sup>8.</sup> See, e.g., Unitive and Procreative Nature of Intercourse, U.S. CONF. CATH. BISHOPS, http://www.usccb.org /issues-and-action /marriage-and-family /natural-family-planning

tives have raised a new objection: that certain forms of contraception cause abortions.<sup>9</sup> This objection has led insurance providers and pharmacists to refuse to provide those forms of contraception lest they be complicit in abortions.<sup>10</sup>

The objection is driven by the belief that certain forms of contraceptives act not by stopping ovulation (the mechanism of most forms of contraception), but instead by destroying an egg that has already been fertilized. Objectors call these contraceptives "abortifacients" because they believe that a pill that stops a fertilized egg from further developing causes an abortion.<sup>11</sup> Emergency contraception pills, commonly called "the morning after pill" or "Plan B," are the forms of contraception most commonly considered to be abortifacients. Antiabortion groups have rallied against abortifacients, most notably in the 2014 *Hobby Lobby* case.<sup>12</sup> Pharmacists have also asserted complicity-based objections to supplying abortifacients.<sup>13</sup>

Public discussion and litigation over refusals to be complicit in abortifacientcaused abortions have generally focused on whether or not a fertilized egg is a new life that ought to be protected.<sup>14</sup> The debate has thus centered on whether pregnancy begins when an egg is fertilized or later, following implantation of that fertilized egg in the uterus. Pro-choice advocates and most obstetricians say there is no pregnancy prior to implantation. Opponents of abortifacients disagree, and this dispute dominates the discourse about abortifacients.<sup>15</sup>

/catholic-teaching/upload/Unitive-and-Proc-Nature-of-Interc.pdf [https://perma.cc /PZE8-5A5U].

- **9.** See, e.g., Abortifacients: An Overview, LIFE ISSUES INST. (Sept. 29, 2014), http://www.lifeissues.org/2014/09/abortifacients-overview [https://perma.cc/YKR3-QNQZ].
- 10. *See Hobby Lobby*, 134 S. Ct. at 2764-65.
- Merriam-Webster dates the term "abortifacient" to 1857 and provides the following definition: "an agent (such as a drug) that induces abortion." *Abortifacient*, MERRIAM WEBSTER, https://www.merriam-webster.com/dictionary/abortifacient [https://perma.cc/5EME-ME25]. For use by objectors to abortion, see, for example, *supra* note 9; and *infra* note 14.
- 12. *Hobby Lobby*, 134 S. Ct. 2751.
- 13. See, e.g., Stormans, Inc. v. Selecky, 854 F. Supp. 2d 925, 932 (W.D. Wash. 2012).
- 14. See, e.g., id.; Abortifacients: An Overview, supra note 9; see also When Does Life Begin?, NAT'L RIGHT TO LIFE, http://www.nrlc.org/abortion/wdlb [https://perma.cc/LS5M-GCMJ] (quoting many sources that state that life begins at conception).

<sup>15.</sup> The American College of Obstetricians and Gynecologists defines pregnancy as beginning with implantation. *September 2015 Practice Bulletin*, AM. C. OBSTETRICIANS & GYNECOLOGISTS 2 (2015), http://acog.org/-/media/Practice-Bulletins/Committee-on-Practice-Bulletins -----Gynecology/Public/pb152.pdf [https://perma.cc/W499-6GQU]. For textbook uses of this definition, see CHARLES R.B. BECKMANN ET AL., OBSTETRICS AND GYNECOLOGY 68 (5th ed. 2006); and OBSTETRIC-GYNECOLOGIC TERMINOLOGY: WITH SECTION ON NEONATOLOGY AND GLOSSARY OF CONGENITAL ANOMALIES 299, 327 (Edward C. Hughes ed., 1972). In his 1852 obstetrics textbook, Charles D. Meigs, a professor of midwifery at Jefferson Medical College,

The dispute misses the point. In this Note, I show that litigants and the public at large ought to focus on how these forms of contraception *actually function*, because a proper understanding of the mechanism of so-called abortifacients makes clear that they do not cause abortion, no matter when one thinks pregnancy begins. The overwhelming weight of the evidence shows that Plan B and its cousin, Ella, work exactly like the common daily contraceptive pill – they stop ovulation. No egg is released, no egg is fertilized, and no fertilized egg is destroyed. Under either the pro-life or pro-choice definition of pregnancy, these "abortifacients" do not interfere with pregnancies. The term is therefore a misnomer, and as a result I will refer to Plan B and Ella as "emergency contraceptives" going forward.

Terming contraception abortive has significant social and legal effects. First, it casts the nation's political, moral, and religious opposition to abortion onto contraception without due cause. Misnaming contraceptives as abortifacients creates a false association with abortion that shapes contraceptive law and policy and impedes access to reproductive health care, making it harder for women to prevent unwanted pregnancies after unprotected sex, contraceptive failure, or rape. Second, as courts confront cases like *Hobby Lobby* that are foundationally

explained that "[f]ecundation [fertilization] is not conception [pregnancy] .... A fecundated ovulum entering into the womb through the Fallopian tube, and falling without delay into the vagina, may be destroyed or lost before conception can take place.... Conception is the fixation of a fecundated ovum upon the living surface of the mother; it is the formation of an attachment to or union with the womb, the tube, &c., of the mother." CHARLES D. MEIGS, OBSTETRICS: THE SCIENCE AND THE ART 175-76 (2d ed. 1852). The Christian Medical and Dental Associations disagree, saying, "Scientifically and biblically, conception is most appropriately defined as fertilization. . . . It is artificial and arbitrary to use other proposed biological 'markers' (such as implantation) ...." The Beginning of Human Life Ethics Statement, CHRIS-TIAN MED. & DENTAL ASS'N 12 (Apr. 2018), https://cmda.org/wp-content/uploads/2018/04 /The-Beginning-of-Human-Life-concfert.pdf [https://perma.cc/6XBW-CQX8]. Obstetricians have generally adopted the former definition because (1) the hormone that prevents menstruation and is the basis of the pregnancy test is not produced before implantation, so women cannot know if they are pregnant prior to implantation, LINDA S. COSTANZO, PHYSI-OLOGY 458 (3d ed. 2006); KEITH L. MOORE ET AL., THE DEVELOPING HUMAN: CLINICALLY ORI-ENTED EMBRYOLOGY 40 (10th ed. 2016); Allen J. Wilcox et al., Time of Implantation of the Conceptus and Loss of Pregnancy, 340 NEW ENG. J. MED. 1796, 1796 (1999); (2) in vitro fertilization allows for fertilization without pregnancy, see In Vitro Fertilization: IVF, AM. PREGNANCY ASS'N (2019), http://americanpregnancy.org/infertility/in-vitro-fertilization [https://perma.cc /UJH7-RE2Y]; and (3) pre-embyro loss occurs at a rate of about fifty percent, meaning miscarriage rates would be double their current number, COSTANZO, supra, at 458. For these reasons, the World Health Organization, Emergency Contraception: Fact Sheet, WORLD HEALTH ORG. (Feb. 2, 2018), https://www.who.int/news-room/fact-sheets/detail/emergency-contraception [https://perma.cc/4Q54-H8T3], and the U.S. Department of Health and Human Services (including the National Institutes of Health and the Food and Drug Administration) define pregnancy as starting at implantation, see 46 C.F.R. § 46.202(f) (2018) ("Pregnancy encompasses the period of time from implantation until delivery.").

reliant on the mechanism of emergency contraception, they incidentally alter our carefully crafted religious-freedom law. This happens when a court defers to a religious claim of opposition to abortion without recognizing the claim's foundation in a factual inaccuracy about how emergency contraception works. By overlooking this factual inaccuracy, the court gives religious deference to a factual claim – a phenomenon that is unprecedented, unwarranted, and carries potentially disastrous implications for broad swaths of constitutional law.

In Part I of this Note, I review the scientific evidence on the mechanisms of different forms of contraception and contrast this understanding with the public misunderstanding of how emergency contraception works. I do this to demonstrate the strength of the evidence that Plan B and other forms of emergency contraception are not abortifacients. In Part II, I discuss the entrenchment of our misunderstandings of contraception and ask who is to blame. I explore the failures of the Food and Drug Administration (FDA), the Department of Health and Human Services (HHS), and the courts to duly consider the evidence of the mechanisms of emergency contraception and restriction of rights. Part III then explores ways that agencies, courts, and the public can realign the scientific and legal understandings of emergency contraception to correct these errors.

Part IV centers on the far-reaching effects of this massive and ongoing public and legal misunderstanding, focusing on two ways in which it distorts law. I start with a discussion of how "abortifacients" have become a convenient tool to link contraception and abortion, dragging contraception into the embattled politics of abortion. I then connect our failure to reject this propagated misunderstanding to a shift in conscience-claim-deference regimes. Courts have begun to apply the deference typically reserved for moral claims ("abortion is wrong") to factual claims ("emergency contraception affects the implantation of a fertilized egg"). I consider the effects this undue deference will have on reproductive rights law as well as on claims under the Religious Freedom Restoration Act (RFRA) and Free Exercise Clause. I then place this improper conflation of facts and opinions into its broader legal context. I conclude with a silver lining: this hotly contested moral and political issue is capable of a resolution without picking and choosing between constitutionally protected rights.

# I. THE MECHANISM OF EMERGENCY CONTRACEPTION: FACT & FICTION

The medical community stands firmly behind the understanding that the mechanism of emergency contraception is nonabortifacient. To understand how the American government and the majority of the general public came to misunderstand how emergency contraception works, one first needs a basic understanding of human conception. After providing these fundamentals, I discuss the different kinds of emergency contraception and compare them to daily contraception and mifepristone, the true "abortion pill." Finally, I analyze the research on different contraceptive mechanisms and assess its strength. As I will show, it was not until recently that this science became available and more recently still that its weight has made it irresponsible to ignore.<sup>16</sup>

# A. The Process of Conception and the Physical Functioning of Emergency Contraceptives

There are three distinct stages of human conception: ovulation, fertilization, and implantation.<sup>17</sup> Ovulation begins when the female brain releases specific hormones that spike in the bloodstream, triggering the release of an egg.<sup>18</sup> Fertilization occurs when a female egg and male sperm meet.<sup>19</sup> Though it is commonly assumed that fertilization takes place during intercourse or very shortly thereafter, it can occur up to five days later.<sup>20</sup> This means that a woman can become pregnant if she ovulates and then has intercourse, or if she has intercourse

- 18. See id.; MOORE ET AL., supra note 15, at 20-22. At this time, another hormone alters the endometrium, which is the lining of the uterus, in preparation for sperm to implant in the egg and the egg to implant in the uterus. Id. at 15, at 18, 20, 23. If the egg is not fertilized, hormone levels fall and the endometrium sheds, resulting in menstruation. Id. at 23-24.
- **19.** MOORE ET AL., *supra* note 15, at 27-29 (noting that "[f]ertilization is a complex sequence of coordinated molecular events that begins with contact between a sperm and an oocyte").
- 20. Sarah Zhang, Why Science Can't Say When a Baby's Life Begins, WIRED (Oct. 2, 2015, 2:25 PM), https://www.wired.com/2015/10/science-cant-say-babys-life-begins [https://perma.cc/L3MN-MGUT] ("As the fertilization researcher Harvey Florman has said, 'Fertilization doesn't take place in a moment of passion. It takes place the next day in the laundromat or the library."). Fertilization can actually occur days after that because sperm can survive in the female body for five days. Conception: How it Works, U.C.S.F. MED. CTR., https://www.ucsfhealth.org/education/conception\_how\_it\_works [https://perma.cc/SB7H -NX9Y]. However, an egg must be fertilized within forty-eight hours after it is released. See Errol R. Norwitz et al., Implantation and the Survival of Early Pregnancy, 345 NEW ENG. J. MED. 1400, 1400 (2001); see also D.B. Dunson et al., Day-Specific Probabilities of Clinical Pregnancy Based on Two Studies with Imperfect Measures of Ovulation, 14 HUM. REPROD. 1835, 1835 (1999) (estimating a "6-day fertile interval" before ovulation); A.J. Wilcox et al., Timing of Sexual

<sup>16.</sup> The evidence presented herein comes from both primary sources, such as scientific papers in peer-reviewed journals, and secondary sources, such as medical textbooks and professional practice guides.

<sup>17.</sup> For the purposes of this paper, I aim to keep the explanation simple but accurate. The human female reproductive system is quite complex and not fully understood, so, while the information presented is correct to the best of human knowledge, the field continues to evolve. *See generally* ROBERT A. HATCHER ET AL., CONTRACEPTIVE TECHNOLOGY (21st rev. ed. 2018).

and then ovulates within the next five days. After the egg and sperm meet, they mature into a blastocyst over an additional five to seven days.<sup>21</sup> When opponents of emergency contraception say that "life begins at conception," they typically mean at this stage, when the egg is fertilized but not yet implanted.<sup>22</sup> Finally, implantation occurs when the blastocyst burrows into the endometrium and begins to transform into the placenta and embryo.<sup>23</sup> Approximately fifty percent of all fertilized eggs are lost prior to implantation.<sup>24</sup> Most obstetricians and the FDA understand pregnancy to begin at implantation.<sup>25</sup>

Emergency contraceptives function in the same way as other hormonal contraception, such as "the pill,"<sup>26</sup> by preventing or delaying ovulation. Hormonal contraceptives disrupt the feedback system between the brain and ovaries, thus inhibiting the release of an egg.<sup>27</sup> The fact that women take emergency contraception *after* intercourse helps enable the perception that emergency contraception works by preventing implantation of a fertilized egg.<sup>28</sup> However, because fertilization can take place up to five days after intercourse,<sup>29</sup> emergency contraception functions only on eggs that have not yet been released and fertilized.

Intercourse in Relation to Ovulation. Effects on Probability of Conception, 333 NEW ENG. J. MED. 1517, 1517 (1995) (estimating a "6-day interval" before ovulation).

- **21.** See MOORE ET AL., *supra* note 15, at 29-35. Maturation involves the egg and sperm reducing their combined forty-six chromosomes into the twenty-three necessary to create a human being. *Id.* at 29. As the number of chromosomes is halved, cells multiply, eventually resulting in a group of fifty to sixty cells, called a blastocyst. *Id.* at 33.
- 22. See, e.g., When Does Life Begin?, supra note 14.
- 23. This occurs approximately six to ten days after fertilization. MOORE ET AL., *supra* note 15, at 39.
- 24. Conception: How it Works, supra note 20; see also MOORE ET AL., supra note 15, at 49. Data are limited, but even under optimal conditions and timing, no more than forty percent of blasto-cysts eventually implant in the endometrium. K. Diedrich et al., *The Role of the Endometrium and Embryo in Human Implantation*, 13 HUM. REPROD. UPDATE 365, 366 (2007). Under the belief that pregnancy starts at fertilization, this loss rate would mean that there are about twice as many miscarriages happening as we currently understand there to be. *See* COSTANZO, *supra* note 15, at 458.
- 25. See supra note 15.
- 26. HATCHER ET AL., supra note 17, at 337.
- 27. *Id.* at 41. The hormones in contraceptives also thicken the cervical mucus, which can prevent or delay sperm from reaching an egg. *Id*.
- 28. Id. at 114 (explaining that although it is taken after intercourse and not before, Plan B does not prevent implantation of a fertilized egg but instead "blocks the effects of progesterone by binding to its receptors, work[ing] by preventing ovulation and disrupting luteal-phase events and endometrial development, depending on whether the drug is administered before or after ovulation").
- 29. See supra note 20 and accompanying text.

This is why doctors advise it should be taken as soon as possible after intercourse: "The best available evidence indicates that [emergency contraceptives] prevent pregnancy without any post-fertilization events."<sup>30</sup>

There are three main emergency contraceptive methods: levonorgestrel (sold as Plan B, NorLevo, and Levonelle), ulipristal acetate (sold as Ella and EllaOne), and the copper IUD (sold as ParaGuard IUD). It is also possible for a woman to take multiple pills (usually four) of a daily contraceptive as emergency contraception.<sup>31</sup>

Plan B (now sold as Plan B One-Step) is a 1.5-mg dose of levonorgestrel that was initially approved in the United States in 1982.<sup>32</sup> It should be taken within seventy-two hours of unprotected sex to be most effective.<sup>33</sup> Initially, scientists lacked the data necessary to develop a clear understanding of Plan B's mechanism. Clinical studies conducted in the early 2000s provided significant evidence that the primary mechanism of Plan B is to inhibit or delay ovulation, akin to "the pill."<sup>34</sup> Although no study identified an effect on implantation,<sup>35</sup> one 2005 study's authors concluded that "it remains uncertain" whether Plan B affected

33. HATCHER ET AL., supra note 17, at 342.

35. Durand et al., supra note 34, at 233; Marions et al., Mechanism of Action, supra note 34, at 65.

<sup>30.</sup> HATCHER ET AL., supra note 17, at 337.

<sup>31.</sup> This is called the Yuzpe Method. *Id.* at 114, 115 tbl.6-1.

<sup>32.</sup> Plan B One-Step Label, FOOD & DRUG ADMIN. 1 (July 2009), https://www.ac-cessdata.fda.gov/drugsatfda\_docs/label/2009/021998lbl.pdf [https://perma.cc/94WS-DS3A]. Plan B has been available over-the-counter since 2006. All Things Considered: 'Plan B' Gets FDA's Over-Counter Approval, NAT'L PUB. RADIO (Aug. 24, 2006, 4:00 PM), http://www.npr.org/templates/story/story.php?storyId=5705260 [https://perma.cc/QEL2-XWXX].

<sup>34.</sup> E.g., H.B. Croxatto et al., Pituitary-Ovarian Function Following the Standard Levonorgestrel Emergency Contraceptive Dose or a Single 0.75-mg Dose Given on the Days Preceding Ovulation, 70 CONTRACEPTION 442, 448 (2004); Marta Durand et al., On the Mechanisms of Action of Short-Term Levonorgestrel Administration in Emergency Contraception, 64 CONTRACEPTION 227, 232 (2001); Dharani Hapangama et al., The Effects of Peri-Ovulatory Administration of Levonorgestrel on the Menstrual Cycle, 63 CONTRACEPTION, 123, 129 (2001); Lena Marions et al., Effect of Emergency Contraception with Levonorgestrel or Mifepristone on Ovarian Function, 69 CONTRACEP-TION. 373, 376 (2004) [hereinafter Marions et al., Ovarian Function]; Lena Marions et al., Emergency Contraception with Mifepristone and Levonorgestrel: Mechanism of Action, 100 OBSTET-RICS & GYNECOLOGY 65, 70 (2002) [hereinafter Marions et al., Mechanism of Action]; Idris A. Okewole et al., Effect of Single Administration of Levonorgestrel on the Menstrual Cycle, 75 CON-TRACEPTION 372, 375-76 (2007).

implantation,<sup>36</sup> likely contributing to the origin of the abortifacient myth of Plan B.

This uncertainty was addressed by studies in the late 2000s that were designed specifically to assess the questions left open by earlier investigations. Like the initial ones, the new studies found no implantation effect of Plan B.<sup>37</sup> Then, in 2011 and 2013, the flagship journal of the Association of Reproductive Health Professionals, *Contraception*, published the two largest studies to date that again reiterated that Plan B does not affect implantation.<sup>38</sup> In recognition of the authoritative weight of the scientific evidence, the American College of Obstetricians and Gynecologists,<sup>39</sup> the National Institutes of Health, the Mayo Clinic,<sup>40</sup> and *Contraceptive Technology*,<sup>41</sup> the leading family-planning textbook and reference for the past thirty years, have all since endorsed the view that Plan B is not an abortifacient.

- 38. Kristina Gemzell-Danielsson et al., Emergency Contraception Mechanisms of Action, 87 CON-TRACEPTION 300, 304 (2013) (examining hundreds of data sets to conclude that Plan B does "not prevent blastocyst attachment and early implantation"); Gabriela Noé et al., Contraceptive Efficacy of Emergency Contraception with Levonorgestrel Given Before or After Ovulation, 84 CONTRACEPTION 486, 491 (2011) (finding that Plan B had no greater effect than a placebo when taken post-ovulation in the largest study to date).
- 39. Facts Are Important: Emergency Contraception (EC) and Intrauterine Devices (IUDs) Are Not Abortifacients, AM. C. OBSTETRICIANS & GYNECOLOGISTS (June 2014), http://www.acog.org /-/media/Departments/Government-Relations-and-Outreach/FactsAreImportantEC.pdf [https://perma.cc/T5QG-XRKA].
- 40. See Pam Belluck, Abortion Qualms on Morning-After Pill May Be Unfounded, N.Y. TIMES (June 5, 2012), http://www.nytimes.com/2012/06/06/health/research/morning-after-pills-dont -block-implantation-science-suggests.html [https://perma.cc/CRZ4-VG2V] (noting that the National Institutes of Health and Mayo Clinic have stated that Plan B works by blocking implantation).
- 41. See, e.g., HATCHER ET AL., supra note 17, at 337; James Trussell et al., Emergency Contraception: A Last Chance to Prevent Unintended Pregnancy, PRINCETON UNIV. OFF. POPULATION RES. 8 (Jan. 2019), https://ec.princeton.edu/questions/ec-review.pdf [https://perma.cc/5KLE-2HHC].

<sup>36.</sup> Marta Durand et al., Late Follicular Phase Administration of Levonorgestrel as an Emergency Contraceptive Changes the Secretory Pattern of Glycodelin in Serum and Endometrium During the Luteal Phase of the Menstrual Cycle, 71 CONTRACEPTION 451, 456 (2005).

<sup>37.</sup> E.g., Natalia Novikova et al., Effectiveness of Levonorgestrel Emergency Contraception Given Before or After Ovulation – A Pilot Study, 75 CONTRACEPTION 112, 116 (2007) (concluding that levonorgestrel has "little or no effect on postovulation events"); see also Josiane A.A. do Nascimento et al., In Vivo Assessment of the Human Sperm Acrosome Reaction and the Expression of Glycodelin-A in Human Endometrium After Levonorgestrel-Emergency Contraceptive Pill Administration, 22 HUM. REPROD. 2190, 2195 (2007); Wilder Alberto Palomino et al., A Single Midcycle Dose of Levonorgestrel Similar to Emergency Contraceptive Does Not Alter the Expression of the L-Selectin Ligand or Molecular Markers of Endometrial Receptivity, 94 FERTILITY & STERILITY 1589,1592-93 (2010).

Although Plan B is the prototypical and oldest dedicated method of emergency contraception, other methods exist and have also been mislabeled as abortifacient. Preliminary – but not insignificant – evidence about Ella, a 30-mg dose of ulipristal acetate that the FDA approved in August 2010,<sup>42</sup> indicates that it, like Plan B, acts to delay ovulation.<sup>43</sup> Unlike Plan B, Ella is capable of acting when ovulation is imminent, making it more effective than Plan B but no more an abortifacient.<sup>44</sup> Evidence about a potential implantation effect for Ella has neither developed beyond speculative theory nor been demonstrated in a lab or in humans.<sup>45</sup> In vitro evidence,<sup>46</sup> as well as numerous studies performed between 2010 and 2016 on the pre- and post-ovulatory effects of Ella, shows no effect on implantation.<sup>47</sup> As with Plan B, leading sources such as the American College of Obstetricians and Gynecologists and Contraceptive Technology take the position that Ella is not an abortifacient.<sup>48</sup> Although Ella has not been available as long as Plan B and the evidence relating to its mechanism of action is more limited, existing evidence suggests that Ella does not impede the implantation of a fertilized egg and presents no reason to suspect otherwise.

Despite strong evidence against an implantation effect with respect to Plan B and Ella, skeptics may still harbor doubt and rest their objections on the possibility that the evidence is incorrect. Yet this sort of doubt should then also apply to other hormonal contraception: the birth control pill, the implant, the vaginal ring, the patch, injectable hormones, and even breastfeeding all have the same potential but unproven postfertilization effects.<sup>49</sup> All hormonal contraception,

<sup>42.</sup> Id. at 113, 124.

**<sup>43.</sup>** V. Brache et al., *Immediate Pre-Ovulatory Administration of 30 mg Ulipristal Acetate Significantly Delays Follicular Rupture*, 25 HUM. REPROD. 2256, 2260 (2010).

**<sup>44.</sup>** See HATCHER ET AL., *supra* note 17, at 341; Trussell et al., *supra* note 41, at 4. Although some people have made policy arguments emphasizing this potential mechanism of action, *see, e.g.*, Robin F. Wilson, *The Calculus of Accommodation: Contraception, Abortion, Same-Sex Marriage, and Other Clashes Between Religion and the State*, 53 B.C. L. REV. 1417, 1454-60 (2012), Ella's late effectiveness window does not mean that it works post-ovulation by preventing ovulation, but rather that it works just up until ovulation occurs, Trussell et al., *supra* note 41, at 4.

<sup>45.</sup> Facts Are Important, supra note 39, at 2.

**<sup>46</sup>**. C. Berger et al., *Effects of Ulipristal Acetate on Human Embryo Attachment and Endometrial Cell Gene Expression in an* In Vitro Co-Culture System, 30 HUM. REPROD. 800, 805-06 (2015).

<sup>47.</sup> Gemzell-Danielsson et al., *supra* note 38; H.W.R. Li et al., *Efficacy of Ulipristal Acetate for Emergency Contraception and its Effect on the Subsequent Bleeding Pattern when Administered Before or After Ovulation*, 31 HUM. REPROD. 1200, 1205 (2016). The 2013 survey study that confirmed the mechanism of Plan B also led to the conclusion that the effect of Ella's dosage on implantation "was similar to that of [a] placebo." Gemzell-Danielsson et al., *supra* note 38, at 304.

<sup>48.</sup> HATCHER ET AL., supra note 17, at 337; Facts are Important, supra note 39.

<sup>49.</sup> HATCHER ET AL., *supra* note 17, at 337.

including emergency contraception, potentially acts to alter the endometrium (the lining of the uterus, where implantation occurs) and or change the motility in the fallopian tubes (through which sperm and fertilized eggs travel).<sup>50</sup> Studies do not demonstrate these effects, but it is of course still possible. In fact, it is more probable that daily contraceptives affect implantation than emergency contraceptives do, because a daily dose of hormones over a long period of time is more likely to have an effect in the body than a single dose.<sup>51</sup>

That said, it is very unlikely that breastfeeding and all hormonal contraceptives are actually abortifacients. Research measuring the rate at which fertilized eggs fail to implant shows that women who use hormonal contraception are no more likely than women who do not to have a fertilized egg not implant.<sup>52</sup> This strongly suggests that contraception is not affecting implantation. While it is scientifically impossible to prove a negative proposition (namely, that none of these contraceptive methods, including breastfeeding, inhibit the implantation of a fertilized egg), the best scientific evidence available suggests that hormonal contraceptives do not have this implantation effect.<sup>53</sup> For this reason, Plan B and Ella ought not to be called abortifacients.

The copper IUD somewhat complicates the picture of emergency contraception's implantation effects. It is a nonhormonal form of emergency contraception that is rarely used in emergency situations.<sup>54</sup> However, insertion of the copper

<sup>50.</sup> Id.; Mary K. Collins, Conscience Clauses and Oral Contraceptives: Conscientious Objection or Calculated Obstruction?, 15 ANNALS HEALTH L. 37, 42 (2006); Roberto Rivera et al., The Mechanism of Action of Hormonal Contraceptives and Intrauterine Contraceptive Devices, 181 AM. J. OBSTET-RICS & GYNECOLOGY 1263, 1264, 1266-67 (1999).

Interview with Dr. Meredith Pensak, Family Planning Fellow, Yale New Haven Hospital, in New Haven, Conn. (Mar. 2, 2017). Dr. Pensak provided guidance on the scientific aspects of this paper and confirmed their medical accuracy.

**<sup>52</sup>**. Collins, *supra* note 50 at 43-44 (showing that research does not demonstrate a higher rate of pre-embryo loss in women who use oral contraceptives than in those who do not).

<sup>53.</sup> Trussell, supra note 41, at 5; see also Christina Cauterucci, Why Aren't More Young Women Choosing Set-It-and-Forget-It IUDs? SLATE (May 12, 2016), http://www.slate.com/blogs/xx\_factor /2016/05/12/why\_aren\_t\_more\_young\_women\_choosing\_iuds.html [https://perma.cc /B4AN-YWNS].

<sup>54.</sup> The copper IUD is both a long-term contraceptive and an effective emergency contraception. A study of California family-planning clinicians found that eighty-five percent do not recommend insertion of a copper IUD as emergency contraception. Cynthia Harper et al., *Copper Intrauterine Device for Emergency Contraception: Clinical Practice Among Contraception Providers*, 119 OBSTETRICS & GYNECOLOGY 220, 223 (Feb. 2012). However, the copper IUD is more than ninety-nine percent effective, which is substantially more effective than emergency-contraception pills. The reluctance of clinicians to offer copper IUDs for emergency contraception is thought to arise from expense, lack of training on IUD insertion, women preferring not to

IUD to prevent pregnancy works in ninety-nine percent of cases, suggesting that the copper IUD has very strong mechanisms of action, which could encompass inhibiting the implantation of a fertilized egg.<sup>55</sup> If one believes that pregnancy starts at fertilization, the copper IUD may be considered a true "abortifacient." The pharmaceutical with an undisputed abortifacient effect is RU-486, also called mifepristone, which physicians use to end pregnancies up to seventy days after intercourse, long after fertilization and implantation.<sup>56</sup> Plan B and Ella, however, have not been shown to have this abortifacient effect, despite claims to the contrary. They are the focus of this Note.

## B. The Myth of Abortifacients

Despite the evidence that emergency contraception does not cause abortions, pro-life groups characterize Plan B and Ella as abortifacients equivalent to mifepristone. Americans United for Life asserts that "Plan B... can kill an embryo,"<sup>57</sup> while other conservatives claim that emergency contraception is "abortion-inducing."<sup>58</sup> The Susan B. Anthony List, an activist organization whose

have a long-term method of birth control, and lack of information. Peter Belden et al., *The Copper IUD for Emergency Contraception, a Neglected Option*, 85 CONTRACEPTION 338 (2012).

- 55. Trussell et al., supra note 41, at 5; see María Elena Ortiz & Horacio B. Croxatto, Copper-T Intrauterine Device and Levonorgestrel Intrauterine System: Biological Bases of Their Mechanism of Action, 75 CONTRACEPTION S16, S17 (2007); Joseph B. Stanford & Rafael T. Mikolajczyk, Mechanisms of Action of Intrauterine Devices: Update and Estimation of Postfertilization Effects, 187 AM. J. OBSTETRIC GYNECOLOGY 1699, 1701-02 (2002).
- 56. See, e.g., Irving M. Spitz et al., Early Pregnancy Termination with Mifepristone and Misoprostol in the United States, 338 NEW ENG. J. MED. 1241 (1998). But see Marions et al., Ovarian Function, supra note 34, at 373, 376 (questioning the abortifacient label). The abortifacient effect of mifepristone is actually dose-dependent; in China, low doses of mifepristone are used as emergency contraception. Linan Cheng et al., Interventions for Emergency Contraception, COCHRANE DATABASE OF SYSTEMATIC REVIEWS 2 (2004). Misoprostol is another true abortifacient that is either used in conjunction with mifepristone or by itself to induce abortion. See A. Faúndes et al., Misoprostol for the Termination of Pregnancy up to 12 Completed Weeks of Pregnancy, 99 INT'L J. GYNECOLOGY & OBSTETRICS (Supplement 2) S172 (2007), http://www.misoprostol.org /downloads/misoprostol-journals/IJGO\_1triabn\_Faundes.pdf [https://perma.cc/LN9S -N67G].
- Back Door Abortion Mandate in Health Care Reform, AM. UNITED FOR LIFE (Nov. 15, 2010), http://www.aul.org/2010/11/back-door-abortion-mandate-in-health-care-reform [https:// perma.cc/TZP7-6EFF].
- 58. E.g., Sarah Torre, Obama Administration's Eighth Try on HHS Mandate and Religious Liberty Still Fails, DAILY SIGNAL (Aug. 22, 2014), http://www.dailysignal.com/2014/08/22/obama -adminstrations-eighth-try-hhs-mandate-religious-liberty-still-fails [https://perma.cc /49Q2-WHPT]; Abortifacients: An Overview, LIFE ISSUES INST. (Sept. 29, 2014), http:// www.lifeissues.org/2014/09/abortifacients-overview [https://perma.cc/735A-65XB]. But see

"mission is to end abortion,"<sup>59</sup> was among those that called the Affordable Care Act's (ACA's) required coverage of contraception an "Abortion Drug Mandate" because it includes emergency contraception.<sup>60</sup> Similarly, the American Association of Pro-Life Obstetricians and Gynecologists filed an amicus brief in *Hobby Lobby* on behalf of the employers seeking to restrict the ACA's contraception coverage because of the inclusion of emergency contraception.<sup>61</sup> Politicians have also called emergency contraception "abortive pills."<sup>62</sup>

This mislabeling of emergency contraception is not a new problem. Between 2002 and 2010, concern from some members of Congress led to extended delay in stocking military hospitals with emergency contraception, which doctors consider to be an essential element in hospital supplies, particularly for victims of sexual assault.<sup>63</sup> Similarly, for nearly a decade, the Department of Justice did not

- Amicus Curiae Brief of Am. Physicians & Surgeons et al. in Support of Appellants, Conestoga Wood Specialties Corp. v. Sebelius, 724 F.3d 377 (3d Cir. 2013) (No. 13-1144).
- 62. See, e.g., Ashley Parker, Romney Attacks Obama on Birth Control Rule, N.Y. TIMES: THE CAUCUS (Feb. 6, 2012, 11:18 PM), https://thecaucus.blogs.nytimes.com/2012/02/06/romney-attacks -obama-on-birth-control-rule [https://perma.cc/PXS6-W83Y]; see also Jenavieve Hatch, Brett Kavanaugh Refers to Birth Control as 'Abortion-Inducing Drugs' at Confirmation Hearing, HUFFPOST (Sept. 6, 2018, 3:37 PM), https://www.huffpost.com/entry/brett-kavanaugh -birth-control\_n\_5b917b79e4b0162f472b3cb8 [https://perma.cc/WY5Z-E4M3].
- **63.** U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-06-109, FOOD AND DRUG ADMINISTRATION: DE-CISION PROCESS TO DENY INITIAL APPLICATION FOR OVER-THE-COUNTER MARKETING OF THE EMERGENCY CONTRACEPTIVE DRUG PLAN B WAS UNUSUAL (2005) [hereinafter GAO REPORT]. The Department of Defense considered the potential abortifacient effect of Plan B when making its determination to exclude Plan B from the list of drugs every military pharmacy should have available. *See* DAVID F. BURRELLI, CONG. RESEARCH SERV., 95-387, ABORTION SERVICES AND MILITARY MEDICAL FACILITIES 11-12 (2013), https://fas.org/sgp/crs/misc/95-387.pdf [https://perma.cc/ARH5-FL5T]; *see also* thedrifter, *Emergency Contraception Still Available*, LEATHERNECK.COM (May 1, 2007, 7:59 AM), http://www.leatherneck.com/forums/archive /index.php/t-45720.html [https://perma.cc/U9AC-FTD8] (quoting Rick Maze, *Emergency Contraception Still Available*, MARINE CORPS TIMES (Apr. 30, 2007, 5:00 PM), which reported: "Plan B was added to the basic core formulary [a list of drugs that every pharmacy should

Rich Poupard, *Plan B EC: No Morphological Changes Found in Endometrium*, LIFE TRAINING INST. BLOG (Sept. 1, 2006), http://lti-blog.blogspot.com/2006/12/plan-b-ec-no-morphological-changes.html [https://perma.cc/74KR-U4DY].

About, SUSAN B. ANTHONY LIST, https://www.sba-list.org/about-susan-b-anthony-list [https://perma.cc/5QWS-DREG].

<sup>60.</sup> Taxpayer Funding of Abortion in Obamacare, SUSAN B. ANTHONY LIST, https://www.sba -list.org/taxpayer-funding-aca [https://perma.cc/8TX2-YTDC]; see also Back Door Abortion Mandate in Health Care Reform, supra note 57; John McCormack, Obamacare Will Mandate Free Coverage of Abortion Drug & Contraception Without Religious Exemption, WKLY. STANDARD (Jan. 20, 2012, 2:03 PM), http://www.weeklystandard.com/obamacare-will-mandate-free -coverage-of-abortion-drug-contraception-without-religious-exemption/article/617361 [https://perma.cc/88B7-JZK8].

#### THE YALE LAW JOURNAL

include emergency contraception in the National Protocol for Sexual Assault Medical Forensic Examinations.<sup>64</sup>

Antagonism toward emergency contraception is likely exacerbated by the fact that large segments of the American public are generally unaware of how Plan B functions. Among women who have heard of emergency contraception,<sup>65</sup> most do not know how it works.<sup>66</sup> A 2005 *Contraception* study found that thirty-nine percent of Boston women believe that emergency contraception works by "preventing pregnancy,"<sup>67</sup> but a study in the *Annals of Family Medicine* found that just twenty-four percent of women correctly identified that emergency contraception works "before fertilization."<sup>68</sup>

- 64. OFFICE ON VIOLENCE AGAINST WOMEN, U.S. DEP'T JUSTICE, NCJ 206554, A NATIONAL PROTO-COL FOR SEXUAL ASSAULT MEDICAL FORENSIC EXAMINATIONS: ADULTS/ADOLESCENTS (2004), https://www.ncjrs.gov/pdffiles1/nij/206554.pdf [https://perma.cc/HGQ8-ZA4E]. The Protocol was updated in 2013 and now includes information on emergency contraception. OFFICE ON VIOLENCE AGAINST WOMEN, U.S. DEP'T. JUSTICE, NCJ 228119, A NATIONAL PROTOCOL FOR SEXUAL ASSAULT MEDICAL FORENSIC EXAMINATIONS: ADULTS/ADOLESCENTS (2013), https:// www.ncjrs.gov/pdffiles1/ovw/241903.pdf [https://perma.cc/KW7R-944R].
- **65.** Studies show that many women, particularly women of color, are not only unaware of how Plan B functions but have, in fact, never heard of emergency contraception. *See* Cynthia H. Chuang & Karen M. Freund, *Emergency Contraception Knowledge Among Women in a Boston Community*, 71 CONTRACEPTION 157, 157 (2005) (documenting that 82% of participants have heard of emergency contraception, but only 51% of Latina women and 75% of black women have heard of emergency *Contraception: Knowledge and Perceptions in a University Population*, 18 J. AM. ACAD. NURSE PRACS. 161-68 (2006) (documenting that 75% of college-age respondents knew of a postcoital method to prevent pregnancy and 96% have heard of emergency contraception).
- 66. See Chuang & Freund, supra note 65. For a discussion of misunderstandings of the functioning of emergency contraception in popular culture, see Hazel Cills, *Film and TV Have No Idea How the Abortion Pill Works*, JEZEBEL: THE MUSE (May 11, 2018, 1:31 PM), https://themuse.jezebel.com/film-and-tv-have-no-idea-how-the-abortion-pill-works-1825891382 [https://perma.cc/98PM-V4ZX].
- 67. Chuang & Freund, supra note 65, at 159.
- John W. Campbell III et al., Attitudes and Beliefs About Emergency Contraception Among Patients at Academic Family Medicine Clinics, 6 ANNALS FAM. MED. S23, S26 tbl. 2 (2008).

have available] in March 2002 but it did not remain on the list for long. Within hours, the Tricare Management Agency started receiving inquir[i]es from lawmakers that centered on whether Plan B caused an abortion. [Defense Department spokesman James] Tyll said it was the Defense Department's view that the drug does not cause an abortion but rather prevents a pregnancy."); boardman, *RAO Bulletin Update – 15 May 2007*, 2ND BATTALION, 5TH MARINES (May 23, 2007 9:53 AM), http://www.2ndbn5thmarines.com/phpBB3/viewtopic.php?t=578 [https://perma.cc/DGN4-HW6Q] (same).

These misunderstandings likely decrease the number of women willing to use emergency contraception. In a *Contraception* study examining why emergency conception use is so low among Latina women in the United States, researchers found that among women who had heard of emergency contraception, willingness to use it depended on whether those women knew its mechanism.<sup>69</sup> Surprisingly, knowing how emergency contraception works was significantly more important than the woman's religious background.<sup>70</sup> Direct survey responses similarly show that willingness to use emergency contraception depends on its mechanism of action.<sup>71</sup> While some women are never willing to use it (11%) and some say they will use it whatever the mechanism is (18%), more women care that it works before the sperm and egg join (20%) and before implantation occurs (18%).<sup>72</sup> This fits with evidence on the high rates of contraceptive use in the United States – women who know how emergency contraception works seem to be comfortable using it, like they are with other forms of contraception.<sup>73</sup>

These studies and surveys demonstrate why the mechanism of emergency contraception matters: women who know the mechanism of emergency contraception are more willing to use it and are therefore better able to take precautions against unwanted pregnancies without facing potentially challenging moral choices. Pro-life women who consider using emergency contraception need not have qualms akin to those they would face when deciding whether to have an abortion. Despite these high stakes, few attempts have been made to combat this misinformation.<sup>74</sup> News sources have rarely addressed the issue, and litigants

**70**. Id.

72. Id.

**<sup>69</sup>**. Laura F. Romo et al., *The Role of Misconceptions on Latino Women's Acceptance of Emergency Contraceptive Pills*, 69 CONTRACEPTION 227, 233 (2004).

<sup>71.</sup> Campbell et al., *supra* note 68, at S26 tbl.2.

<sup>73.</sup> Most women, including religious women, use contraception that has the same functionality as emergency contraception. More than 99% of women aged 15-44 who have had sex have used at least one contraceptive method and 62% of all women of reproductive age are currently using a contraceptive method. *Contraceptive Use in the United States*, GUTTMACHER INST. (July 2018), https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states [https:// perma.cc/5KCE-9QYX]. Moreover, 89% of Catholics at risk of pregnancy and "90% of at-risk Protestants currently use a [contraceptive] method. Among sexually experienced religious women, 99% of Catholics and Protestants have ever used some form of contraception." *Id.* 

<sup>74.</sup> A notable exception is Priscilla Smith's work. Priscilla J. Smith, Contraceptive Comstockery: Reasoning from Immorality to Illness in the Twenty-First Century, 47 CONN. L. REV 971, 1012-17 (2015); see also Joerg Dreweke, Contraception Is Not Abortion: The Strategic Campaign of Antiabortion Groups to Persuade the Public Otherwise, 17 GUTTMACHER POL'Y REV. 14, 15-16 (2014),

have generally avoided delving into the science.<sup>75</sup> As I show in Part II, this is largely driven by the government's reinforcement of contraceptive misinformation.

# **II. MISSTEPS ACROSS THE BRANCHES OF GOVERNMENT**

Emergency contraception has been misunderstood by every branch of government to touch it. The Department of Health and Human Services and the federal courts treat emergency contraception as abortion-inducing, typically citing the FDA's labeling of Plan B for support. In this Part, I look at Plan B's history at the FDA, the Trump Administration's regulations exempting those with religious or moral objections from providing contraception coverage, and two Supreme Court cases that relied on inaccurate factual understandings of the mechanisms of emergency contraception. What emerges is a story of how this misunderstanding pervades government and, in turn, perpetuates the error.

# A. Fumbles at the FDA

The FDA requires that the Plan B labeling state that it "will not work if you are already pregnant and will not affect an existing pregnancy," "there is no medical evidence that Plan B[] . . . would harm a developing baby," and also that Plan B "works mainly by stopping the release of an egg from the ovary."<sup>76</sup> Yet, the labeling also claims that "[i]t is possible that . . . preventing fertilization of an egg (the uniting of sperm with the egg) or . . . preventing attachment (implantation) to the uterus (womb)" is a function of Plan B.<sup>77</sup> The labeling thus gives two mechanisms of action for Plan B, one that remains supported by scientists and one that is outdated and misleading.

The FDA first approved Plan B in 1982 when scientists did not fully understand how the drug worked.<sup>78</sup> The FDA wrote the labeling requirements to encompass all potential mechanisms of action, likely at the behest of the manufacturer. Listing multiple mechanisms was probably thought to suggest that the

78. See supra Section I.A.

https://www.guttmacher.org/pubs/gpr/17/4/gpr170414.pdf [https://perma.cc/DL5H-PJNA].

<sup>75.</sup> See, e.g., Belluck, supra note 40.

<sup>76.</sup> See Plan B One-Step Label, supra note 32, at 3, 7, 10; see also Prescription Drug Products; Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception, 62 Fed. Reg. 8610 (1997) ("Emergency contraceptive pills are not effective if the woman is pregnant....").

**<sup>77</sup>**. *Id*. at 7.

drug was more effective, which would have been an asset for a new pharmaceutical. However, as new studies showed that Plan B has only one mechanism, the FDA did not update the labeling and has not done so since. This is despite the FDA's legal mandate to ensure that pharmaceutical labeling accurately describes drug mechanisms.<sup>79</sup> And even though pharmaceutical companies rarely apply to update labeling because doing so is expensive,<sup>80</sup> Plan B's manufacturer sought to update the labeling. The FDA, however, denied the request without explanation.<sup>81</sup>

Starting in the early 2000s and lasting through the Obama Administration, the FDA was caught in another controversy over Plan B that may help explain its refusal to update the labeling. Plan B's manufacturer sought to make Plan B available over the counter, and politicians in Congress and elsewhere resisted.<sup>82</sup> The FDA committee tasked with making an advisory decision voted overwhelmingly in favor of the change to increase access to Plan B.<sup>83</sup> FDA officials, however, rejected the recommendation, causing the agency's director of women's health

- 79. 21 C.F.R. § 201.56(a)(2) (2018) ("The labeling must be informative and accurate ... [and] must be updated when new information becomes available that causes the labeling to become inaccurate, false, or misleading."); *see also* FOOD & DRUG ADMIN., CLINICAL PHARMACOLOGY SECTION OF LABELING FOR HUMAN PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS CONTENT AND FORMAT: GUIDANCE FOR INDUSTRY 5-6 (2016), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM109739.pdf [https://perma.cc/FEX2-7NVR] ("Speculative claims of untested MOAs [Mechanisms of Action] and unsupported suggestions of therapeutic advantages based on MOA may be false or misleading and, therefore, must be avoided.").
- 80. The cost of a supplemental drug application with clinical data, as would be needed to update the label, has historically cost approximately \$400,000. See FOOD & DRUG ADMIN., STANDARD COSTS (IN THOUSANDS OF DOLLARS) FOR COMPONENTS OF THE PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS (2018), https://www.fda.gov/industry/prescription-drug-user -fee-amendments /standard-costs-thousands-dollars-components -process-review-human -drug-applications [https://perma.cc/A3QM-W7UJ].
- 81. Belluck, supra note 40.
- 82. See Erica S. Mellick, Comment, *Time for Plan B: Increasing Access to Emergency Contraception and Minimizing Conflicts of Conscience*, 9 J. HEALTH CARE L. & POL'Y 402, 409-10 (2006); see also Leslie C. Griffin, *Conscience and Emergency Contraception*, 6 HOUS. J. HEALTH L. & POL'Y 299, 307-08 (2006) (telling the story of Barr Pharmaceutical's attempt to get FDA approval to sell Plan B over the counter); Alastair J.J. Wood et al., A Sad Day for Science at the FDA, 353 NEW ENG. J. MED. 1197, 1197-99 (2005) (same).
- 83. Marcia M. Boumil & Dana Sussman, *Emergency Contraception: Law, Policy and Practice*, 7 CONN. PUB. INT. L.J. 1, 8 (2008).

to resign in protest.<sup>84</sup> The American Medical Association printed the former director's explanation of her resignation, titled *Inappropriate Obstructions to Access: The FDA's Handling of Plan B.*<sup>85</sup>

A federal district court found the FDA had "acted in bad faith and in response to political pressure" by "repeatedly and unreasonably delay[ing] issuing a decision on Plan B" and restricting access based on "fanciful and wholly unsubstantiated 'enforcement' concerns."<sup>86</sup> The decision specifically noted "pressure emanating from the White House" and "the obvious connection between the confirmation process of two FDA Commissioners and the timing of the FDA's decisions."<sup>87</sup> The court therefore ordered the FDA to make Plan B available over the counter to women of all ages. Health and Human Services Secretary Kathleen Sebelius ignored the instruction and directed the FDA Commissioner to deny over-the-counter status to Plan B for women under the age of seventeen.<sup>88</sup> After another court order,<sup>89</sup> the FDA finally acquiesced and made Plan B available over the counter to girls fifteen-years-old and over.<sup>90</sup>

Whereas European regulators have updated the labeling of NorLevo, the European version of Plan B, to state that the drug "cannot stop a fertilized egg from

- Susan F. Wood, Inappropriate Obstructions to Access: The FDA's Handling of Plan B, 16 AM. MED. ASS'N J. ETHICS 295 (2014).
- 86. Tummino v. Torti, 603 F. Supp. 2d 519, 523, 546, 548 (E.D.N.Y. 2009) (*Tummino I*), amended sub nom. Tummino v. Hamburg, No. 05-CV-366 (ERK) (VVP), 2013 WL 865851 (E.D.N.Y. Mar. 6, 2013). The GAO also issued a report in 2005 that similarly found agency bad faith. GAO REPORT, supra note 63.
- 87. Tummino I, 603 F. Supp. 2d at 544.
- Press Release, Food & Drug Admin., Statement from FDA Commissioner Margaret Hamburg, M.D. on Plan B One-Step (Dec. 7, 2011), https://www.prnewswire.com/news -releases /statement-from-fda-commissioner -margaret-hamburg-md -on-plan-b-one-step -135184603.html [https://perma.cc/SN3V-8H8F].
- 89. Tummino v. Hamburg (Tummino II), 936 F. Supp. 2d 162, 171-74 (E.D.N.Y. 2013).
- 90. Sarah Kliff, FDA: Plan B Will Be Over the Counter for Women 15 and Over, WASH. POST (Apr. 30, 2013), https://www.washingtonpost.com/news/wonk/wp/2013/04/30/fda-plan-b-will -be-over-the-counter-for-women-over-15 [https://perma.cc/WMW5-TC6M]. It was thought at the time that making Plan B available over the counter would decrease stigma. See Mellick, *supra* note 82, at 440. This does not seem to have been the case.

<sup>84.</sup> Mellick, supra note 82, at 408-10; Susan F. Wood, The Role of Science in Health Policy Decision-Making: The Case of Emergency Contraception, 17 HEALTH MATRIX 273, 285 (2007); Susan F. Wood, Opinion, When Politics Defeats Science, WASH. POST (Mar. 1, 2006), http:// www.washingtonpost.com /wp-dyn/content/article/2006 /02/28/AR2006022801027.html [https://perma.cc/KZT5-RHWT].

attaching to the womb,"<sup>91</sup> the FDA has made no similar attempt to update Plan B's labeling. Political influence and intervention into FDA decisions regarding Plan B's over-the-counter status raise the question of whether the FDA's failure to update the mechanism of action on the labeling can be attributed to decisionmakers placing political concerns over accuracy and access to health care.<sup>92</sup> Due to the label's inaccuracy, the National Institutes of Health and the Mayo Clinic, institutions that typically follow FDA guidance, no longer follow the FDA's Plan B labeling.<sup>93</sup> The FDA's failure to respond adequately and promptly to the updated scientific consensus enables pro-life groups<sup>94</sup> and the Department of Health and Human Services' new Office of Civil Rights<sup>95</sup> to cite the labeling as the strongest evidence of Plan B's "abortifacient" mechanism. I discuss below how pro-life litigants and HHS use the labeling to explain advocating positions and policy decisions that restrict access to care.

# B. The Trojan Horse Contraceptive Mandate Rollback

In October 2017, HHS issued two interim final rules providing for religious and moral exemptions and accommodations for insurance coverage of contraception.<sup>96</sup> The Affordable Care Act requires by law that insurers cover women's preventive services, which includes all forms of hormonal contraception.<sup>97</sup> Following an Executive Order from President Trump calling religious liberty

- **93**. Belluck, *supra* note 40.
- 94. Christopher M. Gacek, Conceiving "Pregnancy": U.S. Medical Dictionaries and Their Definitions of "Conception" and "Pregnancy", NAT'L FAMILY RES. COUNCIL (Apr. 2009), http:// downloads.frc.org/EF/EF09D12.pdf [https://perma.cc/48MH-48XG]; William Saunders & Mailee Smith, Emergency "Contraception" Can End the Life of a Unique Human, LIFENEWS (May 9, 2013, 5:30 PM), http://www.lifenews.com/2013/05/09/emergency-contraception-can -end-the-life-of-a-unique-human-being [https://perma.cc/SM5Q-3KZX].
- **95**. *See supra* Section I.B.

97. 42 U.S.C. § 300gg-13(a)(4) (2018).

<sup>91.</sup> NorLevo 1.5mg Tablet, DELPHARM 1 (2017), https://www.hpra.ie/img/uploaded /swedocuments/PIL-2194006-28062017105522-636342441250781250.pdf [https://perma.cc /X847-62QQ].

<sup>92.</sup> In addition to failing to update Plan B labeling, the FDA has also failed to update the labeling and dosing information for RU-486, the pill actually used to induce abortion. See Michael F. Greene & Jeffrey M. Drazen, A New Label for Mifepristone, 374 NEW ENG. J. MED. 2281, 2281-82 (2016).

**<sup>96</sup>**. Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,838, 47,840 n.7 (Oct. 13, 2017); Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792, 47,794 n.7 (Oct. 13, 2017).

"Americans' first freedom,"<sup>98</sup> the rules limit the ACA's preventive-care mandate by exempting insurers with religious and moral objections to contraception. To do so, they rely on the abortifacient myth and the FDA's inaccurate labeling.

The interim final rules were over two hundred pages in length, yet devoted a mere footnote to explaining their opposition to emergency contraception.<sup>99</sup> HHS stated that the contraceptive mandate covered all FDA-approved contraceptives, and "[b]ecause FDA includes in the category of 'contraceptives' certain drugs and devices that may not only prevent conception (fertilization), but may also prevent implantation of an embryo," the mandate "included several contraceptive methods that many persons and organizations believe are abortifacient – that is, as causing early abortion – and which they conscientiously oppose for that reason."<sup>100</sup> HHS supported the assertion that some contraceptive drugs may prevent the implantation of an egg with a citation to the FDA's website, which, following the labeling, states that Plan B, Ella, and the copper IUD may stop the implantation of a fertilized egg.<sup>101</sup>

The FDA's outdated Plan B labeling enabled the Trump Administration to exempt employers from providing not only emergency contraception, but also every other form of contraception. The interim final rules cited no evidence of abortifacient effects of daily contraception like the pill or the patch, and yet, under the rules, employers and others will be able to claim religious and moral objections to these forms of contraception. While some people may have religious or moral opposition to nonprocreative sex and thus object to all forms of contraception, the interim final rules do not follow that line of reasoning. Instead, the rules repeatedly cite *Hobby Lobby* and other emergency contraception cases to

Exec. Order No. 13,798, 82 Fed. Reg. 21,675 (May 4, 2017) (directing agencies to "consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under [the Women's Health Amendment]").

<sup>99.</sup> See Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. at 47,840 n.7; Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. at 47,794 n.7.

<sup>100.</sup> Moral Exemptions and Accommodations for Coverage of Certain Preventive Services, 82 Fed. Reg. at 47,840-41; Religious Exemptions and Accommodations for Coverage of Certain Preventive Services, 82 Fed. Reg. at 47,794-95.

<sup>101.</sup> Birth Control, FDA (Mar. 6, 2018), https://www.fda.gov/forconsumers/byaudience /forwomen/freepublications/ucm313215.htm [https://perma.cc/P52X-ZBQR].

reason that all forms of contraception can be excluded from health plans.<sup>102</sup> In Section IV.A, I will consider the legal and political ramifications of such efforts to merge contraception and abortion into the same rhetorical space.

In November 2018, HHS published final versions of the rules that capitalize on the FDA's labeling errors to further enable widespread opposition to contraception.<sup>103</sup> In response to comments from the public disputing that some of the forms of hormonal contraceptives are abortifacient, HHS stated that, "objection on this issue appears to be partially one of semantics" and of differing definitions of contraception and pregnancy.<sup>104</sup> According to HHS, "[t]he Departments do not take a position on the scientific, religious, or moral debates on this issue."105 Yet, as discussed above, under no definition of contraception or pregnancy does hormonal emergency contraception cause abortion.<sup>106</sup> The response to comments went on to point again to "FDA's statement that some contraceptives may prevent implantation" and reiterated that "[t]he Supreme Court has already recognized that such a view can form the basis of a sincerely held religious belief."107 The rules provide no independent legal basis for accommodating opposition to all forms of contraception. They instead rely on the Trojan horse of emergency contraception. Thus, HHS's justification for the rules repeatedly and unproductively circles around the FDA labeling, and litigation in response to the rules has failed to confront the issue.<sup>108</sup>

- 104. Religious Exemptions and Accommodations for Coverage of Certain Preventive Services, 83 Fed. Reg. at 57,554.
- 105. Id.

- 107. Religious Exemptions and Accommodations for Coverage of Certain Preventive Services, 83 Fed. Reg. at 57,554; see also id. at n.39 (citing the FDA).
- 108. See, e.g., California v. Health & Human Servs., 351 F. Supp. 3d 1267 (N.D. Cal. 2019) (challenging the HHS rules on APA and constitutional grounds); Pennsylvania v. Trump, 351 F. Supp. 3d 791 (E.D. Pa. 2019); Complaint, Massachusetts v. U.S. Dep't Health & Human

<sup>102.</sup> See, e.g., Moral Exemptions and Accommodations for Coverage of Certain Preventive Services, 82 Fed. Reg. 47,838 passim (citing Hobby Lobby and other conscience cases over emergency contraception); Religious Exemptions and Accommodations for Coverage of Certain Preventive Services, 82 Fed. Reg. 47,792 passim (same).

<sup>103.</sup> Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,592 (Nov. 15, 2018); Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536 (Nov. 15, 2018).

<sup>106.</sup> See supra Section I.A. It is also difficult to understand what HHS meant when it claimed a difference in semantics on the meaning of pregnancy and that it does not have to take a position on the scientific issue. HHS has adopted by regulation this definition of pregnancy: "Pregnancy encompasses the period of time from implantation until delivery." 46 C.F.R. § 46.202(f) (2018). Even under FDA's incorrect labeling, emergency contraception does not cause abortion based on HHS's own definition of pregnancy.

# C. The Courts

Like the FDA and HHS, the courts have failed to take into account the mechanism of emergency contraception. This has twice affected the outcomes of controversial Supreme Court cases. This Section addresses how two of the most significant legal challenges to contraception in recent years have been based on incorrect assumptions about the mechanism of emergency contraception. The courts' failures to correct litigants' errors have gone unaddressed and carry significant consequences for the future landscape of religious and reproductive rights.

# 1. Stormans

In 2015, the Ninth Circuit decided the closely watched case of *Stormans v*. *Wiesman*, <sup>109</sup> basing its decision on an incorrect understanding of how emergency contraception functions. On appeal to the Supreme Court, none of the Justices – including the Justices who dissented from the Court's denial of certiorari– caught the error.

*Stormans* arose from the refusal of several Washington State pharmacists to deliver Plan B and Ella to their customers. The pharmacists believed that Plan B and Ella cause abortions and objected on religious grounds. The pharmacists' refusal violated state regulations that require pharmacies to deliver all prescription medications.<sup>110</sup> In the litigation, both parties focused on the pharmacists' rights under the Free Exercise Clause. Under Free Exercise, courts do not interrogate the veracity of religious beliefs, so the parties agreed to exclude evidence on the mechanisms of emergency contraception. However, the pharmacists' beliefs were two-part: a religious belief regarding the morality of abortion and an

Servs., 923 F.3d 209 (1st Cir. 2019) (No. 11930); Complaint, Pennsylvania v. Trump, 281 F. Supp. 3d 553 (E.D. Pa. 2017) (No. 2:17-04540); Complaint, Med. Students for Choice v. Wright, No. 1:17-cv-02096 (D.D.C. Oct. 10, 2017); Complaint, Washington v. Trump, No. 01510 (W.D. Wash. Oct. 9, 2017); Complaint, California v. Wright, No. 05783 (N.D. Cal. Oct. 6, 2017); Complaint, Am. Civil Liberties Union v. Wright, No. 05772 (N.D. Cal. Oct. 6, 2017).

<sup>109.</sup> Stormans v. Wiesman, 794 F.3d 1064 (9th Cir. 2015), *rev'g* Stormans, Inc. v. Selecky, 854 F. Supp. 2d 925 (W.D. Wash. 2012).

<sup>110.</sup> See WASH. ADMIN. CODE § 246-869-150(1) (2018) ("The pharmacy must maintain at all times a representative assortment of drugs in order to meet the pharmaceutical needs of its patients."); WASH. REV. CODE § 18.64.005(7) (2018) (establishing that violating state regulations creates grounds for refusing to issue, suspending, or revoking a license).

underlying belief that Plan B and Ella are abortifacients. Neither claim was investigated by the court, even though the mechanism of emergency contraception is a factual rather than religious matter.<sup>111</sup>

The Ninth Circuit ultimately ruled that there was no valid Free Exercise claim and decided the case on due-process grounds. The disposal of the Free Exercise issue revived the need for evidentiary support of the pharmacists' claims about the mechanisms of Plan B, because the Due Process Clause, unlike Free Exercise, triggers no deference to litigants' beliefs. Yet the parties had previously decided to exclude evidence on how Plan B and Ella work.<sup>112</sup> The court purported to treat the pharmacists' belief on the mechanism of Plan B and Ella as a fact (to which there would be no deference)<sup>113</sup> but never confirmed that there was a factual basis for the due-process claim.<sup>114</sup> A correct understanding of Plan B and Ella would have led to the conclusion that the pharmacists had not demonstrated that they suffered any injury and thus had no standing to object to supplying the contraceptives.<sup>115</sup>

It would be essential in this case to know when life begins and, if it begins upon fertilization, whether Plan B and *ella* actually prevent the implantation of a fertilized egg. If the scientific answer is that "life" does not begin upon conception or implantation or that Plan B and *ella* do not prevent the implantation of a fertilized egg, then the new right sought by Plaintiffs would not be implicated by the delivery of Plan B or *ella*, because no human life is being taken. Deciding these issues in this case is impossible because the record contains no scientific evidence – or any evidence whatsoever – addressing these questions.

State Appellants' Reply Brief at 49-50, *Stormans*, 794 F.3d 1064 (Nos. 12-35221, 12-35223), 2012 WL 6801853, at \*48-50.

- **13**. "Whether the drugs at issue prevent implantation of a fertilized ovum, however, strikes us as a proper subject for a finding of fact. Nevertheless, Plaintiffs declined to introduce evidence on that point, so we address Plaintiffs' claim as presented which rests on their 'belief' that the drugs prevent implantation." *Stormans*, 794 F.3d at 1086 n.14.
- n4. The *Stormans* trial court wrote, "Plaintiffs have reviewed the labeling, FDA directives and other literature regarding the mechanism of action of Plan B and *ella* ('emergency contraceptives') and believe that emergency contraceptives can prevent implantation of a fertilized ovum. Accordingly, Plaintiffs' religious beliefs forbid them from dispensing these drugs." *Stormans*, 854 F. Supp. 2d at 932. The Ninth Circuit similarly wrote that "[p]laintiffs believe that dispensing these drugs 'constitutes direct participation in the destruction of human life." *Stormans*, 794 F.3d at 1073 n.1.
- **115.** Standing requires the plaintiff to show (1) injury in fact; (2) causation; and (3) redressability. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992). Failure to show all three bars the court from hearing the claim.

<sup>111.</sup> See infra Section IV.B.

<sup>112.</sup> The plaintiffs and the State had initially assumed the case would be decided on Free Exercise grounds, so they had agreed to exclude evidence on the mechanisms of emergency contraception. Once the case shifted to a due-process matter, however, the State submitted in a brief:

The Supreme Court did not catch the Ninth Circuit's mistake. Justice Alito, joined by Chief Justice Roberts and Justice Thomas, dissented from the Court's denial of certiorari, focusing again on the Free Exercise claim.<sup>116</sup> The dissent characterized the case as a contest between an intolerant state and pharmacists discriminated against because of their religious beliefs.<sup>117</sup> Though this position did not garner enough votes to grant certiorari in *Stormans*, Justice Alito encouraged other as-applied challenges to the Washington regulation.<sup>118</sup> In doing so, he elided the factual dispute, writing instead simply that "emergency contraceptives, such as Plan B, . . . can 'inhibit implantation' of a fertilized egg."<sup>119</sup> Justice Alito's dissent refers to this assertion at times as a belief, <sup>120</sup> but at times also as fact,<sup>121</sup> even though it had been merely stipulated in the district court.<sup>122</sup> The Supreme Court thus failed to notice and resolve the lower courts' error, focusing instead on the religious and cultural conflicts that are so often central to contraception debates.

The Ninth Circuit and the Supreme Court ought to have remanded *Stormans* to the district court to resolve the underlying factual issue in the case. The courts' improper conflation of fact and belief, like the FDA's error and the Administration's error, contributed to the propagation of misinformation about contraception – the effects of which I will consider in Part IV.

2. Hobby Lobby

The *Hobby Lobby* litigation was plagued by the same error as *Stormans*, though the issue arose in a different doctrinal landscape. In *Hobby Lobby*, employers objected to the ACA requirement that the health insurance they supplied to their employees include coverage of contraceptives, believing some of the forms of contraception to be abortifacients.<sup>123</sup> The employers alleged that supplying the contraceptives would make them complicit in abortion, contrary to

- 118. See id. at 2440 n.6.
- 119. Id. at 2433.
- 120. See, e.g., id. at 2433, 2439.
- **121**. *Id*. at 2433.
- 122. See supra note 112.
- 123. Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751, 2759-60 (2014).

<sup>116.</sup> Stormans, Inc. v. Wiesman, 136 S. Ct. 2433, 2435 (2016) (Alito, J., dissenting). See infra Part III.B for a more in-depth analysis of standing in the context of emergency contraception.

**<sup>117</sup>**. *Stormans*, 136 S. Ct. at 2433 ("[T]here is much evidence that the impetus for the adoption of the regulations was hostility to pharmacists whose religious beliefs regarding abortion and contraception are out of step with prevailing opinion in the State.").

their religious beliefs.<sup>124</sup> Unlike *Stormans*, a case decided based on state law in a state without a RFRA, *Hobby Lobby* involved federal law and was thus decided based on RFRA conscience grounds.<sup>125</sup> This meant that the courts did not question the veracity of the plaintiffs' asserted religious beliefs about the morality of abortion and their beliefs about the mechanisms of contraception.<sup>126</sup>

While it is standard to defer to plaintiffs' spiritual or religious beliefs about the acceptability of an act like abortion, *Hobby Lobby* was the first time that the Supreme Court granted deference to plaintiffs' religious beliefs about a factual issue. American courts have long held that it is not within their duty to question where an individual "dr[aws] the line" in defining which practices run afoul of her religious beliefs.<sup>127</sup> They have not, however, addressed what standard to apply to plaintiffs who misdefine what those practices are. For example, courts properly defer when a plaintiff states that peyote is an important part of Native American spiritual ritual<sup>128</sup> but should not defer if a plaintiff claimed protection for smoking marijuana that he mistakenly believed to be peyote.<sup>129</sup>

Given the very strong evidence against the *Hobby Lobby* plaintiffs' beliefs about emergency contraception, this doctrinal change toward unlimited deference to religious beliefs about factual issues was outcome-determinative. As in *Stormans, Hobby Lobby* should have been dismissed at the trial court for lack of standing had the deciding court not deferred to plaintiffs' mistaken beliefs. In Sections IV.B and IV.C, I explore the legal implications of granting deference to religious beliefs about factual questions that contradict scientific consensus.

- 127. Thomas, 450 U.S. at 715.
- 128. Emp't Div. v. Smith (Smith II), 494 U.S. 872 (1990).
- 129. See infra Section IV.C.

<sup>124.</sup> Id. at 2759.

<sup>125.</sup> The federal Religious Freedom Restoration Act (RFRA) directs that the "Government shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability" and requires any law that burdens Free Exercise to pass strict scrutiny. 42 U.S.C. § 2000(b)(b) (2018). The federal RFRA only applies to federal laws, but many states also have their own RFRAs. *See generally* Jonathan Griffin, *Religious Freedom Restoration Acts*, NAT'L CONF. ST. LEGISLATURES (May 2015), http://www.ncsl.org/research/civil-and -criminal-justice/religious-freedom-restoration-acts-lb.aspx [https://perma.cc/9USY-53ZF] (describing twenty-one state religious-freedom-restoration statutes as all containing similar language to the federal RFRA).

<sup>126.</sup> Hobby Lobby, 134 S. Ct. at 2775; see also Thomas v. Review Bd. of Ind. Emp't Sec. Div., 450 U.S. 707, 715 (1981) (explaining that courts are not to question where an individual "dr[aws] the line" in defining which practices run afoul of her religious beliefs).

#### III. REALIGNING SCIENTIFIC AND LEGAL UNDERSTANDINGS

In this Part, I consider the various ways that litigants, agency actors, and private citizens can challenge the emergency contraception myth. I start by discussing how to change the Plan B and Ella labeling through either agency action or litigation, then turn to challenges to the HHS rules. I consider how *Stormans* and *Hobby Lobby* ought to have been decided, then conclude by emphasizing how educators, the media, and politicians can reorient public perception of emergency contraception.

#### A. Agencies

As the preceding Part demonstrates, much of the confusion surrounding the mechanism of emergency contraception can be traced to the FDA labeling.<sup>130</sup> Correcting the labeling thus seems to be an obvious place to start. Indeed, in 2004, Plan B's manufacturer attempted to get the labeling changed to more accurately reflect the drug's mechanisms. No action was taken by the FDA.<sup>131</sup> This may be because the bulk of the scientific literature on Plan B's mechanism was not yet available, but one might also suspect that the highly politicized nature of Plan B affected the FDA's decisions.<sup>132</sup> Plan B's manufacturer did not pursue litigation, and the drug has now gone generic, meaning current manufacturers have little financial incentive to challenge the FDA.<sup>133</sup>

A citizen petition by any member of the public or an advocacy group is another way to challenge the accuracy of the FDA labeling.<sup>134</sup> If the FDA denied or ignored the petition, the petitioners could bring suit under the Administrative Procedure Act (APA) alleging that the denial was arbitrary and capricious and also not supported by sufficient evidence.<sup>135</sup> A similar suit could also challenge the contraceptive mandate rollback on the grounds that it was based on inaccurate factual grounds and was therefore arbitrary and capricious. A reviewing

- **131.** GAO REPORT, *supra* note 63, at 15-16.
- 132. See supra Part II.A.

134. See 21 C.F.R. § 10.30-31 (2019).

135. See 5 U.S.C. § 706(2)(A) (2018).

<sup>130.</sup> Technically, the "label" and the "labeling" of a drug are different. The "label" is what we colloquially understand to be the packaging while the "labeling" includes the package insert with the drug information in fine print. I use the term "label" here to apply to all FDA-provided information on the drug's mechanisms.

<sup>133.</sup> See 21 C.F.R. §§ 201.57, 314.70(c)(6) (2018) (detailing when a manufacturer can request a labeling change and when it needs FDA approval). The FDA charges a fee to review a supplemental new drug application, as this would be.

court would then evaluate "whether the agency's reasons for the change . . . suffice to demonstrate that the new policy rests upon principles that are rational, neutral, and in accord with the agency's proper understanding of its authority."136 To demonstrate that its rollback was not arbitrary and capricious, HHS would need to state why its new rules are superior to the prior rule, based on the available evidence.<sup>137</sup> This standard recognizes that "administrative legitimacy [is] premised on the transparent demonstration that power is being exercised on the basis of knowledge."138 HHS would likely point to the FDA labeling as its source of information, but the challenger would present the above-discussed evidence that the labeling is based on now-defunct claims.<sup>139</sup> A court could then send the rule back to the agency for it to determine if a sufficient factual and legal basis for the rule can be articulated. (The HHS rules face an additional difficulty that the FDA labeling does not: not only are the rules blind to the evidence that the vast majority of emergency contraceptives covered by the ACA do not cause abortions, but the rules also permit employers to avoid all other forms of contraception in addition to the alleged abortifacients.) The APA thus provides a valuable tool for litigants seeking to challenge the Administration's rollback of contraception coverage because this policy is based on false controversy and fails to meet rationality requirements.<sup>140</sup>

# B. Courts

Judges and litigants alike have failed to challenge inaccurate assertions about the mechanisms of emergency contraception. When *Hobby Lobby* was at the Tenth Circuit, the court explicitly declined to "wade into scientific waters" on the question of how emergency contraception works.<sup>141</sup> In *Stormans*, the parties

- 140. See Jost & Keith, supra note 139.
- 141. Hobby Lobby Stores, Inc. v. Sebelius, 723 F.3d 1114, 1123 n.3 (10th Cir. 2013), *aff'd sub nom*. Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682 (2014). *Hobby Lobby* involved challenges to

<sup>136.</sup> FCC v. Fox Television Stations, Inc., 556 U.S. 502, 536 (2009) (Kennedy, J., concurring).

<sup>137.</sup> See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins., 463 U.S. 29, 52 (1983) ("[T]he agency must explain the evidence which is available, and must offer a 'rational connection between the facts found and the choice made." (quoting Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962)).

<sup>138.</sup> Jerry Louis Mashaw, *The Story of* Motor Vehicle Manufacturers Association of the U.S. v. State Farm Mutual Automobile Insurance Co.: *Law, Science and Politics in the Administrative State, in* ADMINISTRATIVE LAW STORIES (Peter L. Strauss ed., 2005).

<sup>139.</sup> See Timothy Jost & Katie Keith, Trump Administration Regulatory Rebalancing Favors Religious and Moral Freedom over Contraceptive Access, HEALTH AFF.: HEALTH AFF. BLOG (Oct. 7, 2017), https://www.healthaffairs.org/do/10.1377/hblog20171021.317078/full [https://perma.cc /E2DM-BT2S]; supra Part I.

agreed not to brief the issue when it was not relevant to the Free Exercise inquiry, but the Ninth Circuit failed to revive the issue when it became clear that the case would be decided on grounds that necessitated a full factual record.<sup>142</sup> Litigants suing over the religious and moral exemptions to ACA coverage have similarly neglected to raise the issue of the inadequate factual basis for the new regulations.<sup>143</sup> As a result, these cases are litigated without recognition that the conscience claims at issue lack factual grounding—a problem under principles of standing and under *Whole Woman's Health*.<sup>144</sup>

Standing is a threshold issue that must be reviewed prior to the evaluation of the merits of a claim. The Article III standing requirements are summed up in *Lujan v. Defenders of Wildlife*.<sup>145</sup> Plaintiffs must show (1) that they have suffered an "injury in fact" that is (a) "concrete and particularized" and (b) "actual or imminent," not "conjectural" or "hypothetical"; (2) that the injury is "fairly . . . traceable to the challenged action of the defendant"; and (3) that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision."<sup>146</sup> In the context of emergency contraception, plaintiffs' claims of its abortifacient effect are pure conjecture. Expert reports and testimony could easily be offered to counter the claims, leaving plaintiffs without any "actual" injury and leading to dismissal of their case.

The failure of courts and litigants to engage in this sort of inquiry is particularly problematic in reproductive-rights cases. Under *Whole Woman's Health*, courts have a duty when reproductive rights are at issue to independently consider evidence to resolve questions of medical uncertainty.<sup>147</sup> The *Whole* 

- 142. See supra Section II.C.1.
- **143**. *See supra* note 108.
- 144. Whole Woman's Health v. Hellerstedt, 136 S. Ct. 2292 (2016).
- 145. Lujan v. Defenders of Wildlife, 504 U.S. 555 (1992).
- 146. Id. at 560-61 (citations omitted).
- 147. Whole Woman's Health, 136 S. Ct. at 2310; see also Linda Greenhouse & Reva B. Siegel, Casey and the Clinic Closings: When "Protecting Health" Obstructs Choice, 125 YALE L.J. 1428 (2015); Linda Greenhouse & Reva B. Siegel, The Difference a Whole Woman Makes: Protection for the Abortion Right After Whole Woman's Health, 126 YALE L.J.F. (2016).

four kinds of contraception: Plan B, Ella, the Copper IUD, and another IUD. As discussed in Section I.B., there is evidence that the Copper IUD has abortifacient effects. I therefore constrain my argument to the other forms of contraception challenged in the case.

Woman's Health majority emphatically dismissed Texas's statement that "legislatures, and not courts, must resolve questions of medical uncertainty"148 as inconsistent with Planned Parenthood v. Casey149 and Gonzales v. Carhart. 150 Noting *Casey*, the Court reiterated that it had "relied heavily on the District Court's factual findings and the research-based submissions of amici in declaring a portion of the law at issue unconstitutional."151 The Whole Woman's Health majority then reviewed Gonzales, glossing over Gonzales's statement that legislative factfinding ought to be reviewed "under a deferential standard," and instead highlighting that Gonzales "went on to point out that the 'Court retains an independent constitutional duty to review factual findings where constitutional rights are at stake."152 Although the Supreme Court upheld the abortion regulation in Gonzales, it emphasized in Whole Woman's Health that Gonzales did not solely rely on legislative findings because "[u]ncritical deference to Congress' factual findings... is inappropriate."<sup>153</sup> The Whole Woman's Health decision accordingly relied on expert testimony and peer-reviewed studies to demonstrate that a factual inquiry rendered the law at issue unconstitutional.

This factual scrutiny should apply to contraception with at least as much force as it applies to abortion. The Court's original contraception cases, *Griswold v. Connecticut*<sup>154</sup> and *Eisenstadt v. Baird*,<sup>155</sup> while not unchallenged, have remained on stronger constitutional footing than *Roe*.<sup>156</sup> Furthermore, the government interest in providing women access to contraception has long been considered a compelling interest.<sup>157</sup> The *Casey* Court found that "[t]he ability of women to participate equally in the economic and social life of the Nation has

- 149. Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833 (1992).
- 150. Gonzales v. Carhart, 550 U.S. 124, 165 (2007).
- 151. Whole Woman's Health, 136 S. Ct. at 2310 (emphasis removed) (citing Casey, 505 U.S. at 888-94).
- 152. Id. (quoting Gonzales, 550 U.S. at 165).
- 153. Id. (quoting Gonzales, 550 U.S. at 166).
- 154. 381 U.S. 479 (1965).
- **155.** 405 U.S. 438 (1972).

157. See Hobby Lobby, 573 U.S. at 726-27; Eisenstadt, 405 U.S. 438; Griswold, 381 U.S. at 485-86.

<sup>148.</sup> Whole Woman's Health, 136 S. Ct. at 2310.

<sup>156.</sup> Roe v. Wade, 410 U.S. 113 (1973); see also Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682, 727 (2014) ("Under our cases, women (and men) have a constitutional right to obtain contraceptives . . . ."). Compare Carey v. Population Servs. Int'l, 431 U.S. 678 (1997), with Casey, 505 U.S. 833, and Gonzales, 550 U.S. 124.

#### THE YALE LAW JOURNAL

been facilitated by their ability to control their reproductive lives,"<sup>158</sup> and contraception has been understood to be crucial to that control.<sup>159</sup> Thus, *Whole Woman's Health*'s insistence on evidence-based decision-making to protect fundamental rights should easily include the contraception right.

An evidence-based approach similar to that required by Whole Woman's Health was at the center of an English court's 2002 emergency-contraception decision. In Smeaton v. Secretary of State for Health,<sup>160</sup> England's Administrative Court determined that supplying Levonelle (Plan B in the United States) was not a criminal offense under an 1861 act prohibiting the provision of "any [p]oison or other noxious [t]hing" with "[i]ntent to procure the [m]iscarriage of any [w]oman."<sup>161</sup> The Smeaton court emphasized that "so far as the court is concerned, this case has nothing to do with either morality or religious belief," but rather whether the pill is an abortifacient in violation of the criminal law.<sup>162</sup> Stating that the court "can and must hear expert medical evidence," the decision relied on evidence brought by dozens of experts and published in numerous medical dictionaries to hold that the "[c]urrent medical . . . understanding of what is meant by 'miscarriage' plainly excludes results brought about by IUDs, the pill, the mini-pill and the morning-after pill."163 In doing so, the decision carefully addressed the mechanisms of emergency contraception and concluded that it is not an abortifacient.<sup>164</sup> Curiously, although the United States is absent from the decision's review of international law, the last sentence of the Smeaton decision asks: "The reasoning of the Supreme Court of the United States of America in Griswold, Eisenstadt and Carey no doubt reflects a different constitutional background, but are not the underlying principles the same?"165 Indeed, one might think that they are and that American courts should be required to make evidence-based determinations on claims about the mechanisms of contraception.

- 161. Offences Against the Person Act 1861, 24 & 25 Vict. c. 100, §§ 58-59 (Eng., Wales, Ir.).
- 162. Smeaton, [2002] 2 FLR at 157.
- 163. Id. at 232.
- **164**. *Smeaton* relies primarily on understandings of the start of pregnancy and does not make a determination on the mechanisms of Levonelle. At the time of *Smeaton*, the evidence relied on by doctors today was not available, so the *Smeaton* judge would have been unable to state unequivocally that Levonelle does not impede implantation of a fertilized egg.
- 165. Smeaton, [2002] 2 FLR at 103 (citing Griswold v. Connecticut, 381 U.S. 479 (1965), Eisenstadt v. Baird, 405 U.S. 438 (1972), and Carey v. Population Servs. Int'l, 431 U.S. 678 (1977)).

**<sup>158</sup>**. *Casey*, 505 U.S. at 856.

**<sup>159</sup>**. *Hobby Lobby*, 573 U.S. at 727.

<sup>160.</sup> R (on the Application of Smeaton) v. Secretary of State for Health [2002] EWHC (Admin) 610, [2002] 2 FLR 146 (Eng.).

Some questions remain over what level of scientific consensus courts will require. The typical standard in a civil case is the preponderance of evidence. In *Whole Woman's Health*, the "great weight of evidence" showed that clinic closures would have harmful effects, which provoked a higher standard of review.<sup>166</sup> As discussed above, the evidence regarding the mechanism of Plan B and, to a somewhat lesser extent, Ella is sufficiently well established and well tested that it meets both of these bars. Courts constantly engage with scientific uncertainty in other areas of law,<sup>167</sup> and unless all far-fetched claims are to be taken as truth, judicial fact-finding must occur. Our legal system would cease to function were courts incapable of conducting trials and making legal determinations as to what is most probable. Courts ought to take this familiar analytic toolkit and apply it in the context of emergency contraception.

#### C. Politics and Public Education

There are also important opportunities outside the courts and agencies to challenge false assertions about emergency contraception. Educators, the media, and politicians ought to alter their rhetoric to realign it with the scientific community's understanding of how emergency contraception actually functions. Political engagement and public education campaigns can be effective methods for countering misinformation and stigma, and they can be employed in the context of emergency contraception.

Countering misinformation is critical because the myth of Plan B as an abortifacient is so widespread. Studies show that only roughly thirty percent of women know how Plan B actually works.<sup>168</sup> Yet, just eighteen states require that information on contraception be provided during school sex education classes, and only thirteen states require that any information provided be medically accurate.<sup>169</sup> Teenagers and young adults are simply not being provided with sufficient information on emergency contraception at the outset of their reproductive lives. Young women ought to know, for example, that four regular contraception pills can be substituted for Plan B, via a medically approved method called the

<sup>166. 136</sup> S. Ct. 2292, 2311 (2016) (quoting Whole Woman's Health v. Lakey, 46 F. Supp. 3d 673, 684 (W.D. Tex. 2014)).

<sup>167.</sup> Cf. Kenneth S. Abraham & Richard A. Merrill, Scientific Uncertainty in the Courts, 2 ISSUES SCI. & TECH. 93 (1986) (reviewing judicial approaches to scientific uncertainty).

<sup>168.</sup> See supra notes 67-68 and accompanying text.

<sup>169.</sup> See Sex and HIV Education, GUTTMACHER INST. (Aug. 1, 2019), https://www.guttmacher.org /state-policy/explore/sex-and-hiv-education [https://perma.cc/K835-4NCT].

Yuzpe regimen that predates Plan B.<sup>170</sup> Complete and accurate sex education is necessary to enable women to prevent unwanted pregnancies.

The obvious problems associated with limited sex education are compounded in the case of emergency contraception by political rhetoric that characterizes Plan B as an "abortion pill."<sup>171</sup> News outlets,<sup>172</sup> politicians,<sup>173</sup> and health advocacy groups<sup>174</sup> that inaccurately frame emergency contraception this way add stigma to existing uncertainty. In turn, this increases doubt as to the ethics of emergency contraception. Responsibility to correct these errors is widespread, but there are also many opportunities to debunk the abortifacient myth. A critical first step will be referring to Plan B and Ella only as contraceptives and not as abortifacients. Second, those who participate in public debate on emergency contraception ought not gloss over false claims or misstate the science. This will require careful attention to religious claims that are contrary to the medical understanding and proper delineation of fact and belief. These are important initial steps to change the public perception of emergency contraception and to mitigate the implications of the emergency-contraception misconception that I discuss in the following Part.

# IV. CULTURAL AND LEGAL IMPLICATIONS

The law has so far embraced our collective disregard for how emergency contraception functions, and not without cost. In this Part, I explore the impact of this disregard on reproductive rights law and conscience claims. Rhetoric about "abortifacients" has pulled contraception into the contested space that abortion occupies, opening the door to conservative efforts to restrict access to contraception. Beyond the realm of reproductive rights, litigation over emergency contraception shows the potential for the application of Free Exercise protections to both facts and beliefs. I discuss why these developments ought to be concerning and identify a problem on the other side of the same coin: due process doctrine is adapting to this new landscape in a manner that threatens to impede the longheld right to define life as one wishes. I conclude by addressing the broader applicability of the fact/belief distinction.

<sup>170.</sup> See James Trussell et al., New Estimates of the Effectiveness of the Yuzpe Regimen of Emergency Contraception, 57 CONTRACEPTION 363, 366-68 (1998).

<sup>171.</sup> See supra notes 57-64 and accompanying text.

<sup>172.</sup> See Molly Moorhead, PAC Ad Says Obama Will Force Christian Groups to Pay for Abortions, POLITIFACT (Sept. 26, 2012, 6:01 PM), https://www.politifact.com/truth-o-meter /statements/2012/sep/26/government-not-god-pac/pac-ad-says-obama-will-force-christian -groups-pay- [https://perma.cc/8KL4-CKRJ].

<sup>173.</sup> See supra note 62.

<sup>174.</sup> See supra note 61.

#### A. Merging Contraception and Abortion

Emergency contraception has proven to be a powerful point of conflict in American politics. In this Section, I use Lawrence Lessig's work on "tying" to argue that our collective misunderstanding of how emergency contraception functions and the government's exacerbation of that misunderstanding has unnecessarily fueled conflict over contraception by imbuing it with the moral divisiveness of abortion.

Rhetoric surrounding emergency contraception pits women seeking basic health services against Catholic nuns forced to pay for abortions, reproductive rights against religious rights, and the Left against the Right.<sup>175</sup> Using the FDA's labeling, activist groups, regulators, and the courts entrench this conflict by reiterating that emergency contraception really does cause abortion, forcing a choice between reproductive rights and religious rights.

Regular hormonal contraception does not invoke the same tension. Some religious people of course do not use contraception, and occasionally they refuse to supply it to others, but we have not yet seen the same rallying against general contraception as we have against emergency contraception.<sup>176</sup> The link to abortion has therefore been critical for pro-life groups garnering opposition to emergency contraception.<sup>177</sup>

Lessig calls this approach "tying."<sup>178</sup> Those seeking to change the social perception of an act can transform it by "associating it with[] another social meaning that conforms to the meaning that the architect wishes the managed act to have."<sup>179</sup> Those with more extreme views on contraception thereby harness opposition to abortion to spread hostility from abortion to contraception.<sup>180</sup> It thus

- 176. This is likely due to the rates at which religious women use contraception. See supra note 73.
- 177. For a critique of pro-life groups' anticontraception messaging, see Priscilla J. Smith, Contraceptive Comstockery: Reasoning from Immorality to Illness in the Twenty-First Century, 47 CONN. L. REV. 971, 1012-17 (2015).
- 178. See Lawrence Lessig, The Regulation of Social Meaning, 62 U. CHI. L. REV. 943, 1009 (1995).
- 179. Id.

<sup>175.</sup> See, e.g., Steven Ertelt, Ruth Bader Ginsburg Wants to Force Catholic Nuns to Pay for Abortion Drugs: "It Can't Be All My Way," LIFENEWS (Mar. 23 2016, 12:37 PM), http:// www.lifenews.com /2016/03/23 /ruth-bader-ginsburg-wants-to-force-catholic-nuns-to-pay -for-abortion-drugs-it-cant-be-all-my-way [https://perma.cc/5VDX-X6QU]. See generally NeJaime & Siegel, supra note 2, at 2542 (describing the advent of complicity-based conscience claims and their role in the present-day culture war).

<sup>180.</sup> See Amanda Marcotte, Emergency Contraception Is Not Abortion, SLATE (June 6, 2012), https://www.slate.com/blogs/xx\_factor/2012/06/06/the\_new\_york\_times\_confirms\_that \_emergency\_contraception\_only\_works\_by\_suppressing\_ovulation\_.html [https:// perma.cc/957A-3VMX].

becomes evident why the Trump Administration's contraception rules cite opposition to "abortifacients" to allow the exclusion of all forms of contraception from insurance plans. By speaking in one breath and failing to differentiate between emergency contraception and other contraception, the two become tied, and abortion-related enmity is spread to unrelated forms of women's reproductive care.<sup>181</sup>

Tying has also made it harder to question the science behind the abortifacient understanding of the mechanisms of emergency contraception. By connecting emergency contraception to abortion, "abortifacients" have been made taboo. As Dan Kahan's work shows,<sup>182</sup> the more contested a topic is, the less likely science will be able to persuade people differently. Just as a person who believes in a strong Second Amendment is likely to think that gun ownership makes society safer, a person who suspects Plan B causes abortions is going to accept scientific studies on Plan B's mechanisms selectively.<sup>183</sup> Cultural and political commitments affect our interpretations of evidence, no matter how significant the results or authoritative the sources.<sup>184</sup> Tying very effectively confers both hostility and assurance, promoting further entrenchment. The simple mistake of failing to stay up to date on contraceptive science, augmented by a combative political culture eager to capitalize on the most convenient version of the truth, has led us to fight bitterly over cultural values without any grounding in reality.

Priscilla Smith similarly understands pro-life opposition to emergency contraception as ignorant of facts out of a concern "reaching far beyond the 'abortion question,' and the ethics of protection of 'human life.'"<sup>185</sup> She writes that "the campaign [against emergency contraception] reflects conflicts concerning the propriety of non-procreative sex and particularly the ability of women to express their sexual desire without consequences, without fear of pregnancy."<sup>186</sup>

185. Smith, *supra* note 177, at 1012-17.

186. Id.

<sup>181.</sup> The tendency of opponents of contraception to liken emergency contraception to oral contraceptives in order to make oral contraceptives seem to be abortifacient has been noted before, in the context of university health policy. See Briana C. Hill, Widening the Battlefield: Using Emergency Contraception to Get from Abortion to Birth Control, 16 UCLA WOMEN'S L.J. 281, 304 (2007).

<sup>182.</sup> Dan M. Kahan, The Cognitively Illiberal State, 60 STAN. L. REV. 115 (2007).

See Jeffrey J. Rachlinski, Evidence-Based Law, 96 CORNELL L. REV. 901, 922 (2010) (citing Kahan, supra note 182).

<sup>184.</sup> See Kahan, supra note 182, at 153 (observing that prospects for agreement have diminished notwithstanding advancement in collective knowledge, and attributing this decline to the important role played by cultural pluralism and cultural ideology in shaping opinions).

Smith draws on Reva Siegel's work demonstrating that concerns regarding gender roles, motherhood, and women's sexuality lurk behind opposition to abortion, even when pro-life people purport to protect the fetus.<sup>187</sup> Contraception presents similar affronts to socially conservative ideals, but rather than making forthright appeals to those ideals, activists and politicians manipulate the public's understanding of the facts behind contraception.

The next stage of abortion-contraception merging is on the horizon. In March 2019, the Trump Administration issued notice of a new final rule that will forbid Title X family-planning providers from referring or counseling pregnant patients regarding abortion and require any providers that also perform abortions to make those facilities physically and financially separate from clinics that receive federal funds.<sup>188</sup> These changes led Planned Parenthood, whose clinics were serving forty percent of Title X patients with family-planning care and contraception, to plan to refuse Title X funding so that it can continue to provide abortion-related services.<sup>189</sup> The new rule, however, did more. It also eliminated the preexisting requirement that Title X clinics provide only medically approved family-planning services. This is expected to shift funding away from clinics that provide hormonal contraception and IUDs (like Planned Parenthood) and redirect those funds toward crisis-pregnancy centers and other faith-based organizations that emphasize abstinence and natural family planning.<sup>190</sup> As a result, unknown numbers of poor women who depend on Title X clinics for effective and scientifically proven contraceptive methods will lose the ability to control their reproductive futures, in the name of antiabortion politics.<sup>191</sup>

<sup>187.</sup> Reva B. Siegel, Reasoning from the Body: An Historical Perspective on Abortion Regulation and Questions of Equal Protection, 44 STAN. L. REV. 261, 264-66 (1992).

<sup>188.</sup> Office of Population Affairs, *Title X Notice of Final Rule*, U.S. DEP'T HEALTH & HUM. SERV. (Mar. 4, 2019), https://www.hhs.gov/opa/title-x-family-planning/about-title-x-grants /statutes-and-regulations/index.html [https://perma.cc/T6AZ-X62P] (to be codified at 42 C.F.R. pt. 59).

<sup>189.</sup> Pam Belluck, Planned Parenthood Refuses Federal Funds over Abortion Restrictions, N.Y. TIMES (Aug. 19, 2019), https://www.nytimes.com/2019/08/19/health/planned-parenthood-title -x.html [https://perma.cc/X2HX-S8LC].

<sup>190.</sup> See Michelle Goldberg, Opinion, The Republicans of Gilead, N.Y. TIMES (Feb. 25, 2019), https://www.nytimes.com/2019/02/25/opinion/trump-planned-parenthood -abortion.html [https://perma.cc/UEG7-4KPV].

<sup>191.</sup> See Priscilla Smith, There Goes Title X; Title X is Contraception Folks, BALKINIZATION (June 20, 2019), https://balkin.blogspot.com/2019/06/there-goes-title-x-title-x-is.html [https://perma.cc/DUP6-K6WA].

# B. Conflating Moral and Factual Deference Under Roe

The failure of courts to check claims about the mechanism of emergency contraception that are grounded in moral or religious beliefs rather than in medical science has begun to adversely affect religious-freedom law. If other RFRA or Free Exercise cases adhere to this *Hobby Lobby* precedent, the invocation of religious freedom will permit plaintiffs to win cases based on unsupported, untested, and untrue factual claims. In this Section, I consider the error of deference to factual claims as a matter of law and conclude that following this path might ultimately restrict courts' long-held and proper deference to moral beliefs.

In the Free Exercise and RFRA contexts, freedom of belief is "absolute,"<sup>192</sup> and religious beliefs are not tested for their scientific veracity. Courts will not question where an individual "dr[aws] the line" in defining which practices run afoul of her religious beliefs, and instead take the plaintiff at her word.<sup>193</sup> In *Bowen v. Roy*, for example, the Supreme Court declined to question belief in the supernatural power of a Social Security number when parents of a young girl refused to supply their daughter's Social Security number to the government to enable her to receive benefits.<sup>194</sup>

The Supreme Court's *Hobby Lobby* decision improperly extended this deference from moral beliefs to factual beliefs. The Hobby Lobby store owners sought to protect their beliefs about how emergency contraception works – a purely factual inquiry – but the Court treated the belief as if it were religious, spiritual, or metaphysical and deferred to it.<sup>195</sup> This was a feature of both the majority opinion and the dissent, with Justice Ginsburg writing in dissent, "In no way does the dissent 'tell the plaintiffs that their beliefs are flawed' . . . . Right or wrong in this domain is a judgment no Member of this Court, or any civil court, is authorized or equipped to make."<sup>196</sup>

This slippage ought to concern us. It is appropriate for courts to defer to religious beliefs insofar as plaintiffs think abortion is morally wrong. But it is inappropriate for courts to go further and let plaintiffs decide what is and what

196. Id. at 758 n.21 (Ginsburg, J., dissenting).

<sup>192.</sup> Bowen v. Roy, 476 U.S. 693, 699 (1986) ("[T]he freedom of individual belief... is absolute...."). Bowen does, however, draw a distinction between belief and conduct, and the Bowen plaintiffs lost their suit.

<sup>193.</sup> Thomas v. Review Bd. of Ind. Emp't Sec. Div., 450 U.S. 707, 715 (1981).

<sup>194.</sup> Bowen, 476 U.S. at 699.

<sup>195.</sup> The majority simply refers to the store owners as "conduct[ing] business in accordance with their religious beliefs." Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682, 724 (2014) (emphasis omitted).

is not abortion.<sup>197</sup> That belief is simply a statement about the physical world and, critically, a falsifiable belief. Factual claims are not sacrosanct, and courts are obliged to serve their fact-finding mission. Amy Sepinwall notes that courts have "a role in policing empirical truth" because "there is no state license for 'epistemic abstinence' when it comes to taking cognizance of empirical facts about the world."<sup>198</sup>

The elision of fact and faith has not only led to undue deference to plaintiffs' factual opinions, but also to slippage away from long-held deference to moral questions. The Court has traditionally granted deference to moral opposition to abortion, as it does with other moral or religious beliefs. In *Roe v. Wade*, the Court was explicitly agnostic to the question of when life begins because, "[w]hen those trained in the respective disciplines of medicine, philosophy, and theology are unable to arrive at any consensus, the judiciary, at this point in the development of man's knowledge, is not in a position to speculate as to the answer."<sup>199</sup> The Court chose not to resolve a deeply contested issue so as not to pick sides in moral debates. This long-held deference, which I term *Roe* deference, is put at risk by the elision of moral and factual beliefs. Law has begun to adjust to a landscape where fact and faith are one and the same, at the cost of *Roe* deference.

In *Stormans*, rather than remanding to the district court for fact finding, the Ninth Circuit resolved the case by breaking new ground in due process law and invading the space *Roe* carved out for moral beliefs. The *Stormans* plaintiffs asserted that Washington's rules infringed a new fundamental right, the "right to refrain from taking human life."<sup>200</sup> The court rejected this claim, writing that "[p]laintiffs have not attempted to establish that Plan B and Ella *objectively* cause the taking of human life."<sup>201</sup> Judge Graber accepted that emergency contraception could inhibit implantation, but said that because it is disputed whether life begins at implantation or some other point during conception, the plaintiffs' belief that a life had ended was entirely subjective.<sup>202</sup> Judge Graber's reasoning

<sup>197.</sup> See supra notes 127-130 and accompanying text.

<sup>198.</sup> Amy J. Sepinwall, Conscience and Complicity: Assessing Pleas for Religious Exemptions in Hobby Lobby's Wake, 82 U. CHI. L. REV. 1897, 1933 (2015). Not all cases have the weight of evidence strongly supporting one scientific proposition. In cases in which the science is less certain, judgments will need to be made about when a trial is likely to come to a clear conclusion. When scientists come to conflicting conclusions, challenging a religious plaintiff makes less sense. But when scientific consensus exists, a religious belief in opposition to that scientific consensus ought not to be given the same deference as a religious belief.

<sup>199. 410</sup> U.S. 113, 159 (1973).

<sup>200.</sup> Stormans, Inc. v. Wiesman, 794 F.3d 1064, 1086 (9th Cir. 2015).

<sup>201.</sup> Id.

<sup>202.</sup> See id. at 1086-87.

broke new constitutional ground by separating due process into subjective and objective halves. This distinction requires beliefs to meet some standard of objectivity prior to receiving due process protection. When applied to claims about when life begins, this threatens *Roe*'s requirement that courts leave certain beliefs up to individual determination. It also seems to contradict the Free Exercise principle of *Bowen v. Roy* that plaintiffs are to be taken at their word about their religious beliefs. By deciding the case based on the question of when life begins, rather than on how emergency contraception functions, the court was backed into resolving the case by determining new constitutional due process rights and cordoning off plaintiffs' religious beliefs.

*Roe* deference is an essential part of constitutional jurisprudence because it preserves moral questions for legislatures and for the people. In this way, it is akin to Free Exercise and Establishment Clause protections that explicitly protect matters of faith from being decided by courts. Courts ought to maintain the line between fact and faith because doing so is essential for reproductive rights, religious rights, and moral freedom.

## C. The Broader Context of Fact Versus Belief

The propagation of the claim that Plan B is an abortifacient exemplifies a new trend of disclaiming facts and evidence in exchange for political messaging. As fact and opinion are conflated, both in politics and law, ever-more topics become debatable and thus conflict-generating. For this reason, if evidence emerged that Ella actually can affect implantation and religious groups could meet the preponderance-of-the-evidence standard for their claims that Ella is an abortifacient, we should still care that those claims are treated as assertions of fact and not belief. In that world, the case would have the same outcome as *Hobby Lobby*, but we would still benefit from the proper categorization of claims. This is because factual assertions are meant to be challenged, defended, and proved true or false. Claims of belief or opinion are insulated from the adversarial system and definitionally immune from resolution.

This fact/belief distinction is relevant, too, in other arenas where science runs against claimants' moral or religious beliefs, as can be the case in vaccine litigation or debates over the content of school curricula. Allison Orr Larsen argues that constitutional law is in an "age of alternative facts," where evidence is

martialed selectively and activist groups, legislatures, and courts are each inundated with false claims.<sup>203</sup> "[C]onstitutional litigants have become quite sophisticated" at finding friendly facts,<sup>204</sup> and "constitutional law has become increasingly dependent on factual claims,"<sup>205</sup> leading to Supreme Court decisions based on false claims, such as the widespread existence of voter fraud.<sup>206</sup> Larsen explains that social media and political polarization have also contributed to this "post-truth" society in which what we think is true is more important than what can actually be shown.<sup>207</sup> In the abortion context, Larsen explores the pervasiveness of false claims about fetal pain and that abortion can increase the risk of breast cancer – theories without evidentiary bases that have nevertheless made it into the informed consent laws of a half-dozen states.<sup>208</sup> The stakes of this problem thus extend beyond the emergency-contraception context – though the tools used to combat misinformation regarding vaccines or evolution would be the same.

The trial over the effect of legalizing same-sex marriage provides a model to consider when facts are bound up in moral debates. In 2009, long before *Ober-gefell* and *Windsor*, Judge Walker ordered a trial in *Hollingsworth v. Perry* for the litigants to present evidence on California's Proposition 8, which banned same-sex marriage.<sup>209</sup> The trial involved addressing issues such as how having same-

- 205. *Id*. at 181.
- **206**. See id. at 212.
- **207**. See id. at 190-93.
- 208. See id. at 202-10. Larsen explains that six states Kansas, Mississippi, North Dakota, Texas, Oklahoma, and Alaska require women seeking an abortion to be told that abortion may increase risk for breast cancer. Kansas, Mississippi, North Dakota, and Texas have all codified the requirement by statute. Two other states Alaska and Oklahoma require a warning in printed material. *Id.*; see also The Abortion-Breast Cancer Link, LIFESITENEWS: LIFEFACTS, https://www.lifesitenews.com/resources/abortion/the-abortion-breast-cancer-link [https://perma.cc/9GAJ-7M5M] (stating that for the connection between induced abortions and breast cancer, "the proof is in the pudding"). For a report by the National Cancer Institute, see Abortion, Miscarriage, and Breast Cancer Risk: 2003 Workshop, NAT'L CANCER INST. (Jan. 12, 2010), https://www.cancer.gov/types/breast/abortion-miscarriage-risk [https://perma.cc/ET8T-B48R] (finding that "[i]nduced abortion is not associated with an increase in breast cancer risk").
- 209. Bob Egelko, Judge Sets January Trial for Prop. 8 Lawsuit, SFGATE (Aug. 20, 2009, 4:00 AM PDT), http://www.sfgate.com/news/article/Judge-sets-January-trial-for-Prop-8-lawsuit -3220955.php [https://perma.cc/XQ5P-5H72].

<sup>203.</sup> Allison Orr Larsen, Constitutional Law in an Age of Alternative Facts, 93 N.Y.U. L. REV. 175 (2018).

<sup>204.</sup> Id. at 180.

sex parents affects children, whether the existence of same-sex marriage is detrimental to marriage, and the history of discrimination against gay people.<sup>210</sup> These issues were addressed as factual contentions needing evidentiary support, distinct from moral or religious beliefs based in faith. The trial culminated in "a 136-page compendium of factual and legal conclusions," with Judge Walker finding for the plaintiffs (proponents of same-sex marriage legalization) on every major issue.<sup>211</sup>

Commenting on the effect of the trial, David Boies, cocounsel for the plaintiffs, considered the presentation of evidence at the trial to have been the plaintiff's true coup: "[The LGBT community] put fear and prejudice on trial, and fear and prejudice lost."<sup>212</sup> Boies further commented that litigating facts was superior to political debates, because in the latter form of discourse, one could "throw around opinions, appeal to people's fear and prejudice," and "cite studies that either don't exist or don't say what you say they do."<sup>213</sup> In a trial, "you've got to stand up under oath and cross-examination"<sup>214</sup> and you "can't fall back on bumper sticker slogans."<sup>215</sup> Kenji Yoshino's book on *Hollingsworth* emphasizes the trial's fact-finding capacity and the pressure of adversarial cross-examination.<sup>216</sup> Public battles of expert witnesses can "discredit fringe scholars and viewpoints with finality and authority."<sup>217</sup> In the courtroom, "a passion is not a reason, much less a reason for a law."<sup>218</sup>

To support his argument about the importance of adjudicating the fact/belief divide, Yoshino uses the examples of the *Scopes* "monkey trial," as well as *Kitzmiller v. Dover Area School District*, in which a modern court determined that intelligent design was not substantially different from creationism, and therefore

212. KENJI YOSHINO, SPEAK NOW: MARRIAGE EQUALITY ON TRIAL 8 (2015).

216. See YOSHINO, supra note 212, at 267.

<sup>210.</sup> See Emily Bazelon, For Better or for Worse, SLATE (Jan. 8, 2010, 3:17 PM), http://www.slate.com/articles/news\_and\_politics/jurisprudence/2010/01/for\_better\_or \_for\_worse.single.html [https://perma.cc/JM94-XRTQ].

<sup>21.</sup> Dale Carpenter, On the Legal Front Lines of Same-Sex Marriage, N.Y. TIMES (June 29, 2014), https://www.nytimes.com/2014/06/30/books/redeeming-the-dream-by-theodore-b-olson -and-david-boies.html [https://perma.cc/NUX6-PFKB].

<sup>213.</sup> Id. at 7.

<sup>214.</sup> Id.

<sup>215.</sup> Margaret Talbot, The Gay-Marriage Classroom, NEW YORKER (Feb. 1, 2010), https://www.newyorker.com/news/news-desk/the-gay-marriage-classroom [https:// perma.cc/W5PS-6NXL] (quoting Boies).

**<sup>217</sup>**. *Id*. at 271.

<sup>218.</sup> Id. at 269.

that public schools cannot be required by law to teach intelligent design.<sup>219</sup> In doing so, the court recognized the distinction between the religious belief in creationism and the factual evidence supporting evolution. The *Kitzmiller* decision, like *Hollingsworth*, produced a massive record and became an important tool in the effort to require that evolutionary science be taught in schools.<sup>220</sup> If the *Kitzmiller* and *Hollingsworth* trials had come out differently, the state of the law on science curricula and same-sex marriage might be different. But the sheer existence of the trials established what is grounds for debate and what is not, confirming that we are each entitled to our own opinions but not to our own facts. We ought to be mindful of the convergence of fact and belief because when the state of the world is manipulable, assertions will sail by each other like ships in the night, and debate will become that much harder. Correcting false assertions of how emergency contraception functions is one means by which we can recommit to a proper fact/belief distinction.

# CONCLUSION

The conflation of fact and belief, especially when the belief is factually incorrect, threatens important underpinnings of our legal system, as the case of emergency contraception demonstrates. While the medical community understands that emergency contraception is not abortion, public debate has not caught up. The widespread misunderstanding of the mechanism of emergency contraception has been exacerbated by different actors in the American legal system, including federal agencies and the courts. The FDA's failure to update Plan B's labeling in particular has had deep practical consequences for regulation, for law, and for those who use and supply emergency contraception. Abortion opponents have used the mislabeling as an opportunity to muddle the distinction between contraception and abortion, and their rhetorical moves have resulted in increased antagonism toward all forms of hormonal contraception. Meanwhile, agencies, courts, and parties on both sides of contraception litigation have failed to identify and challenge the underlying factual misconceptions, and religious-freedom claims have morphed as courts have unwittingly granted deference to factual, as well as moral, claims.

Despite such concern, disagreement over emergency contraception also brings opportunity. The Left and Right have the rare opportunity to come together without conceding any ground on moral values. In debates over physician-assisted suicide and capital punishment, there is no piece of scientific knowledge that will allow us to avoid questions of life and death. The legal status

*Id.* (referencing Kitzmiller v. Dover Area Sch. Dist., 400 F. Supp. 2d 707 (2005)).*See id.* at 269-70.

#### THE YALE LAW JOURNAL

of abortion will similarly not be determined in a laboratory. But emergency contraception is different—it poses a solvable factual question rather than an unsolvable moral dilemma. Recognizing how emergency contraception functions opens a doorway to escape moral reckoning and avoid creating constitutional law based on hard choices and entanglement in culture wars. We ought to set aside politics and walk through that doorway.