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I. Introduction

The Obama Administration's (Adminstration) mandate under the Patient Protection and Affordable Care Act (ACA)[1] that nearly all employers cover certain contraceptive drugs and devices in any employee health plan (the Mandate)[2] opened a new front in the American abortion debate. Religious objectors charge that coverage of six specific "abortion-inducing"[3] drugs and

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1. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended at scattered sections of the Internal Revenue Code and at 42 U.S.C.), *amended by* Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 through May 1, 2010.

2. The ACA requires coverage "with respect to women, [of] such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration ('HRSA') for purposes of this paragraph." *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 § 1001 (codified at 42 U.S.C. § 300GG-13(a)(4) (2010)). The HRSA Guidelines recommended coverage of "[a]ll Food and Drug Administration approved contraceptive methods [and] sterilization procedures." *See Women's Preventive Services Guidelines: Affordable Care Act Expands Prevention Coverage for Women's Health and Well-Being*, U.S. DEPT. OF HEALTH & HUMAN SERVS., http://www.hrsa. gov/womensguidelines/ (last visited Jan. 21, 2014) (on file with the Washington and Lee Law Review). Relying on the HRSA Guidelines, the Administration finalized rules requiring coverage of "preventive care . . . provided for in comprehensive guidelines supported by HRSA." Interim Final Rule on Preventive Services Under the ACA, 76 Fed. Reg. 46621, 46623 (Aug. 3, 2011); Final Rule on Preventive Services under the ACA, 77 Fed. Reg. 8724, 8725 (Feb. 15, 2012). The Mandate does not include drugs that are known to work after implantation as chemical abortions, like RU-486. RU-486 is marketed under the tradename "Korlym" and "Mifeprex." *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, FOOD & DRUG ADMIN. (2013), http://www.accessdata.fda.gov/scripts/Cder/ob/docs/temptn. cfm (last visited Jan. 21, 2014) (on file with the Washington and Lee Law Review).

For a synopsis of the Administration's accommodations of religious non-profits, see Robin Fretwell Wilson, *Demagoguing Abortion* (working title), in THE RIGHTS OF RELIGIOUS INSTITUTIONS (Zoe Robinson, Micah Schwartzman & Chad Flanders eds., forthcoming 2014) (on file with author). For penalties imposed on objecting, non-exempt, for-profit employers if they drop all coverage, see Robin Fretwell Wilson, *The Calculus of Accommodation: Contraception, Abortion, Same-Sex Marriage, and Other Clashes Between Religion and the State*, 53 B.C. L. REV. 1417, 1489–1505 (2012) [hereinafter Wilson, *The Calculus*].

3. Complaint at 6, Wheaton Coll. v. Sebelius, 887 F. Supp. 2d. 102 (D.D.C. July 18, 2012) (No. 1:12CV01169), http://www.becketfund.org/wp-content/ uploads/2012/07/Wheaton-Complaint-timestamped.pdf; *see also Birth Control: Medicines to Help You*, FOOD & DRUG ADMIN., http://www.fda.gov/forconsumers/

devices is tantamount to providing an "abortion on demand."[4] The Administration and Mandate supporters insist that "drugs that cause abortion are not covered by [the Mandate]."[5] This firestorm over such drugs and devices (together, emergency contraceptives or EC) reverberates far outside the Washington Beltway, spilling over to decisions facing women about whether to use EC after "unanticipated sexual activity, contraceptive failure, or sexual assault."[6]

This Article explores how it is possible that such wildly different claims can be made about the same drugs and devices, claims that create real confusion for real women who are deciding whether to use EC. It shows that both sides—Mandate supporters *and* opponents, family planning advocates *and* opponents of abortion—use conclusory labels to shorthand an extraordinarily complex and still-unfolding scientific understanding about how different kinds of EC work. Notwithstanding key differences in their mechanisms of action—that is, how the drug acts in a woman's body—supporters and opponents alike lump all EC together as if they work by precisely the same mechanism, glossing over important differences.[7]

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byaudience/forwomen/freepublications/ucm313215.htm (last updated May 2013) (last visited Feb. 11, 2014) [hereinafter *FDA Birth Control Guide*] (describing various types of birth control, their utility, and how they work) (on file with the Washington and Lee Law Review).

4. Complaint at 7, Sharpe Holding v. U.S. Dep't. of Health and Human Servs., (E.D. Mo. 2012) (No. 2:12-CV-92), http://www.becketfund.org/wp-content/uploads/2013/04/Sharpe-Holdings-complaint.pdf; *see also* Timothy Dolan, *HHS Contraception Mandate "Un-American"*, USA TODAY (Jan. 25, 2012, 2:04 PM), http://usatoday30.usatoday.com/news/opinion/ forum/story/2012-01-25/dolan-hhs-health-contraceptive-mandate/52788780/1 (last visited Jan. 14, 2014) ("[T]he contraceptives mandated as 'preventive services' will include abortifacients.") (on file with the Washington and Lee Law Review).

5. Cecila Munoz, *Health Reform, Preventative Services, and Religious Institutions*, THE WHITE HOUSE BLOG (Feb. 1, 2012, 6:35PM), http://www.whitehouse.gov/blog/2012/02/01/health-reform-preventive-services-and-religious-institutions (last visited Jan. 14, 2014) (on file with the Washington and Lee Law Review). The Administration has consistently maintained that the Mandate does "not include abortifacient drugs." *See infra* note 36 and accompanying text.

6. WHAT YOU NEED TO KNOW: THE DIFFERENCE BETWEEN MEDICAL ABORTION AND EMERGENCY CONTRACEPTIVE PILLS, ASS'N OF REPROD. HEALTH PROF'LS 1 (Dec. 2010), http://www.arhp.org/uploadDocs/mifepristone_ecfact sheet.pdf [hereinafter WHAT YOU NEED TO KNOW].

7. *See infra* Part III.A and accompanying footnotes (discussing the

Compounding the competing explanations about how EC works is the fact that both sides mean very different things when they claim something is or is not "abortion-causing."[8] Mandate supporters contend that pregnancy begins when "a pre-embryo completes implantation,"[9] while objectors believe the "life of every human being [begins at] the moment of conception/fertilization,"[10] making its destruction "the killing of an innocent person."[11]

For women contemplating EC, separating "fact from fiction" is no easy task[12]: "Since the approval of [*ella*] . . . there has been even more confusion and controversy."[13] Precisely because of "myths" swirling around "in the popular press and on the internet," some women are now asking "tough questions about mechanisms of action."[14]

While some discount concerns about whether EC works after fertilization as a form of "zygote worship"[15] shared only by

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different likely mechanisms of action for Plan B and *ella* and how they affect the female reproductive system).

8. *See infra* Part II (discussing the confusion over what is and is not an abortion-causing drug).

9. *What You Need to Know*, *supra* note 6, at 1.

10. Complaint at 2, 9, 11–13, Tyndale House Publishers v. Sebelius, (D.D.C. Dec. 3, 2013) (No. 1:12-CV-1635-RBW), http://www.adfmedia.org/files/TyndaleComplaint.pdf.

11. Verified Complaint for Declaratory & Injunctive Relief at 3, QC Group, Inc. v. Sebelius, (D. Minn. July 2, 2013) (No. 0:13-CV-01726), http://www.becketfund.org/wp-content/uploads/2013/08/1-Verified-Complaint-for-Declaratory-and-Injunctive-Relief-7-2-13.pdf. Like many Catholic groups that have sued the Administration, QC also believes that:

> God, the Creator of human life, does not condone the use of birth control (which includes *ella*, Plan B, the Pill, and other forms of contraceptive required by the HHS Mandate) in any form because they interfere with God's sovereign will regarding whether and when human beings should be born.

Id. As one of the authors notes elsewhere, few Americans object to contraceptive use. *See* Wilson, *The Calculus*, supra note 2, at 1454 n.134 (citing a CBS News opinion poll).

12. Pelin Batur, *Emergency contraception: Separating fact from fiction*, 79 CLEVELAND CLINIC J. OF MED. 771, 771 (2012), *available at* http://www.ccjm.org/content/79/11/771.full.pdf+html.

13. *See id*. (identifying and explaining common misunderstandings about *ella*).

14. *Id.* at 771, 774.

15. I am indebted to Professor Jacqueline R. Fox, University of South Carolina, School of Law, for bringing this term to my attention at the August

religious zealots, many women of child-bearing age remain torn over using EC.[16] For some, these qualms flow directly from their belief that life begins at fertilization. Although not an universally held view, deeply personal views about the beginning of life raise the question: Shouldn't doctors have an "open and honest conversation[ ] in layman's terms regarding EC, its benefits, and its potential consequences and let the patient make her own decision"?[17]

This Article maintains that a physician's "guidance on how and when to use [EC]"[18] is necessary to equip women with the information needed to make informed decisions about their bodies and healthcare, guided by "their own moral or religious beliefs."[19] Part II briefly recaps how the Mandate reinvigorated public concerns about abortion. It shows that religious objectors lifted their concerns about the contested drugs and devices directly from each label approved by the Food and Drug Administration (FDA)—as the Administration concedes in the litigation over the

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2013 Southeastern Association of Law Schools conference.

16. *See infra* Part IV (discussing the ethical dilemma women often face in deciding whether to use EC).

17. Jennifer L. Wallace, et al., *Letters to the Editor, In Response, Does Pregnancy Begin at Fertilization?, Author's Response*, 36 FAM. MED. 690, 691 (2004), http://www.stfm.org/fmhub/fm2004/November/Walter690.pdf.

18. Batur, *supra* note 12, at 771. Plan B's accessibility on the shelf presents added complexity to this issue. *See* infra note 66 (discussing the availability of Plan B without a prescription or required interaction with a pharmacist). Thus, women may not consult a physician or other professional before taking Plan B. Therefore, the drug's label should reflect accurate, accessible, and up-to-date information regarding the drug's mechanism of action. *See* infra Part III (discussing fourteen years of scientific evidence that Plan B does not act after fertilization, despite disclosures on Plan B's label). Furthermore, primary care physicians may also want to inform women seeking contraceptives about how specific kinds of EC work.

19. Charles J. Lockwood, *OTC Emergency Contraception: The Right Choice,* 49 CONTEMP. OB/GYN 12, 15 (2004). Other healthcare professionals, such as pharmacists, also have a role to play in providing women with the necessary information to make informed decisions regarding EC use. *See generally* EUROPEAN CONSORTIUM FOR EMERGENCY CONTRACEPTION, EMERGENCY CONTRACEPTION GUIDELINES IN THE EUROPEAN UNION COUNTRIES (2014), http://www.ec-ec.org/custom-content/uploads/2014/03/ECEC_EC-Guidelines-in-EU-countries_Feb2014.pdf. Therefore, while this Article deals primarily with informed consent law as applied to physicians, informed consent principles should animate the responsibilities of other healthcare professionals as well.

Mandate presently before the U.S. Supreme Court.[20] Part III then assesses the conflicting claims made by both sides about how the contested drugs and devices actually work, focusing on two: Plan B and *ella*.[21] This Part shows that since Plan B's approval in 1999, it has never been shown to work after fertilization—despite statements on its own label.[22] By contrast, *ella* is believed to "have an additional action of affecting the ability of the embryo to either attach to the endometrium or maintain its attachment, by a variety of mechanisms" after fertilization.[23] As Part IV documents, significant numbers of women care deeply about whether a given drug acts after fertilization to prevent or disrupt implantation.[24]

Part V turns to the two prevailing standards for determining what patients should be told when providing fully informed consent to a treatment—the professional standard and the material risk standard. This Part concludes that under either standard, doctors have a duty to help women decipher the dense, technical explanations found on the FDA-approved labels if women are to make informed decisions to use EC guided by their own values.[25] In doing so, physicians can add much-needed clarity to an issue muddied by political rancor, while enhancing the autonomy of the very women the Mandate sought to empower and assist.[26]

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20. *See infra* Parts II and III; *Birth Control: Medicines to Help You*, *supra* note 3 (explaining various types of birth control).

21. *See infra* Part III.A (detailing how Plan B and *ella* work).

22. *See infra* notes 38–39 and accompanying text (comparing the drug labels of *ella* and Plan B); *infra* Part III.A.1 (discussing when and how Plan B works).

23. Batur, *supra* note 12, at 774; *see also* Part III.A.2.

24. *See infra* notes 118–21 and accompanying text.

25. *See infra* Part V.

26. *See* Coverage of Certain Preventive Services Under the Affordance Care Act, 78 Fed. Reg. 39,870, 39,873 (July 2, 2013) (to be codified at 26 C.F.R. pt. 54; 29 C.F.R. pts. 2510, 2590; 45 C.F.R. pts. 147, 156) ("[B]oth existing health coverage and existing preventive services recommendations often did not adequately serve the unique health needs of women. This disparity placed women in the workforce at a disadvantage . . . . [A]ccess to contraception improves the social and economic status of women.").

II. A Resurgent Abortion Debate

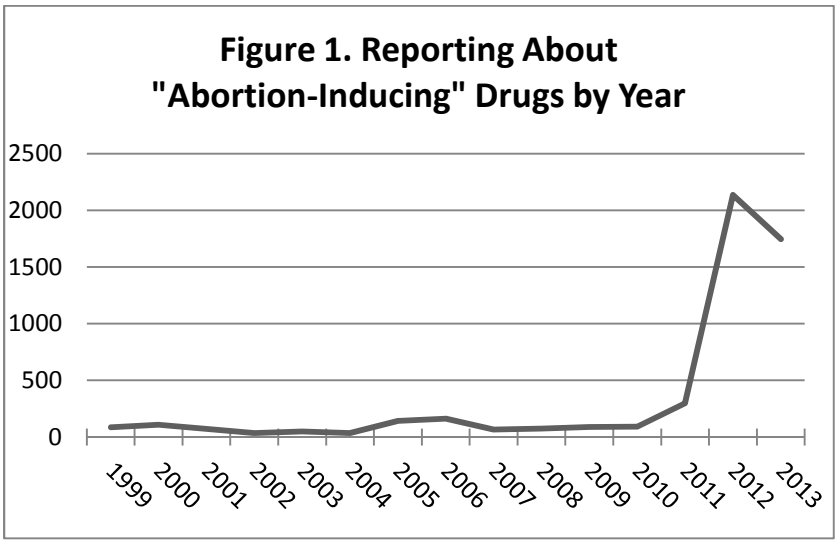
In the years before the Mandate entered the public psyche, reporting about "abortion-inducing drugs" was minimal.[27] As Figure 1 illustrates, after the Administration promulgated rules requiring coverage of "all-FDA approved contraceptives" in August 2011,[28] news reports about "abortion-inducing," "abortifacient," and "abortion-causing" drugs spiked and brought this concern fully into the American consciousness.[29]

27. Prior to the Mandate, it was healthcare providers who principally asserted religious objections to EC. *See* Robin Fretwell Wilson, *The Limits of Conscience: Moral Clashes over Deeply Divisive Health Care Procedures,* 34 AM. J.L. & MED. 41, 52–54 (2008) [hereinafter *The Limits*] (discussing refusals from healthcare facilities to perform abortions and prescribe EC, which resulted in the development of a private clinic industry); Robin Fretwell Wilson, *The Erupting Clash Between Religion and the State Over Contraception, Sterilization, and Abortion*, in RELIGIOUS FREEDOM IN AMERICA: CONSTITUTIONAL ROOTS AND CONTEMPORARY CHALLENGES (Allen D. Hertzke, ed., Univ. of Okla. Press 2014) (forthcoming) (discussing recent clashes over providing EC and abortions by nurses at two major medical centers); *see also* GUTTMACHER INSTITUTE, STATE POLICIES IN BRIEF: REFUSING TO PROVIDE HEALTH SERVICES 3 (Dec. 1, 2013), http://www.guttmacher.org/statecenter/spibs/spib_RPHS.pdf (charting "policies allowing providers to refuse" to provide abortion, contraception, and sterilization).

28. *See supra* note 2 (charting the evolution of the regulations requiring expanded coverage in accordance with HRSA Guidelines).

29. Three "All News" searches on Lexis for U.S. news pieces containing the terms "abortion-inducing," "abortifacient," or "abortion-causing" are telling:

TERM	FREQUENCY OF TERM IN A GIVEN YEAR														
	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
"abortion-inducing"	43	73	31	8	20	3	46	33	6	5	12	20	125	1193	1225
"abortifacient"	36	30	34	26	22	30	79	116	49	64	64	56	143	816	428
"abortion-causing"	6	5	5	1	7	2	16	12	11	6	11	14	28	125	91
TOTAL	85	108	70	35	49	35	141	161	66	75	87	90	296	2134	1744



Reporters quickly spotlighted the controversy. Headlines routinely touted one perspective or another: "Obamacare Mandates (Free) Coverage of Abortion Drug"[30] and "Emergency Contraception Is Not Abortion."[31]

Mandate supporters and opponents staked out opposing, public positions. In "Six Things Everyone Should Know About the HHS [Department of Health and Human Services] Mandate," the United States Conference of Catholic Bishops, a Mandate opponent, forcefully asserted: "[B]y including all drugs approved by the FDA for use as contraceptives, the HHS mandate includes drugs that can induce abortion, such as '*ella*,' a close cousin of the abortion pill RU-486."[32] Supporters, like the American Congress

30. *See* Jeffrey Anderson, *Obamacare Mandates (Free) Coverage of Abortion Drug*, THE WEEKLY STANDARD: THE BLOG (Aug. 4, 2011, 6:00 AM), http://www.weeklystandard.com/blogs/obamacare-mandates-coverage-abortion-drug_581969.html (last visited Jan. 21, 2014) (criticizing the Mandate) (on file with the Washington and Lee Law Review).

31. *See* Amanda Marcotte, *Emergency Contraception Is Not Abortion*, SLATE: THE XX FACTOR (June 6, 2012, 12:53 PM), http://www.slate.com/blogs/xx_factor/2012/06/06/the_new_york_times_confirms_that_emergency_contraception_only_works_by_suppressing_ovulation_.html (last visited Jan. 21, 2014) (discussing a recent New York Times article on EC) (on file with the Washington and Lee Law Review).

32. *Six Things Everyone Should Know About the Health and Human Services Mandate,* U.S. CONFERENCE OF CATHOLIC BISHOPS (Feb. 6, 2012), http://www.usccb.org/news/2012/12-021.cfm (last visited Dec. 29, 2013) (on file

of Obstetricians and Gynecologists, came to the Mandate's defense: "Abortion coverage is not required to be part of a minimum benefits package, and no federal funds or tax credits may be used to pay for abortions, except for abortions in case of rape, incest, and when the pregnancy puts the mother's life in danger."[33]

Although the better news reports and public statements unpacked exactly what they meant by "abortifacient" or "abortion-causing drug,"[34] many did not.[35] Even the Administration could have shed more light than it did. An HHS-drafted Factsheet about the Mandate flatly declared that "[a]bortifacient drugs are not included."[36] After exempting nonprofit religious objectors, the Administration continued to

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with the Washington and Lee Law Review).

33. AM. CONG. OF OBSTETRICIANS AND GYNECOLOGISTS, ACOG'S HEALTH CARE REFORM FAQS FOR WOMEN 1–2 (May 2010), *available at* http://www.acog.org/~/media/Departments/Health%20Care%20Reform/201005HCRFAQsForWomen.pdf?dmc=1&ts=20131211T1254164769. The American Congress and the American College of Obstetricians and Gynecologists are companion entities. *Id.*

34. *See* Marcotte, *supra* note 31 ("[A]bortion terminates pregnancy, which begins at implantation."); Anderson, *supra* note 30 (stating that abortifacients work by "by keeping a fertilized egg (or a newly conceived being) from implanting in the uterine wall"); *Six Things Everyone Should Know*, *supra* note 32 (noting that the HHS Mandate included coverage of *ella*, which the Conference considered to be an abortion-inducing drug).

35. *See, e.g.*, Steven Ertelt, *Obama Revises Mandate: Free Abortion-Causing Drugs for Women*, LIFENEWS.COM (Feb. 20, 2012, 12:55 PM), http://www.lifenews.com/2012/02/10/obama-revises-mandate-free-abortion-causing-drugs-for-women/ (last visited Jan. 31, 2014) ("The Obama administration has revised its controversial mandate that had forced religious employers to pay for health insurance coverage that includes birth control and drugs like Plan B, the morning after pill, and ella that can cause abortions.") (on file with the Washington and Lee Law Review); Paige Winfield Cunningham, *White House: Insurers Must Cover Abortion Pill*, THE WASH. TIMES (Aug. 1, 2011), http://www.washingtontimes.com/news/2011/aug/1/white-house-insurers-must-cover-abortion-pill/?page=all (last visited Jan. 31, 2014) (failing to define "abortion" in distinguishing required coverage of Plan B, but not RU-486) (on file with the Washington and Lee Law Review).

36. *Factsheet: Affordable Care Act Rules on Expanding Access to Preventive Services for Women*, on file with the author. HHS appears to have taken down the Factsheet, but a search now leads to this: *Affordable Care Act Rules on Expanding Access to Preventive Services for Women*, U.S. DEP'T. OF HEALTH & HUMAN SERVS., http://www.hhs.gov/healthcare/facts/factsheets/2011/08/womensprevention08012011a.html (last updated Jun. 2013) (last visited Mar. 5, 2014) (on file with the Washington and Lee Law Review).

summarily dismiss concerns that mandated drugs in fact cause abortions: "[T]he regulations do not violate federal restrictions relating to abortion because FDA-approved methods, including Plan B, *ella*, and IUDs, are not abortifacients within the meaning of federal law."[37]

Ironically, the FDA labels for each contested drug supplied the basis for objectors' concerns. The label for Plan B One-Step reads:

> Emergency contraceptive pills are not effective if a woman is already pregnant. Plan B One-Step is believed to act as an emergency contraceptive principally by preventing ovulation or fertilization (by altering tubal transport of sperm and/or ova). In addition, it *may inhibit implantation* (by altering the endometrium). It is not effective once the process of implantation has begun.[38]

The label for *ella* says: "When taken immediately before ovulation is to occur, *ella* postpones follicular rupture. The likely primary mechanism of action of [*ella*] for emergency contraception is therefore inhibition or delay of ovulation; however, alterations to the endometrium that *may affect implantation* may also contribute to efficacy."[39]

While both drugs indicate that they may function postfertilization, the fine print in their package inserts—for those who bother to read them[40]—would only muddy the question of whether the drug acts as an abortifacient.[41] For example, in

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37. Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 39,870 (July 2, 2013) (to be codified at 26 C.F.R. pt. 54; 29 C.F.R. pts. 2510, 2590; 45 C.F.R. pts. 147, 156) (quoting 62 Fed. Reg. 8611 (Feb. 25, 1997) ("Emergency contraceptive pills are not effective if the woman is pregnant[.]"); 45 C.F.R. § 46.202(f) ("Pregnancy encompasses the period of time from implantation until delivery.").

38. FOOD & DRUG ADMIN., PLAN B ONE-STEP PRESCRIBING INFORMATION, http://www.accessdata.fda.gov/drugsatfda_docs/label /2009/021998lbl.pdf (listing drug information for Plan B) (emphasis added).

39. *See* FOOD & DRUG ADMIN., ELLA PRESCRIBING INFORMATION, http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf (listing drug information for *ella*) (emphasis added).

40. *See infra* Part V (detailing that drug inserts are designed for physicians who act as an intermediary).

41. *See The FDA Announces New Prescription Drug Information Format*, FOOD & DRUG ADMIN, http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/LawsActsandRules/ucm188665.htm (last visited Dec. 30,

highly technical language,[42] Plan B One-Step's label says: "Plan B One-Step is believed to act as an emergency contraceptive principally by preventing ovulation or fertilization (by altering tubal transport of sperm and/or ova). In addition, it may inhibit implantation (by altering the endometrium)."[43] Even though the label recognizes the possibility that Plan B One-Step may act postfertilization—a time that some would consider during "pregnancy"[44]—the label elsewhere flatly says it "is not effective in terminating an existing pregnancy."[45]

Implicit in both disclosures is a central claim: a woman is not "pregnant" until "implantation" occurs. Skeptics dismiss concerns that EC may destroy a zygote after fertilization but before implantation as just so much religious gibberish: "There's no reason to think [the anti-choice movement will] suddenly grow respectful of actual science now that it has shown that emergency contraception has no effect on egg cells who've had their good Christian souls injected into them by those emissaries of the Lord known as sperm."[46]

Religious concerns about destroying a life, however, animate the *Hobby Lobby Store, Inc. v. Sebelius*[47] and *Conestoga Wood Specialties Corp. v. Sebelius*[48] cases challenging the

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2013) ("By improving the package insert to make it more useful for healthcare providers in their day-to-day clinical practice, we are making it easier for them to explain the benefits and risks of medications for their patients." (quoting Health and Human Services Secretary Mike Leavit)) (on file with the Washington and Lee Law Review).

42. Generally, informed consent forms should be understandable by people with an eighth grade or lower reading level. *See* CARL H. COLEMAN, JERRY A. MENIKOFF, ET AL., THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS 181 (LexisNexis 2005).

43. PLAN B ONE-STEP PRESCRIBING INFORMATION, *supra* note 38, at 4.

44. *See infra* Part III.A.1.

45. PLAN B ONE-STEP PRESCRIBING INFORMATION, *supra* note 38, at 2. Plan B One-Step's label also says it does not work "once the process of implantation has begun." *Id.* at 4. By contrast, *ella*'s label provides no such assurance. *But see* ELLA PRESCRIBING INFORMATION, *supra* note 39, at 5 (stating that *ella* "postpones follicular rupture").

46. Marcotte, *supra* note 31.

47. Hobby Lobby Stores, Inc. v. Sebelius, 723 F.3d 1114 (10th Cir. 2013) (en banc), *appeal docketed*, No. 13-354 (S. Ct. Sept. 19, 2013).

48. Conestoga Wood Specialties Corp. v. Sebelius, No. 13-1144 (3d Cir. 2013), *appeal docketed*, No. 13-356 (S. Ct. Sept. 19, 2013).

Mandate,[49] which are now set before the United States Supreme Court for argument on March 25, 2014.[50] In that litigation, the plaintiffs object to "drugs or devices that may cause the demise of an already conceived but not yet attached human embryo," although they assert no objection to drugs that prevent fertilization.[51] The *en banc* United States Court of Appeals for the Tenth Circuit chose not to "wade into scientific waters," noting that "the government and the medical amici supporting the government concede that at least some [EC] to which the plaintiffs object have the potential to prevent uterine implantation."[52] Given the parties' agreement that some forms of EC function in a manner that the plaintiffs "find morally problematic," the *en banc* court found "no material dispute" about the science. Apart from the other issues those cases raises, the

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49. *See* Hobby Lobby Stores, Inc. v. Sebelius, 723 F.3d 1114, 1120 (10th Cir. 2013) (en banc) (challenging the Mandate). The plaintiffs sought declaratory and injunctive relief, alleging that the Mandate violated the Free Exercise Clause and the Religious Freedom Restoration Act. *Id.* The court held that the plaintiffs had standing, that the Anti-Injunction Act did not bar the action, that corporations constituted "persons" within the meaning of the Religious Freedom Restoration Act, that corporations had rights under the Free Exercise Clause, that the plaintiffs showed a likelihood of success on the merits, that the Administration's interests in public health and gender equality do not constitute compelling interests, that the plaintiffs satisfied the irreparable injury prong for the preliminary injunction test, and that the case required remanding for consideration of the remaining preliminary injunction factors. *Id.* at 1121, 1129, 1143–47; *see also* Conestoga Wood Specialties Corp. v. Sebelius, 724 F.3d 377, 380 (3d Cir. 2013) (challenging aspects of the Mandate). A corporate employer and five owners brought an action for declaratory and injunctive relief, alleging that the Mandate violated the Religious Freedom Restoration Act, the First and Fifth Amendments, and the Administrative Procedure Act. *Id.* The court held that a for-profit, secular employer could not assert claims under the Free Exercise Clause or the Religious Freedom Restoration Act. *Id.* at 388. The court further held that the shareholders probably did not have a viable claim under the Free Exercise Clause. *Id.* at 389.

50. SUPREME COURT OF THE UNITED STATES, OCTOBER TERM 2014: FOR THE SESSION BEGINNING MARCH 24, 2014, 1 (2014), http://www.supremecourt.gov/oral_arguments/argument_calendars/MonthlyArgumentCalMar2014.pdf.

51. Complaint at 10, Conestoga Wood Specialties Corp. v. Sebelius, 917 F. Supp. 2d 394 (E.D. Penn. 2013) (No. 12-6744); *see also* Complaint Paragraph at 24, Hobby Lobby Sores, Inc. v. Sebelius, 870 F. Supp. 2d 1278 (W.D. Okla. 2012) (No. CIV-12-1000-HE) ("Plan B, Ella, and certain IUDs can cause the death of the embryo.").

52. Hobby Lobby Stores, Inc. v. Sebelius, 723 F.3d 1114, 1123 n.3 (10th Cir. 2013) (en banc).

science remains deeply contested by many, in part because of where different parties draw the line for when they believe life begins.[53]

The next Part evaluates the factual claim that neither Plan B nor *ella* act after fertilization.

III. Factual Basis for Religious Concerns

The claim that EC does not cause abortion rests on two notions: (1) that EC works only as a contraceptive to prevent fertilization and never functions afterwards; and (2) that even if a drug worked postfertilization, nobody could possibly believe that a pregnancy—or a life—exists in the hours and days after fertilization, so any drug that works at this time cannot induce an "abortion" by definition.[54]

This Part shows first that in the fifteen years since its approval, Plan B has never been shown to work after fertilization. Since *ella*'s approval in 2010,[55] however, more than one expert has posited that *ella* not only works before fertilization but it may work after fertilization as well—in ways that would give some women pause about whether to use *ella*.[56] Second, this Part

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53. *Id.*

54. Nobody disputes that an abortion ends a pregnancy. *See Abortion*, THE FREE DICTIONARY, http://www.thefreedictionary.com/abortion (last visited Feb. 11, 2014) (defining abortion as "[i]nduced termination of a pregnancy with destruction of the embryo or fetus") (on file with the Washington and Lee Law Review).

55. News Release, Food & Drug Admin., FDA Approves *ella* Tablets for Prescription Emergency Contraception (Aug. 13, 2010) (on file with the Washington and Lee Law Review), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm222428.htm (announcing FDA approval of *ella* for use as emergency contraception).

56. *See infra* Part III.A.2 (describing how *ella* may work). This Article does not examine the science behind the other contested drugs and devices because the contrast between Plan B and *ella* sufficiently illustrates the factual debate over how different ECs work. Although not necessary to this Article, the IUD labels contain similar disclosures to those for *ella*. For a discussion of copper IUDs, see Batur, *supra* note 12, at 774 (explaining that "the copper IUD also prevents implantation after fertilization, which likely explains its high efficacy"). For further discussion, see generally Kristina Gemzell-Danielsson, Cecilia Berger & P.G.L. Lalitkumar, *Review Article: Emergency Contraception—Mechanisms of Action*, 87 CONTRACEPTION 300 (2013) (discussing mechanisms of action of IUDs and their physiological effects). For a searchable database of FDA

documents that—although a handful of medical organizations and federal regulators share the same view of when pregnancy begins—medical treatises, dictionaries, and practicing Ob/Gyns are all over the map on the question of when pregnancy—or for that matter, when life—begins. More fundamentally, women themselves have strikingly different views about when life begins—and what would count as ending it.[57] Ultimately, what matters is their view as to whether a given drug constitutes an abortion.

A. Contraceptives or Abortifacients?: Unraveling Science and Semantics

Nearly everyone—from the Administration to religious objectors to the *New York Times*—lumps all EC together, charging that they do or do not cause abortions.[58] As Part II

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drugs, see FOOD & DRUG ADMIN., DRUGS AT FDA: FDA APPROVED DRUG PRODUCTS (2013), *available at* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/.

57. *See infra* Part IV.

58. *See* Editorial, *How Morning After Pills Really Work*, N.Y. TIMES, June 8, 2012 at A20, *available at* http://www.nytimes.com/2012/06/09/opinion/how-morning-after-pills-really-work.html (referring to all EC as simply the "the pill"); *What You Need to Know*, *supra* note 6, at 1 (stating that "[a]ccording to the best scientific evidence available, all FDA-approved emergency contraceptive pills work by interfering with ovulation or fertilization before pregnancy begins and are not so-called 'abortion pills'"); *Q&A with Dr. Cullins: Emergency Contraception*, PLANNED PARENTHOOD, http://www.plannedparenthood.org/health-topics/ask-dr-cullins/cullins-ec-5360.htm (last visited Dec. 20, 2013) (discussing the mechanism of action of EC as if all EC is the same, stating "EC works by stopping ovulation or fertilization . . . it could interfere with the implantation of a fertilized egg, but there is no scientific proof that this happens") (on file with the Washington and Lee Law Review); Complaint at 5, La. Coll. v. Sebelius, (W.D. La. Feb. 18, 2012) (No. 12-cv-463), http://www.adfmedia.org/files/LouisianaCollegeComplaint.pdf

> In the category of "FDA approved contraceptives" included in this Mandate are several drugs or devices that may cause the demise of an already-conceived but not-yet implanted human embryo. . . . Likewise in that category are "emergency contraception" or "Plan B" (the "morning after" pill), and variations of oral contraceptives ("birth control pills" or "the Pill") taken regularly through a cycle. . . . The FDA approved in this same category a drug called "*ella*" (the "week after" pill), which studies show can function to kill embryos even after they have implanted in the uterus, by a mechanism similar to the

illustrated, the FDA label disclosures lend to a singular narrative about how these drugs work, but the science plainly does not.[59]

Consider the 2013 review article, "Separating Fact from Fiction,"[60] by the Independent Family Health Center at the Cleveland Clinic, home of the third-ranked gynecology program in the United States.[61] The review article surveyed dozens of scientific, peer-reviewed articles across more than a decade, including one meta-analysis of the literature. The author, Dr. Pelin Batur, Education Director of Primary Care of Women's Health, concluded that both Plan B and *ella* "work[] primarily by delaying or inhibiting ovulation and inhibiting fertilization."[62] Nonetheless, important differences exist between Plan B's and *ella*'s mechanisms of action: "[Plan B] . . . would be unlikely to have any adverse effects on the endometrium after fertilization, since [it] would only serve to enhance the progesterone effect. Therefore, [it is] unlikely to affect the ability of the embryo to attach to the endometrium."[63] By contrast, *ella*

> can have just the opposite effect on the postovulatory endometrium because of its inhibitory action on progesterone. [*Ella*] is structurally similar to [RU-486], and its mechanism of action varies depending on the time of administration during the menstrual cycle. When unprotected intercourse occurs during a time when fertility is not possible, [*ella*] behaves like a placebo. When intercourse occurs just before ovulation, [*ella*] acts by delaying ovulation and thereby preventing fertilization (similar to [Plan B]). [*Ella*] may have an additional action of affecting the ability of the embryo to either attach to the endometrium or maintain its attachment, by a variety of mechanisms of action.[64]

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abortion drug RU-486.

59. *See infra* note 77 and accompanying text (noting that *ella* can work very differently from Plan B under certain circumstances).

60. Batur, *supra* note 12, at 771 (dispelling common misunderstandings about EC).

61. *Top-Ranked Hospitals for Gynecology*, U.S. NEWS AND WORLD REP. (2013), http://health.usnews.com/best-hospitals/rankings/gynecology (last visited Dec. 30, 2013) (on file with the Washington and Lee Law Review).

62. Batur, *supra* note 12, at 774.

63. *Id.*

64. *Id.*

As the next subparts detail, our independent review of the scientific literature reaches the same conclusion: in all probability, Plan B does not work after fertilization, despite the FDA-approved label, while *ella* may act after fertilization, *sometimes*.

1. How Plan B Works

It is no surprise that many want to lump Plan B and *ella* together: both work after unprotected sex to prevent "expected pregnancy."[65] At one point, both drugs required a prescription, although Plan B can now be found on the shelf next to common cold medicines, suppositories, and condoms.[66]

While Plan B is effective for only 72 hours after sex,[67] *ella* works over a longer time span. *Ella* remains effective up to 120 hours after sex.[68] Given the longer timespan, *ella* is much more effective in preventing pregnancy than Plan B.[69] In one 2006 study, women who received *ella* experienced "about half the number of pregnancies than in those treated with [Plan B], with

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65. *See* PLAN B ONE-STEP PRESCRIBING INFORMATION, *supra* note 38, at 1 (stating that Plan B is intended for use as an EC after unprotected intercourse); ELLA PRESCRIBING INFORMATION, *supra* note 39, at 1 (noting the *ella* is also intended for use after unprotected intercourse to prevent pregnancy)."Expected Pregnancy" "calculate[es] the number of pregnancies that might have occurred without use of the intervention." Anna F. Glacier et al., *Ulipristal Acetate Versus Levonorgestrel for Emergency Contraception: A Randomised Non-Inferiority Trial and Meta-Analysis*, 375 LANCET 555, 555 (2010).

66. *See* Julie Rovner, *Plan B to Hit Shelves, Protected from Generics*, NPR (July 24, 2013, 3:18 PM), http://www.npr.org/blogs/health/2013/07/24/205182187/plan-b-to-hit-shelves-protected-from-generics (last visited Jan. 21, 2014) ("Plan B One-Step . . . will be available on pharmacy and other retail shelves without restriction.") (on file with the Washington and Lee Law Review); Sydney Lupkin, *Judge Orders "Morning-After" Pill Be Sold Over-the-Counter to Those Under 17*, ABCNEWS (Apr. 5, 2013), http://abcnews.go.com/Health/morning-pill-sold-counter/story?id=18889946 (last visited Jan. 21, 2014) ("The FDA allowed Plan B to become available without a prescription to women 18 and over in 2006.") (on file with the Washington and Lee Law Review). *Ella* still requires a prescription. *See* News Release, *supra* note 55 (noting that *ella* is available "by prescription-only").

67. PLAN B ONE-STEP PRESCRIBING INFORMATION, *supra* note 38, at 1.

68. ELLA PRESCRIBING INFORMATION, *supra* note 39, at 1.

69. *See* Batur, *supra* note 12, at 772 (noting that *ella* is the most effective oral EC).

pregnancy rates of 0.9% vs 1.7%."[70] A later study found that *ella* prevented 85% of expected pregnancies compared to Plan B's 69%.[71]

Part and parcel of Plan B's reduced efficacy are the mechanisms by which it is now understood to work. Amassed across fifteen years and thousands of articles,[72] authorities agree that Plan B works[73] to delay or inhibit ovulation: "Early treatment with [EC]s containing only the progestin levonorgestrel [as Plan B does] has been shown to impair the ovulatory process and luteal function."[74] While a single study has suggested that Plan B may affect receptivity of the endometrium, two later studies directly designed to assess this possibility could not confirm it.[75]All available evidence suggests Plan B acts prior

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70. *Id.*

71. *See* Kristina Gemzell-Danielsson & Chun-Xia Meng, *Emergency Contraception: Potential Role of Ulipristal Acetate*, 2 INT'L J. WOMEN'S HEALTH 53, 57 (2010) (comparing results in an efficacy study of ECs).

72. Two searches on ScienceDirect.com, one limited by "levonorgestrel," Plan B's chemical name, and the other by "ulipristal acetate," *ella*'s chemical name, yield 7,815 journals, 627 books, and 43 reference works for Plan B and a mere 114 journals, 29 book, and 0 reference works for *ella*. Review articles show the same pattern. One review article of the mechanism of action for various EC canvassed 28 studies of Plan B but included only 3 studies of *ella*. *See* Gemzell-Danielsson, Berger & Lalitkumar, *supra* note 56, at 306–08 (listing references for the article, including the studies on which the discussion was based).

73. At one time, some speculated that Plan B also impeded the sperm, but authorities now agree that Plan B is not likely to work this way at commercially available doses. *See* James Trussell, Elizabeth G. Raymond & Kelly Cleland, Emergency Contraception: A Last Chance to Prevent Unintended Pregnancy 6 (Dec. 2013) (unpublished manuscript), http://ec.princeton.edu/questions/ec-review.pdf

> In a study conducted more than 30 years ago, levonorgestrel was found to interfere with sperm migration and function at all levels of the genital tract; however, a study designed to assess this issue found that 1.5 mg levonorgestrel had no effect on the quality of cervical mucus or on the penetration of spermatozoa in the uterine cavity.

(on file with the Washington and Lee Law Review); Gemzell-Danielsson, Berger & Lalitkumar, *supra* note 56, at 302 ("In vitro data indicate that [Plan B] . . . in doses relevant for EC has no direct effect on sperm function.").

74. Trussell, Raymond & Cleland, *supra* note 73, at 6.

75. *See id.* (discussing studies on early treatment with EC pills). Further, one study found no effect on the endometrium while the other found that Plan B does affect concentrations of glycodelin, a molecule that "inhibits fertilization, [and] may indicate an additional mechanism of action when ovulation is not inhibited." *Id.*

to fertilization, as an ordinary contraceptive. In essence, the sperm never meets the egg.

While Plan B's mechanism of action has been extensively studied, permitting experts to now rule out a postfertilization mechanism of action,[76] *ella* lacks this depth of research.[77] Although nascent, a burgeoning literature seeks to pinpoint precisely what explains *ella*'s "enhanced effectiveness."[78]

2. How Ella May Work

Leading authorities agree that, like Plan B, *ella*'s primary mechanism of action is to prevent ovulation.[79] The key difference

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76. *See* Batur, *supra* note 12, at 774 (finding Plan B unlikely to have any effects after fertilization); Trussell, *supra* note 73, at 7 (noting Plan B has no effect after fertilization), Gemzell-Danielsson, *supra* note 56, at 302 (finding no effect after fertilization when using Plan B in studies with monkeys and rats). Of course, no study can definitely, positively, absolutely exclude the possibility of a postfertilization effect, even as to Plan B. Authors of the studies showing a contraceptive effect acknowledge that "[i]t is unlikely that this question can ever be unequivocally answered, and we therefore cannot conclude that [ECs] never prevent pregnancy after fertilization." James Trussell & Beth Jordan, *Mechanism of Action of Emergency Contraception Pills*, 74 CONTRACEPTION 87, 87 (2006); *see also* Gabriela Noe et al., *Contraceptive Efficacy of Emergency Contraception with Levonorgestrel Given Before or After Ovulation*, 81 CONTRACEPTION 414, 414 (2010) (conceding that studies of Plan B's impact on "endometrial receptivity," a post fertilization effect, "are not consistent, and current knowledge on cellular and molecular markers of endometrial receptivity in the human is insufficient to resolve this controversy").

As Jeffrey Keenan, a professor of obstetrics and gynecology and director of the Division of Reproductive Endocrinology and Infertility at the University of Tennessee Medical Center, explains, clinical studies of Plan B "were not designed to assess this possibility." Jeffrey Keenan, *Ulipristal Acetate: Contraceptive or Contragestive?*, 45 ANNALS OF PHARMACOTHERAPY 813, 814 (2011). To give of the kind of certainty that some would like to see, "each study participant [would have had] to undergo laboratory evaluation and possibly sonographic examination to determine whether ovulation had already occurred." *Id*. Asking women themselves may not be promising, given the fact that "over 30% of women presenting for [EC]s had inaccurately dated their own menstrual cycles." Trussell, Raymond & Cleland, *supra* note 73, at 3.

77. *See supra* note 72 (noting that available information on *ella* is somewhat limited).

78. Keenan, *supra* note 76, at 814.

79. *See* Trussell, Raymond & Cleland, *supra* note 73, at 7 (discussing more than a half dozen studies that indicated *ella* prevents ovulation); Gemzell-Danielsson, Berger & Lalitkumar, *supra* note 56, at 302 (discussing the effect of

between the two: *ella* "is able to inhibit or significantly delay follicular rupture for over 5 days if given immediately before ovulation by postponing the LH peak"—that is, the spike of the hormone that triggers ovulation.[80] Thus, "when ovulation is imminent, [*ella*] is more effective than [Plan B] in delaying [ovulation]."[81]

While authorities universally agree that *ella* delays ovulation,[82] they are divided about whether *ella* may work by other mechanisms as well, as *ella*'s label suggests. Some posit that *ella* may work through a "contragestive" effect, in which "only gestation (implantation and growth) of the embryo [fertilized egg] is prevented."[83] When would this occur?

It would occur if *ella* altered the endometrium and the change "hamper[ed] implantation."[84] In a 2010 study, Pamela Stratton and colleagues examined the effects of three different doses of *ella* on the endometrium and compared them to a

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ella on ovulation); Ralph P. Miech, *Immunopharmacology of Ulipristal as an Emergency Contraceptive*, 3 INT'L J. WOMEN'S HEALTH 391, 392 (2011) (noting that *ella* acts by delaying ovulation); Keenan, *supra* note 76, at 813 (noting that *ella*'s primary function is to prevent ovulation, and that *ella* is "significantly more effective in this role than other forms of [EC]").

80. *See* V. Brache et al., *Immediate Pre-Ovulatory Administration of 30 mg Ulipristal Acetate Significantly Delays Follicular Rupture*, HUM. REPROD. 2256, 2262 (2010) (concluding that "this study provides mechanistic evidence to explain how [*ella*] could be more effective in preventing pregnancy than current reference EC methods").

As another review article puts it, the primary explanation for *ella*'s increased effectiveness over Plan B is that *ella* is "effective even when administered before ovulation, when LH has already started to rise, a time period when [Plan B] is no longer effective." Gemzell-Danielsson, Berger & Lalitkumar, *supra* note 56, at 305.

81. Trussell, Raymond & Cleland, *supra* note 73, at 4.

82. *See also* Miech, *supra* note 79, at 392 ("[*ella*'s] effectiveness as an EC is extended up to 120 hours after intercourse . . . and is [] effective as an EC if taken during rising LH levels prior to ovulation."); Keenan, *supra* note 76, at 813 ("There is good reason to believe that one mechanism of action for [*ella*] is the inhibition of ovulation. In fact, it appears to be significantly more effective in this role than other forms of [EC] such as [Plan B] . . . .").

83. Keenan, *supra* note 76, at 814; *see also* ELLA PRESCRIBING INFORMATION, *supra* note 39, at 9 (noting that *ella* may work to prevent implantation).

84. Pamela Stratton et al., *Dometrial Effects of a Single Early Luteal Dose of the Selective Progesterone Receptor Modulator CDB-2914*, 93 FERTILITY AND STERILITY 2035, 2040 (2010).

placebo.[85] The authors found "a significant reduction in endometrial thickness among those subjects receiving [*ella*] compared with those receiving placebo."[86] They concluded that "taken together, these endometrial effects in the absence of ovarian and menstrual cycle effects suggest mechanisms by which [*ella*] might be effective as an emergency contraceptive."[87] Importantly, others caution that "whether this change would inhibit implantation is unknown."[88]

A pair of experts has asked whether *ella*, if taken sufficiently late, is in fact working after fertilization.[89] Ralph Miech, an associate professor emeritus of molecular pharmacology, physiology, and biotechnology at Brown University, contends that *ella* has a "direct abortifacient effect" in a very narrow set of circumstances.[90] He defines "abortifacient" to mean the "loss of the embryo occurring either at the preimplantation stage or at the post-implantation stage."[91] According to Miech, this would occur "[w]hen unprotected intercourse occurs within the fertility window (i.e., less than 120 hours (5 days) before ovulation or not more than 24 hours after ovulation) and [*ella*] is taken after fertilization."[92] He envisions a "host-versus-graft rejection

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85. *See id.* at 2036 (examining whether *ella*, at any doses, delayed endometrial maturation, reduced endometrial thickness, or affected the number of progesterone receptors).

86. *Id.* at 2038.

87. *Id.* at 2040.

88. *See* Trussell, Raymond & Cleland, *supra* note 73, at 5 (discussing Stratton's findings). Gemzell-Danielsson, Berger, and Lalitkumar contend that "the effect of lower doses equivalent to the 30 mg used for EC was similar to that of placebo," but this synopsis does not accord with the study findings themselves. Gemzell-Danielsson, Berger & Lalitkumar, *supra* note 56, at 304. *Cf.* Stratton et al., *supra* note 84, at 2038 tbl.1 (reporting the endometrial effects of *ella*).

89. *See supra* note 79 (noting that both authorities, Miech and Keenan, agree that *ella* works primarily to prevent ovulation).

90. Miech, *supra* note 79, at 392.

91. *Id.* ("This report [uses] the classical definitions of abortion and contraceptive. Abortion is defined as the loss of the embryo occurring either at the preimplantation stage or at the post-implantation stage and contraception is defined as the prevention of fertilization."). A post-implantation effect would be an abortifacient under almost every medical definition and those Federal regulations in place since the 1970s. *See supra* note 37 and accompanying text (discussing the difference between contraception and abortifacient drugs).

92. Miech, *supra* note 79, at 392.

mechanism *during* the embryo's attempt to implant into the decidua."[93] In other words, *ella* may actually operate on the embryo during the implantation process.

In a 2011 article in the *Annals of Pharmacotherapy,* Jeffrey Keenan, Professor of Obstetrics and Gynecology at the University of Tennessee Medical Center in Knoxville, concluded that if a woman takes *ella* within five days of unprotected sex and *after* the fertilization, *ella*'s "mechanism of action is much more accurately described as contragestive, since only gestation (implantation and growth) of the embryo [fertilized egg] is prevented."[94] Keenan believes this action likely accounts for *ella*'s "enhanced effectiveness" relative to Plan B.[95] Disclosures from medical professionals and drug manufacturers should be "provided according to the best evidence available," as is the standard in European Union countries.[96] Some scientists move past the concern that any kind of EC might act as an abortifacient—in the views of women using them—by noting that ECs "do not interrupt an established pregnancy, defined . . . as beginning with implantation."[97] And as the next subpart illustrates, even the meaning of pregnancy is deeply contested.

B. The Meaning of Life—Or at Least Pregnancy

Obviously, how one defines pregnancy determines whether a given drug or device may induce an abortion in one's view.[98] Some

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93. *Id.* (emphasis added).

94. Keenan, *supra* note 76, at 814; *see also* ELLA PRESCRIBING INFORMATION, *supra* note 39, at 9 (noting that *ella* "may also work by preventing attachment").

95. *See* Keenan, *supra* note 76, at 814 (noting that *ella*'s "contragestive effect" is likely why it is so effective).

96. *See generally* EUROPEAN CONSORTIUM FOR EMERGENCY CONTRACEPTION, *supra* note 19.

97. Trussell, Raymond & Cleland, *supra* note 73, at 7.

98. Vivian W. Y. Leung, Marc Levine & Judith A. Soon, *Mechanisms of Action of Hormonal Emergency Contraceptives*, 30 PHARMACOTHERAPY 158, 160 (2010) ("For people who define pregnancy as beginning at implantation, an abortifacient is an agent that interferes with subsequent processes. . . . For those who consider pregnancy to begin with the completion of fertilization, an abortifacient is an agent that interferes with any postfertilization event, including implantation.").

Some people may believe that pregnancy begins at implantation, yet

groups, like the Guttmacher Institute, assert that the medical profession uniformly measures pregnancy from "implantation."[99] The evidence for this proposition: "Major medical organizations . . . as well as U.S. government policy, consider a pregnancy to have begun only when the entire process of conception is complete, which is to say after the fertilized egg has implanted in the lining of the uterus."[100]

Despite this confident assertion, a quick review of medical authorities reveals no unitary view. Some authorities measure pregnancy from fertilization[101] and some from implantation.[102] Others measure pregnancy from an "established pregnancy,"[103] a

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nonetheless believe that a drug that prevents implantation ends the existence of either a living, human organism (short of a pregnancy) or destroys something that has a special moral status. *See* infra notes 113–44.

99. *See* Sneha Barot, *Past Due: Emergency Contraception in U.S. Reproductive Health Programs Overseas*, 13 GUTTMACHER POL'Y REV. 8, 8 (2010), *available at* http://www.guttmacher.org/pubs/gpr/13/2/gpr130208.html (noting that "the Catholic Church and many antiabortion advocates" embrace a definition of pregnancy "flatly rejected by the medical profession" and that "under this definition, pregnancy begins with the 'moment of fertilization'—the union of an egg and sperm").

100. *Id.* at 8–9. Guttmacher also asserts that the meaning of "abortifacient" in federal law is clear; however, it is not as unambiguous as Guttmacher would have people believe. *See* Wilson, *The Calculus*, *supra* note 2, at 1456, 1459 (reviewing federal guidance about what counts as an abortifacient under federal regulations); Wilson, *Demagoguing Abortion*, *supra* note 2 (summarizing federal hearings in 1975 over the classifications of diethylstilbestrol as a contraceptive, a drug that studies in the Congressional Record indicated works on the endometrial implantation site, but was later pulled from the market as a teratogen). The FDA classified diethylstilbestrol as a contraceptive because it "prevent[ed] implantation." *Id. Ella* is posited to work, sometimes, during the process of implantation itself, raising a thorny question of how to construe FDA's definition. *Id.*

101. *See* Grace S. Chung et. al, *Obstetrician-Gynecologists' Beliefs About When Pregnancy Begins*, 206 AM. J. OBSTETRICS & GYNECOLOGY 132.e1, 132.e1 (2012), *available at* http://www.ajog.org/article/S0002-9378(11)02223-X/fulltext (showing some measure pregnancy from fertilization).

102. *See id.* ("Since 1965, the American College of Obstetricians and Gynecologists (ACOG) has defined *pregnancy* as beginning with implantation of the embryo in the uterine wall. This definition is used also by the Guttmacher Institute, Planned Parenthood, and some textbooks." (footnotes omitted)).

103. *See* AM. COLL. OF OBSTETRICS AND GYNECOLOGY, STATEMENT ON CONTRACEPTIVE METHODS 1 (1998) (listing the "[e]ssential steps necessary for pregnancy" as ending with "implantation of the blastocyst into the lining of the uterus at the conclusion of which pregnancy is established").

positive pregnancy test,[104] and the first heartbeat,[105] among others.[106] Clearly, however, the two leading contenders for the beginning of pregnancy are "implantation"[107] and "fertilization."[108]

Medical professionals themselves split on what marks the start of pregnancy. Fifty-seven percent of U.S. Ob/Gyns said pregnancy begins at "conception," by which the study authors believed respondents meant fertilization.[109] Twenty-eight percent of Ob/Gyns said pregnancy begins at implantation, and sixteen percent were "not sure which statement comes closest to their beliefs."[110] Those surveyed brought preconceived notions to the question. The strongest predictors of how Ob/Gyns defined pregnancy were the importance of religion in their lives and their own views on abortion.[111]

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104. *See* Keenan, *supra* note 76, at 814 (attributing to ACOG a definition of pregnancy that "begin[s] not with fertilization of the egg, but advancing implantation as demonstrated by a positive pregnancy test" (footnote omitted)).

105. Chung et. al, *supra* note 102, at 132.e5.

106. *See id.* (noting that "a significant percentage of Ob/Gyn physicians (16%) [who completed the questionnaire] marked 'not sure' when asked to indicate when pregnancy begins"). The two primary options were "conception" and "implantation." *Id.* at 132.e1. Given the percentage of "not sure" responses, "it is possible that a significant minority of physicians have not made up their minds or that they believe that their views could not be reduced to either of the 2 options that were offered." *Id.* at 132.e5.

107. *See* John K. Jain, *When Does Pregnancy Begin?*, SHARECARE, http://www.sharecare.com/health/prior-to-conception/when-does-pregnancy-beg in;jsessionid=787ABB31090D6282CC87D03389AE56BD (last visited Jan. 31, 2014) (concluding that "pregnancy officially begins at the time of implantation but is usually not detectable until the pregnancy hormone shows up in the blood and urine") (on file with the Washington and Lee Law Review).

108. *See* Walter L. Larimore, Joseph B. Stanford & Chris Kahlenborn, *Letters to the Editor: In Response: Does Pregnancy Begin at Fertilization?*, 36 FAM. MED. 690, 690 (2004) (stating that many maintain pregnancy starts the "instant that a spermatozoon enters an ovum and forms a viable zygote").

109. Chung et. al, *supra* note 102, at 132.e6.

110. *Id.*

111. *See id.* at 132.e3–e4 ("[R]eligious doctors and those who objected to abortion were less likely to be 'not sure'. . . . [B]elieving that pregnancy begins at implantation rather than conception (excluding those who were 'not sure') was associated with religious affiliation, the importance of religion, and objections to abortion.").

Just as important as this split, pregnancy is often a proxy for measuring the "onset of life."[112] Fertilization and implantation are not the only two markers for measuring the "onset of life," as Dr. Maureen Condic, Associate Professor of Neurobiology and Anatomy at the University of Utah School of Medicine, explains:

> Recently, it has been asserted that the life and moral status of the embryo begin at the eight-cell stage, because zygotic transcription (the active utilization of embryonic genes) commences at this time; and prior to this moment, whatever is happening in the "fertilized egg" is being driven by maternal factors. Some push the onset of life to even later, to the formation of specific structures or the onset of specific developmental processes. [113]

Philosophers, theologians, ethicists, and others have devoted thousands of pages to whether "personhood determines the beginning of human life," whether "rationality is necessary for personhood," and whether personhood begins with the "active potential for further development as a person," the "development of the primitive streak," or when the organism becomes a "unique" individual.[114] Some ask whether, even absent personhood, the "embryo has a significant moral status" worthy of respect.[115]

While the Guttmacher Institute, the Administration, and others rely on the Code of Federal Regulations[116] in dismissing religiously grounded concerns, individual women follow their personal moral codes, as the next Part explains.

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112. *See* Condic, *supra* note 101, at 1–2 (describing various ways to biologically define when life begins). For a general discussion of the beginning of life, whether at pregnancy or other points or whether a potential life is due special consideration, see the excellent book, DEFINING THE BEGINNING AND END OF LIFE: READINGS ON PERSONAL IDENTITY AND BIOETHICS (John. P. Lizza ed., 2009).

113. Condic, *supra* note 101, at 1 (footnotes omitted).

114. *See* John P. Lizza, *Introduction* to DEFINING THE BEGINNING AND END OF LIFE: READINGS ON PERSONAL IDENTITY AND BIOETHICS 1, 5 (John. P. Lizza ed., 2009) (summarizing various theories included in the book on when life begins).

115. *See id.* (noting that "most Jewish thinkers" believe an embryo does not become a "person" until birth but is nonetheless entitled to protection during "gestation").

116. *See supra* note 37 (showing reliance by the Administration on regulatory definitions of pregnancy in other contexts); *see also supra* note 100 and accompanying text (discussing the definition of pregnancy).

IV. Women Care About Mechanisms of Action

Caught in the midst of an argument by label, women are now no more informed about how EC works than before the Mandate.[117] But they still care.

Physicians have long recognized that "the majority of women . . . want to be informed . . . about mechanisms of action taking place after fertilization and implantation, regardless of their religiosity or whether they believed that human life begins at fertilization or implantation."[118] In 2004, when the FDA made Plan B available over the counter, the scientific advisory committee to the FDA urged the FDA to include appropriate disclosures on Plan B's label precisely "so that women could make an informed choice about its use and avoid inadvertently violating their own moral or religious beliefs."[119] Disclosures from medical professionals and drug manufacturers should be "provided according to the best evidence available," as is the standard in European Union countries.[120]

Empirical studies of women's attitudes across the United States, in both urban and suburban settings, confirm the importance that women place on information. A 2005 study of women 18–50 seen in Utah and Oklahoma family practices and Ob/Gyn clinics found that 53% would not use a birth-control method that acts after fertilization but before implantation.[121]

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117. *Supra* Part II.

118. Cristina Lopez-del Burgo et al., *Knowledge and Beliefs About Mechanism of Action Birth Control Methods Among European Women*, 85 CONTRACEPTION 69, 75 (2012); *see also* Christy A. Sherman, S. Marie Harvey, Linda J. Beckman & Diana B. Petitti, *Emergency Contraception: Knowledge and Attitudes of Health Care Providers in a Health Maintenance Organization*, 11 WOMEN'S HEALTH ISSUES 448, 452 (2001) (surveying San Diego County, California healthcare providers including Ob/Gyns and reporting that "[n]early all (99.4%) of the providers surveyed reported they agreed with the statement 'Women who specifically ask for information about emergency contraceptive pills should be given information,' with 85% of providers indicating strong agreement").

119. *See* Lockwood, *supra* note 19, at 15 (noting that "[m]any on the FDA panel perceived that a contragestive effect [e.g., an effect after fertilization occurs] was possible and we recommended that the package labeling should describe the drug's potential mechanism of action").

120. *See generally* EUROPEAN CONSORTIUM FOR EMERGENCY CONTRACEPTION, *supra* note 19.

121. Huong M. Dye et al., *Women and Post-Fertilization Effects of Birth*

Seventy-four percent would not use a method that acts after implantation.[122] When asked if they would change their own birth control method if told that "there was a remote possibility" that it acted after fertilization but before implantation, 44% "would stop using it," while 69% "would stop using it" if there was a "remote possibility" of it acting after implantation.[123]

For many of these women, their reticence directly reflects their beliefs about when life begins. Forty-eight percent of women "reported the personal belief that human life begins at fertilization" and another 5% answered that "life begins after fertilization, but before implantation."[124] Of all women surveyed, 34% answered that "life begins at fertilization and [that they] would not use a birth control method that acts [after fertilization]"—while 3% answered that life starts at fertilization but they would nonetheless use a birth control method that acts after fertilization.[125]

Women in the southeastern United States also expressed deep discomfort with EC that acts after fertilization. In an anonymous 2008 questionnaire of women seen at two academic family medicine clinics, 38% of all respondents said they would use EC but only if "it worked before fertilization or implantation,"[126]—

Control: Consistency of Beliefs, Intentions and Reported Use, 5 BMC WOMEN'S HEALTH, Nov. 29, 2005, at 4, http://www.biomedcentral.com/content/pdf/1472-6874-5-11.pdf. For a description of the study sites, see *id.* at 2–3 (noting that the Oklahoma site was "a teaching clinic associated with a family medicine residency program sponsored by a Protestant religious organization" and that "[n]one of the clinics in Utah were religiously affiliated or sponsored").

122. *Id.* at 4.

123. *Id.* No EC required by the Mandate is presently understood to act after implantation. *See supra* Part III (discussing RU-486, which is not mandated). Surveys of women who are not faced directly with the possibility of pregnancy after unprotected sex may not capture the views of women faced with that possibility. Choices presented in a vacuum might look very different if a woman suddenly finds herself in need of EC.

124. Dye et al., *supra* note 111, at 5.

125. *Id.* at 5–6.

126. *See* John W. Campbell III et al., *Attitudes and Beliefs About Emergency Contraception Among Patients at Academic Family Medicine Clinics*, 6 ANNALS FAM. MED. S23, S23 (2008) (utilizing a "convenience sample [size of 178] of female patients aged 18 to 50 years."). Researchers asked: "Pregnancy begins when[:] A. Sperm and egg join within the female reproductive tract. B. Implantation occurs. C. The heart starts beating. D. Unsure. E. Other." *Id.* at S24.

admittedly an inartful question.[127] Nearly half, 47%, "believed that pregnancy begins with fertilization."[128] Isolating the impact of socioeconomic factors, only annual household income of less than $40,000 correlated with a woman's belief that life begins at fertilization—with those under $25,000 most likely to believe the life begins at fertilization.[129] Strength of religious beliefs, age, race, and level of education were irrelevant.[130] Ironically, the women whose life chances are likely to be most impacted by an unintended pregnancy—poorer women with fewer resources—were precisely the ones most likely to believe that life begins at fertilization.[131]

Researchers for John W. Campbell III and colleagues also gauged knowledge of EC's mechanism of action. A "majority of women surveyed did not know that one possible mechanism of action of EC is to prevent implantation of a fertilized ovum."[132] Although "women aged 25 years or younger were more likely to think that EC works before the egg and sperm join than older women[,] [t]here w[ere] no significant differences in the perception . . . based on age, race, income, education, or strength of religious beliefs."[133] The authors' takeaway message was that "m[a]ny women are uninformed about the possible mechanisms of action of EC, and we found no reliable predictors for those who were better informed."[134] Better knowledge would not matter to everyone—42% were unsure whether better knowledge of a drug's

127. The inartfully drafted "fertilization or implantation" question is not as probative as it would have been if it had separated views about prefertilization methods from postfertilization, pre-implantation methods.

128. Campbell et al., *supra* note 126, at S23. Although 47% of respondents indicated that "*pregnancy* begins with fertilization," only 30% believed that "*life* begins with fertilization" even if pregnancy was not present. *Id.* (emphasis added).

129. *See id.* at S25 ("Women with incomes of less than $40,000 [per year] were more likely to believe that life begins at the joining of sperm and egg than women with higher incomes.").

130. *Id.* at S25–S26.

131. *See generally* NAOMI CAHN & JUNE CARBONE, RED FAMILIES V. BLUE FAMILIES: LEGAL POLARIZATION AND THE CREATION OF CULTURE (2010).

132. Campbell et al., *supra* note 126, at S26.

133. *Id.* at S25–S26.

134. *Id.* at S23.

mechanism would change their practices.[135] Nonetheless, the authors stressed the "need to better educate [women] about [EC's] possible mechanisms of action."[136]

In a 2004 study of Latino women seen at two reproductive health clinics in southeast Texas, "women who believed that EC worked mainly by preventing implantation were significantly less willing to use it than those who believed that it prevented ovulation."[137] Religious background did not affect this willingness,[138] although factual misconceptions about EC did.[139] As the authors noted, "EC reduces the risk of pregnancy by preventing or delaying ovulation, inhibiting fertilization, and possibly inhibiting implantation. However, a belief that implantation is the primary mechanism or that EC interrupts gestation would not be correct."[140] The authors found "the odds of being unwilling to use EC were roughly six times higher among women who believed that EC prevents pregnancy at implantation when compared to women who believed that EC affects ovulation processes."[141] The researchers chalked up unwillingness to use EC to "misinformation about the mechanism of action."[142] Education to correct misconceptions about the mechanism of action of EC would "help alleviate [Latino women's] concerns, which in turn may increase their willingness to use EC."[143] Although the researchers surveyed women in 2004—long before *ella* came on the scene—the general proposition stands. For many women, EC that "affects fertilization or implantation" is morally objectionable.[144]

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135. *Id.* at S25.

136. *Id.*

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

138. *Id.*

139. *Id.*

140. *Id.* at 229 (endnote omitted).

141. *Id.* at 232.

142. *Id.* at 233 ("Specifically women who believed that EC prevents pregnancy at ovulation reported less moral objections to its use than women who believe that EC affects fertilization or implantation.").

143. *Id.*

144. *Id.*

While there is good reason to worry about the representativeness of these studies, women in Europe,[145] Mexico,[146] and Spain[147] also communicate uneasiness about drugs that may act after fertilization. As the next Part argues, women can vindicate their own beliefs and values only if informed, in layman's terms, about how these drugs may act in their own bodies.

V. The Duty of Informed Consent

Aimed at autonomy, individual rights, and self-determination,[148] informed consent fits naturally with American

145. *See* Lopez-del Burgo et al., *supra* note 118, at 69 (randomly surveying women in "Germany, France, the UK, Sweden, and Romania" and finding that, "[r]egardless of [participants'] sociodemographic characteristics and their belief about when human life begins," the "majority [of women surveyed, 75%,] want to be informed about possible postfertilization effects [of contraceptive methods]").

146. *See* Heather Gould, Charlotte Ellertson & Georgina Corona, *Knowledge and Attitudes About the Difference Between Emergency Contraception and Medical Abortion Among Middle-Class Women and Men of Reproductive Age in Mexico City*, 66 CONTRACEPTION 417, 423 (2002) ("Because one possible mechanism of action involves impeding implantation of a fertilized egg, some participants continue to equate EC with abortion.").

147. *See* Cristina Lopez-del Burgo et al., *Spanish Women's Attitudes Toward Post-Fertilization Effects of Birth Control Methods*, 151 EUR. J. OBSTETRICS & GYNECOLOGY AND REPROD. BIOLOGY 56, 57 (2010) (finding that "45% of women [surveyed] . . . would not consider using a [contraceptive] method that may work after fertilization and 57% would not consider using one that may work after implantation").

148. *See* JESSICA W. BERG ET AL., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 14 (2d ed. 2001) (noting the values that guide informed consent). As Bernard Lo notes, "participation in decisions generally has other beneficial consequences for patients, such as increased sense of control, self-efficacy, and adherence to plans for care." BERNARD LO, RESOLVING ETHICAL DILEMMAS: A GUIDE OF CLINICIANS 21 (2d ed. 2000). Not all patients want this. *See* Cathy J. Jones, *Autonomy and Informed Consent in Medical Decisionmaking: Toward a New Self-Fulfilling Prophecy*, 47 WASH. & LEE L. REV. 379, 419 (1990) (surveying evidence that "in many cases patients do request or allow physicians to make decisions for them" (footnote omitted)); *see also infra* note 166 and accompanying text (describing the "model of shared decision making" between patients and doctors as responding to the desire of some patients to provide input but not necessarily to make a decision on their own).

values and culture.[149] As Justice Cardozo famously observed in 1914, "[e]very human being of adult years and sound mind has a right to determine what shall be done with his body."[150] For much of our history, however, informed consent played little to no role in the doctor–patient relationship. In an era of paternalism, "simple consent" sufficed before a physician treated a patient.[151] Not surprisingly, "simple consent" sometimes amounted to no consent at all.[152]

By the late 1950s, courts began to require meaningful consent by patients. In *Salgo v. Leland Stanford Junior*

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149. *See* BERG ET AL., *supra* note 148, at 14 (explaining that such values are "deeply embedded in American culture" and thus "[i]t is not surprising that informed consent is a cornerstone of contemporary medical ethics and health law in the United States").

150. Schloendorff v. Soc'y of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914).

151. *See* BERG ET AL., *supra* note 149, at 43 (noting that historically "courts have generally agreed that the patient has, by speaking some phrase, authorized the physician to proceed and thereby provided the physician with a defense to an action for battery"). We refer to this as a "simple consent" requirement. *Id.*

152. *See id.* (noting that in early- to mid-twentieth-century cases courts often found consent even when patients had expressly told the doctor not to render treatment) (citing Markart v. Zeimer, 227 P. 683 (Cal. Ct. App. 1924); Meek v. City of Loveland, 276 Pac. 30 (Colo. 1929); Corn v. French, 289 P.2d 173 (Nev. 1955)).

As late as the 1950s, a Nevada trial court granted a defendant-doctor's motion to dismiss even though the plaintiff-patient maintained that the doctor deliberately deceived her into consenting. *See* Corn, 289 P.2d at 281–82 (noting trial court's grant of involuntary dismissal and plaintiff's assignments of error). There, Ruth Corn visited Dr. James French about a lump under her right breast. *Id.* at 174–75. Suspecting breast cancer, Dr. French indicated that the breast may need to be removed and began making arrangements over the phone for a procedure at a hospital, including a request for particular tools. *Id.* Ruth immediately told Dr. French, "If that's my breast you are talking about, you are not going to remove it." *Id.* at 175. Doctor French responded, "I have no intentions of removing your breast. I wouldn't think of doing so without first making a test," explaining that the test required the same tools. *Id.* When Ruth arrived at the hospital for the procedure, she signed a form "giv[ing] [her] consent to James B. French, M.D., to perform an operation for mastectomy . . . upon [her], and to do whatever may be deemed necessary in his judgment." *Id.* Ruth had never heard of a mastectomy and Dr. French never explained what mastectomy meant. *Id.* Ruth told Dr. French a second time that he only was to conduct a test. Dr. French removed Ruth's breast anyway. *Id.* Although the Supreme Court of Nevada ultimately reversed the decision and remanded it for a new trial on a claim of negligence, *id.* at 182, the trial court's decision exemplifies the historical resistance to imposing duties of informed consent.

University Board of Trustees,[153] a California appellate court imposed on doctors an affirmative duty of honest and meaningful disclosure.[154] Fleshing out the contours of informed consent, the *Salgo* court noted that "[a] physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment."[155]

A. Two Approaches to Informed Consent

Today, as a result of judicial decisions or state legislation, all fifty states require physicians to secure informed consent.[156] But states differ in how they determine what must be disclosed to patients.[157] Under the earliest test, the professional standard, physicians must disclose only that "which a reasonable medical practitioner would [disclose] under the same or similar circumstances."[158] This standard offered physicians, as a group, the freedom to define appropriate disclosure based on medical knowledge,[159] giving them considerable certainty about what needed to be disclosed.[160] Clearly, the professional standard gives physician's substantial control over what is disclosed and,

153. 317 P.2d 170 (Cal. Dist. Ct. App. 1957).

154. *See id.* at 181 (noting that despite this duty, the trial court's jury instruction on the physician's duty to disclose was "rather broad" and explaining the duty in detail).

155. *Id.*

156. *See* Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Decision-Making,* 32 AM. J.L. & MED. 429, 493 (2006) (providing appendix of state laws and key cases).

157. *See* BERG ET AL., *supra* note 149, at 46–51 (discussing the differences between the "professional" and "patient-oriented" standards of informed consent). "[I]n practice the boundary between these two standards is often blurred." *Id.* at 52.

158. Natanson v. Kline, 350 P.2d 1093 (Kan. 1960).

159. *See* BERG ET AL., *supra* note 148, at 46 (recognizing the "maintenance of the medical profession's freedom . . . to shape the contours of appropriate disclosure" as an advantage of the professional standard).

160. *Id.* at 46–47 (noting that "the professional standard places no extra burden on physicians to conform to an externally imposed standard, since they presumably already know about and observe professional norms," but there may be instances in which no "professional custom of disclosing," or an inadequate custom, exists).

therefore, over the ultimate decision whether to proceed with a treatment.[161] Roughly half the states continue to follow this standard.[162]

The more patient-centered material risk standard emerged to "safeguard the patient's interest in achieving his own determination on treatment."[163] The material risk standard generally requires the physician "to disclose all information about a proposed treatment that a *reasonable* person in the patient's circumstances would find material to a decision either to undergo or forgo treatment."[164] Although the material risk standard imposes a significantly greater burden on physicians,[165] "[i]ndividuals place different values on health, medical care, and risk," preferences that "physicians cannot accurately predict."[166]

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161. *See id.* at 47 ("[E]ven where professional standards exist, they may be set too low to satisfy the needs of patients who wish to participate in medical decision making in accord with the idea of informed consent.").

162. *See* David M. Studdert et al., *Geographic Variation in Informed Consent Law: Two Standards for Disclosures of Treatment Risks*, 4 J. EMPIRICAL LEGAL STUD. 103, 105 (2007) (noting that "23 states have maintained the professional standard").

163. *See* Canterbury v. Spence, 464 F.2d 772, 786–87 (D.C. Cir. 1972) (explaining why the court declined to adopt a standard for disclosure "framed with reference to prevailing fashion within the medical profession" and instead defined the contours of what is disclosed by "the patient's right of self-decision").

164. BERG ET AL., *supra* note 149, at 48. A handful of jurisdictions "take an even more protective approach, requiring disclosure of information that a particular patient (as contrasted with a [reasonable] patient) would have wanted to make his or her decision." HALL ET AL., HEALTH CARE LAW AND ETHICS 204 (7th ed. 2007). Clearly, what the reasonable person finds material and what an individual patient finds material may differ. Berg offers the example of a watch repairer who would be interested in knowing that a particular medication can cause a fine tremor, a risk most patients may not find material. *See* BERG ET AL., *supra* note 149, at 50.

165. This is especially true when the law requires physicians to divine what individual patients would want to know. *See* Robert Gatter, *Informed Consent and the Forgotten Duty of Physician Inquiry,* 31 LOY. U. CHI. L.J. 557, 596 (2000) (arguing that "physicians [should] reasonably inquire about the subjective treatment goals of patients" and that "[w]ithout an objective limitation to a physician's inquiry, physicians could be held liable for failing to ask the one question that, in hindsight, would have brought forth key information about the patient's treatment goals"); *see also* LO, *supra* note 149, at 24 (discussing how problematic a subjective standard is in malpractice litigation).

166. *Id.* at 20. Over the last decade, healthcare professionals have embraced a model of shared decision making, which some describe as the "process of interacting with patients who wish to be involved in arriving at an informed, values-based choice among two or more medically reasonable alternatives."

Under both standards for disclosure, patients must be informed of "the *nature* of the intervention, the expected *benefits*, the *risks*, and the likely *consequences*."[167] Under both, physicians have a duty to apprise patients of alternatives to treatment,[168] as well as the risk of "doing nothing."[169] Under both, physicians are not absolved of a duty to discuss the risks of a medication with patients even if those risks are disclosed on a drug's labeling. The drug's label is intended for consumption by the physician, who must independently explain its importance to patients.[170]

Annette O'Connor, Hilary A. Llewellyn-Thomas & Ann Barry Flood, *Modifying Unwarranted Variations in Health Care: Shared Decision Making Using Patient Decision Aids*, HEALTH AFFAIRS 63, 64 (2004), http://geiselmed.dartmouth.edu/cfm/education/PDF/shared_decision_making.pdf. One impetus for the model is studies showing while that a significant number of patients (a fourth in one study) want physicians to make the decision for them, a significant majority, roughly one-half in one study and 68% in another, wanted to select the treatment option together with their physician. Deber RB, Kraetschmer N, Irvine J., *What Role Do Patients Wish to Play in Treatment Decision-Making?*, 154 ARCHIVES INTERNAL MED. 1414, 1414–20 (1996); *see also* Dennis J. Mazur & David H. Hickam, *Patients' Preferences for Risk Disclosure and Role in Decision Making for Invasive Medical Procedures,* 12 J. GEN. INTERNAL MED. 114, 115 (1997) (studying patient attitudes about the role they desire to have in medical decision-making). For a critique of shared decision making, arguing that "the skimpiest reflection reveals that [shared decision making] is ambiguous unto incoherence," see Carl E. Schneider, *Void for Vagueness*, 37 HASTINGS CTR. REP. 10, 10–11 (2007); *see also* Simon N. Whitney et al., *Beyond Shared Decision Making: An Expanded Typology of Medical Decisions*, 28 MED. DECISION MAKING 699, 701–02 (2008) (discussing situations in which one viable treatment option exists and contrasting these with situations in which patients and doctors disagree about treatment options).

167. *See* LO, *supra* note 149, at 21 (laying out requirements for informed consent).

168. *See generally* John H. Derrick, Annotation, *Medical Malpractice: Liability for Failure of Physician to Inform Patient of Alternative Modes of Diagnosis or Treatment*, 38 A.L.R.4th 900 (originally published in 1985) (collecting and discussing physician liability for failing to disclose alternative methods of treatment to patients under both standards).

169. *See* Wecker v. Amend, 918 P.2d 658, 661 (Kan. Ct. App. 1996) (concluding that a physician should inform a patient of the option of forgoing treatment "in situations where no treatment at all is a reasonably medically acceptable option" under the professional standard); Truman v. Thomas, 611 P.2d 902, 906–07 (Cal. 1980) (explaining that "if the recommended test or treatment is itself risky, then the physician should always explain the potential consequences of declining to follow the recommended course of action" since it would be material to a reasonable patient).

170. *See* Niemiera *ex rel.* Niemiera v. Schneider, 555 A.2d 1112, 1119 (N.J. 1989) (holding a prescription drug maker did not owe a duty to warn of side-

Under both, physicians must disclose not only "biomedical risks" but "psychosocial" harms as well.[171] Indeed, sometimes the psychosocial harms are the ones that matter most. As the medical ethicist Bernard Lo notes: "[For HIV] and genetic testing, the pertinent risks are not the risks of venipuncture, but the risks of stigma and discrimination in employment or health insurance. Many states have enacted special provisions requiring written informed consent and pretest counseling for HIV testing."[172] Neither standard, however, requires physicians to inform patients of things that patients already know or reasonably should know.[173]

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effects because of the "learned intermediary" doctrine and noting that "[t]he duty of the manufacturer of the vaccine is to warn the learned intermediary who passes it on to the patient through informed consent" (internal quotation marks omitted)).

171. *See* LO, *supra* note 148, at 21 (explaining the types of information physicians must discuss with patients to obtain informed consent). Some question whether the information provided to women, or all patients, should be limited to medical information. For example, family practitioners might choose to disclose to women risks to their children from cohabiting with someone other than the child's legal parent. For a discussion of risks to children cohabiting with mother's boyfriends, in particular, see generally Robin Fretwell Wilson, *Trusting Mothers: A Critique of the American Law Institute's Treatment of De Facto Parents*, 38 HOFSTRA L. REV. 1103 (2010); Robin Fretwell Wilson, *Undeserved Trust: Reflections on the ALI's Treatment of De Facto Parents*, *in* RECONCEIVING THE FAMILY: CRITICAL REFLECTIONS ON THE AMERICAN LAW INSTITUTE'S PRINCIPALS OF THE LAW OF FAMILY DISSOLUTION 90 (Robin Fretwell Wilson ed., 2006); Robin Fretwell Wilson, *Children at Risk: The Sexual Exploitation of Female Children After Divorce*, 86 CORNELL L. REVIEW 251 (2001).

172. LO, *supra* note 148, at 21 (citation omitted).

173. Physicians may also be excused "from a duty to disclose information concerning dangers related to proposed treatment of which patients of average sophistication would already be aware, apparently without a requirement that any given patient actually be 'of average sophistication.'" Jones, *supra* note 148, 393–94 (quoting Canterbury v. Spence, 464 F.2d 772, 788 (D.C. Cir. 1972)). Five general exceptions exist to the duty to provide informed consent: "threats to public health, medical emergency, therapeutic privilege, waiver of informed consent by the patient, and a patient's lack of competence to make decisions." THOMAS MAY, BIOETHICS IN A LIBERAL SOCIETY: THE POLITICAL FRAMEWORK OF BIOETHICS DECISION MAKING 21 (paperback ed. 2009). Today, the therapeutic privilege has fallen into disfavor as too easily leveraged to "overrid[e] a patient's values." *Id.* at 21–22, 26–30 (explaining how the therapeutic privilege was relied upon to preclude disclosure of alternative treatments to patients who would rather let the doctor decide); *see also* Nathan A. Bostick, Robert Sade, John W. McMahon & Regina Benjamin, *Report of the American Medical Association Council on Ethical and Judicial Affairs: Withholding Information from Patients: Rethinking the Propriety of "Therapeutic Privilege,"* 17 THE J. OF CLINICAL

In short, then, "all risks potentially affecting the decision must be unmasked."[174]

B. Abortion Cases

A pair of recent cases brought by women after abortions they later regretted affirms that, under both standards, patients must be informed about factual information like gestational stage.

In the past few years, state courts in New Jersey and Illinois have grappled with the limits of disclosure provided to women seeking an abortion. In both, the plaintiffs lost.[175] The plaintiffs maintained—in virtually identical terms[176]—that they should

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ETHICS 302 (2006) (concluding that withholding information is unethical and early communication should only be avoided if early communication is "clearly contraindicated").

174. Canterbury v. Spence, 464 F.2d 772, 787 (D.C. Cir. 1972) (footnote omitted). Of course, disclosure does not always work this way on the ground. *See* BERG ET AL., *supra* note 148, at 147 (noting that some proponents of informed consent "are troubled by the failure of the current law to protect [patient] autonomy as fully as it might and by what they see as a consistent pattern of subordinating patient autonomy to the interests of the medical profession" (endnotes omitted)).

175. *See* Doe v. Planned Parenthood/Chi. Area, 956 N.E.2d 564, 574 (Ill. App. Ct. 2011) (affirming lower court's dismissal of complaint that included claim for lack of informed consent); Acuna v. Turkish, 930 A.2d 416, 428 (N.J. 2007) ("We . . . reinstate the order dismissing plaintiff's lack-of-informed-consent and emotional distress claims, which were the only remaining claims in this case.").

To succeed on a claim of a breach of the duty to provide informed consent, plaintiffs must demonstrate three elements: failure to disclose a specific risk in violation of the applicable standard, the materialization of the specific risk, and that had the risk been disclosed, the patient, or a prudent person in the patient's position, would not have proceeded as she did. *See* HALL ET AL, *supra* note 164, at 215 (laying out elements of a cause of action for nondisclosure).

On causation, the dominant standard is the prudent person standard, but a handful of jurisdictions follow a subjective standard. *Compare Canterbury*, 464 F.2d at 791 (establishing the objective "reasonable person" test for causation and noting that "[t]he [particular] patient's testimony is relevant on that score of course but it would not threaten to dominate the findings"), *with* Scott v. Bradford, 606 P.2d 554, 559 (Okla. 1979) (rejecting the *Canterbury* "'reasonable man' standard" and opting instead for a test that places significant weight on the testimony of the particular patient).

176. The striking parallels between the plaintiffs' complaints are not surprising because both cases were brought by the same counsel. *See Doe*, 956

have been told the procedure would terminate a "complete, separate, unique and irreplaceable human being," and so would "kill[] an existing human being."[177]

In *Acuna v. Turkish*,[178] the court accepted as true the plaintiff's allegations that she had asked whether it was a "baby in there."[179] In *Doe v. Planned Parenthood/Chicago Area*,[180] plaintiff alleged she asked if a "life of a human being in the biological sense" would be terminated.[181] In both, the patients said the provider assured them that no life was at stake. In *Acuna*, the doctor allegedly said "don't be stupid, its only blood,"[182] and in *Doe*, plaintiff alleged Planned Parenthood's counselor told her that "an abortion did not terminate the life of a human being."[183] Both later learned, as Acuna says in her words, that there "'was a baby and not just blood' inside of her."[184] Both wanted to be told far more than they say they were—in extremely explicit terms. Acuna claimed that the physician failed to inform her that "[Andres] Acuna [(The name she gave to her terminated "child")], although a person unborn, was a complete, separate, unique[,] and irreplaceable human being."[185] Doe charged that

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N.E.2d at 571 ("The remarkable similarity with the instant case may be explained by the statement at oral argument of plaintiff's counsel that he represented Acuna before the New Jersey Supreme Court.")

177. *Acuna*, 930 A.2d at 418 (internal quotations omitted).

178. 930 A.2d 416 (N.J. 2007).

179. *Id.* at 419.

180. 956 N.E.2d 564 (Ill. App. Ct. 2011).

181. *Id. at* 567.

182. *Acuna*, 930 A.2d at 419. "Defendant could not recall how he responded but believes he likely would have told her that a 'seven-week pregnancy is not a living human being,' but rather it 'is just tissue at this time.'" *Id.*

183. *Doe*, 956 N.E.2d at 567. It is unclear whether the defendant disputes this allegation. *See id.* (accepting the plaintiff's facts as true). The plaintiff further contended "the defendants had a duty to inform her there is a greater risk of death, depression, suicide and breast cancer in women who undergo an abortion than in those who give birth." *Id.*

184. Acuna v. Turkish, 930 A.2d 416, 419 (N.J. 2007). Acuna says that after experiencing vaginal bleeding as the result of "incomplete abortion," a nurse told her that "the doctor had left parts of the baby inside of her." *Id.* (footnote omitted).

185. *Id.* at 420. Acuna also claimed the physician failed to inform her that

> . . . (2) there existed the potential risk that Andres "was capable of experiencing pain" at eight weeks gestation; (3) abortion involved "actually killing an existing human being"; (4) she would be at risk of

Planned Parenthood failed to "inform her that an abortion 'procedure would terminate the life of a second patient, a living human being as a matter of biological fact.'"[186]

Both courts made short work of the duty to be so explicit. In *Acuna*, the court first noted that the plaintiff "must demonstrate that a physician withheld *medical information* that a reasonably prudent pregnant woman in like circumstances would have considered material before consenting to a termination of pregnancy."[187]

The court held it would "not place a duty on doctors when there is no consensus in the medical community or among the public supporting plaintiff's assertions."[188] Indeed, "the knowledge that plaintiff sought from defendant cannot be compelled from a doctor who may have a different scientific, moral, or philosophical viewpoint on the issue of when life begins."[189] The court refused to use "the engine of the common law" to "drive public policy in one particular direction" on an issue on which there is a "deep societal and philosophical divide:" "the profound issue of when life begins."[190] The common law requires that physicians "provide their pregnant patients seeking an abortion *only* with material medical information, including gestational stage and medical risks."[191]

Evaluating Planned Parenthood's disclosures by "that of the reasonable physician,"[192] the *Doe* court also rejected the patient's

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> suffering from "post-abortion syndrome," a form of a post-traumatic stress disorder; and (5) she would come to realize that she "was responsible for killing her own child" and bear a weight of guilt for the rest of her life.

Id.

186. Doe v. Planned Parenthood/Chi. Area, 956 N.E.2d 564, 567 (Ill. App. Ct. 2011).

187. *Acuna*, 930 A.2d at 425 (citation omitted).

188. *Id.* at 428.

189. *Id.* The defendant and amici argued: "[M]andating that a physician express a non-medical and value-laden viewpoint conflicting with the physician's own strongly held personal and moral beliefs violates his First Amendment right to the exercise of free—not coerced—speech." *Id*.

190. Acuna v. Turkish, 930 A.2d 416, 427 (N.J. 2007).

191. *Id*. at 427–28.

192. Doe v. Planned Parenthood/Chi. Area, 956 N.E.2d 564, 570 (Ill. App. Ct. 2011) (citing Weekly v. Solomon, 510 N.E.2d 152 (Ill. App. Ct. 1987)).

informed consent claim.[193] It cited the *Acuna* court's description of the common law with approval, namely that it "requires doctors to provide their pregnant patients seeking an abortion *only* with material medical information, including gestational stage and medical risks involved in the procedure."[194] It added that "[n]o court, regardless of where it sits, has found a *common law duty* requiring doctors to tell their pregnant patients that aborting an embryo, or fetus, is the killing of an existing human being."[195] The court then rejected the "plaintiff's claims that the defendants owed her disclosures under Illinois common law that reflected something other than the scientific, moral, or philosophical viewpoint of Planned Parenthood as an abortion clinic."[196]

C. The Disclosure Owed to Women

As these cases illustrate, a sensible line can be drawn between disclosure of factual medical information that would be material to the prudent patient, as the *Acuna* court did, and weighing in on the ultimate issue of when life begins. In this context, doctors owe women factual disclosures faithful to the science around EC. Physicians should give each woman specific, fact-based information on when a given form of EC likely works (pre-fertilization, post-fertilization but pre-implantation, or during implantation) so that she can make decisions based on her own views of when life begins—or whether that question even matters to her.

The juncture at which EC works is material to many patients. Ordinary women care deeply about how EC functions. Likewise, medical providers—from family practitioners and members of the FDA scientific panel to academic researchers and women's health educators—recognize that women should be told far more than they are told now.[197] The need for factual

193. *See id.* at 573 ("Illinois common law does not compel the disclosures the plaintiff claims should have been made to her . . . .").

194. *Id.*

195. *Id.* at 572 (citing Acuna v. Turkish, 930 A.2d 416, 418 (N.J. 2007)).

196. *Id.* at 573.

197. *Supra* Part IV.

information is especially compelling because many women labor under misconceptions about how EC functions. Without better information, some women will make choices that may "inadvertently violat[e] their own religious or moral values."[198]

Of equal force is the fact that some women will choose *not* to use EC,[199] believing all forms of EC work after fertilization—when, for Plan B, that is highly unlikely. In one study of "never-users" of EC in Canada, researchers found that "[n]ever-users who had believed [EC] to be an abortifacient said that they would be more likely to consider using it, if the need arose, now that they understood how it functions."[200]

Nonetheless, concerns about compelled speech need to be taken seriously. Doctors cannot—and should not—be compelled to express an ultimate conclusion about whether "pregnancy" or "life" begins at one junction or another. Conversely, doctors should not be asked to express an opinion on the ultimate decision of whether a given drug acts as an "abortifacient." As the *Acuna* court noted, "it would be bad public policy, and probably unconstitutional, under the banner of the law of informed consent, to compel obstetricians to voice plaintiff's non-medical and ideologically-driven viewpoint in the ongoing debate on abortion."[201] Both courts made clear, however, that factual, scientific disclosure required by the duty to provide informed consent does comport with the First Amendment.

D. Practical Considerations

198. Lockwood, *supra* note 19, at 15.

199. Gemzell-Danielsson, Berger & Lalitkumar, *supra* note 56, at 300 (arguing that "an increased knowledge about the mechanisms of action and safety of EC is essential for the development of new methods as well as for optimizing the use of those already available"). "This knowledge may also influence individual and cultural acceptability of EC use." *Id.* Another article argues that in order "[t]o make an informed choice, women must know that [EC] . . . prevent[s] pregnancy primarily by delaying or inhibiting ovulation and inhibiting fertilization." Trussell, Raymond & Cleland, *supra* note 73, at 7.

200. Jean Shoveller et al., *Identifying Barriers to Emergency Contraception Use Among Young Women from Various Sociocultural Groups in British Columbia, Canada*, 39 PERSP. ON SEXUAL & REPROD. HEALTH 13, 16 (2007).

201. *Acuna*, 930 A.2d at 424.

The aspiration for informed consent, as guidance to federal family planning agencies under Title X encapsulates the duty, is to have "individualized dialogue[s] with a client."[202] In the fast-paced medical practices of today, physicians sometimes see informed consent as a "nuisance." The impulse may be to deal with it "in relatively mechanical ways, such as making sure patients sign consent forms before major procedures."[203]

Paper consent is not likely to advance women's understanding.[204] As many have recognized, patients are no more likely to read long consent forms than they are to read the FDA insert. And unless explained in more accessible, nonspecialized terms, patients are no more likely to understand the content of a consent form without a physician's guidance than they are the FDA label.

True, providing informed consent is not without costs.[205] Doctors face enormous time constraints in daily practice.[206]

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202. U.S. DEP'T OF HEALTH & HUMAN SERVS., PROGRAM GUIDELINES FOR PROJECT GRANTS FOR FAMILY PLANNING SERVICES 18 (2001), http://www.hhs.gov/opa/pdfs/2001-ofp-guidelines-complete.pdf.

203. TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (3d ed. 1989).

204. A rich literature exists on the failings of paper consent. *See e.g.*, Carl E. Schneider, *Void for Vagueness*, HASTINGS CTR. REPORT 11 (2007) ("The long-standing principle—informed consent—is administratively practical but a paper tiger.").

205. *See* Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 904 (1994) (footnotes omitted)

> The realists—primarily practicing physicians—harbor a different vision of informed consent. Although they emphatically do not contest the principle and goals of informed consent, they do question whether most patients really desire the kind of dialogue that the idealists propose. They also question whether, whatever patients desire, the gains in patient autonomy and improved outcomes produced by the dialogue are worth the additional time, money, and needless patient anxiety and confusion that informed consent may entail.

206. *See generally* Andrew Gottschalk & Susan A. Flocke, *Time Spent in Face-to-Face Patient Care and Work Outside the Examination Room*, 3 ANNALS FAM. MED. 488 (2005); David Mechanic, *Physician Discontent Challenges and Opportunities*, 7 J. AM. MED. ASS'N 941 (2003); Jerome P. Kassirer, *Doctor Discontent*, 339 NEW ENG. J. MED. 1543 (1998).

For example, as of 1997, 41% of physicians reported a decrease in the amount of time devoted to face-time with patients. KAREN SCOTT COLLINS, CATHY SCHOEN & DAVID R. SANDMAN, THE COMMONWEALTH FUND, THE COMMONWEALTH FUND SURVEY OF PHYSICIAN EXPERIENCES WITH MANAGED CARE 5 (1997). While

Mounting administrative responsibilities tied to navigating payment by insurers, like authorization requests and utilization review, take time away from interaction with patients.[207] Moreover, keeping up with the dense literature on mechanisms of action of various forms of EC takes time, and demystifying it for patients will take more time. In the best of circumstances, patients often do not understand what a physician means.[208]

Here, easy-to-follow summaries by the Cleveland Clinic and others can facilitate these conversations, making conversations less taxing for all. Doctors need only give a snapshot of the literature drawn from quick summaries of the maturing evidence about how Plan B and *ella* work.[209]

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many say that "visit rates above three to four per hour are associated with suboptimal visit content," in the U.S., visit lengths were "10 to 20 minutes or more" in 1999, and are likely more crunched today. *See* David C. Dugdale, Ronald Epstein & Steven Z. Pantilat, *Time and the Patient-Physician Relationship*, 14 J. GEN. INTERNAL MED. S34, S34 (1999) ("[I]n Great Britain, average visit lengths for general practitioners are between 5 and 8 minutes, whereas in the United States and Sweden, they are 10 to 20 minutes or more.").

207. *See* David C. Dugdale, Ronald Epstein & Steven Z. Pantilat, *Time and the Patient-Physician Relationship*, 14 J. GEN. INTERNAL MED. S34, S34 (1999) ("[P]hysicians face mounting demands on their time. Increasing administrative requirements for health care delivery (e.g., service and authorization requests, utilization review processes) encroach on time spent with patients.").

208. *See, e.g.*, Pauline W. Chen, *Do You Know What Your Doctor Is Talking About?*, N.Y. TIMES (Apr. 2, 2009), http://www.nytimes.com/2009/04/02/health/02chen.html (last visited Jan. 15, 2014) (discussing the problems presented by patients' lack of health literacy) (on file with the Washington and Lee Law Review); Omri Ben-Shahar & Carl E. Schneider, *The Failure of Mandated Disclosure*, 159 U. PA. L. REV. 647, 651 (2013) (arguing that "mandated disclosure . . . chronically fails to accomplish its purpose" of enlightening patients so that they can participate meaningfully in decision-making processes with professionals).

209. Physicians' prescribing of EC to patients may change with updated information, as well. Some physicians hesitate to prescribe EC on religious grounds. *See* Jennifer L. Wallace et al., *Emergency Contraception: Knowledge and Attitudes of Family Providers*, 36 FAM. MED. 417, 421 (2004) (identifying a "subset of physicians who would not prescribe under any circumstance . . . [because of] feeling uncomfortable with EC secondary to religious/ethical beliefs"). This reluctance may be allayed as to Plan B with better information. *See supra* Part III.A.1 (discussing how Plan B works). Citing a "lack of knowledge," physicians are understandably hesitant to prescribe to adolescents. Neville H. Golden et al., *Emergency Contraception: Pediatricians' Knowledge, Attitudes, and Opinions*, 107 PEDIATRICS 287, 291 (2001). In 2001, "most pediatricians did not feel comfortable prescribing EC and cited lack of knowledge as the main concern for lack of comfort," although this may have

Physicians do have to "remember[] to discuss EC during routine visits," which is not the easiest thing to do in a crush of patients and is "one of the most significant barriers" to EC use.[210] To some extent, operationalizing informed consent falls not solely on the doctor but can be facilitated by good practices and good office staff. Videos and print brochures can introduce the patient to the needed information, supplementing the interactions between doctor and patient. Perhaps more for this topic than most, a visual will go a long way towards illuminating the junctures at which a particular form of EC may work—whether (a) before fertilization, (b) after fertilization and before implantation, or (c) during implantation. A visual would also assist a woman who did not already have a set notion about when pregnancy begins to decide, for herself, among competing medical understandings. In studies of video consent, some patients better understand and are more satisfied with their treatments when medical professionals supplement their verbal interaction with audio-visual aids.[211]

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changed. *Id.*

> Twelve percent cited moral or religious reasons and [seventeen percent] were concerned about teratogenic effects. There were no differences in comfort level based on age, gender, or practice type. Twenty-two percent of respondents believed that providing EC encourages adolescent risk-taking behavior and 52.4% would restrict the number of times they would dispense EC to an individual [adolescent] patient.

Id. at 287. Better information may again allay physician concerns, an important benefit since girls need this information as much as women—or perhaps even more. *See* CAHN & CARBONE, *supra* note 131, at 20–24 (discussing teen pregnancy and life chances).

210. *See* Wallace et al., *supra* note 209, at 421 (discussing "[b]arriers to EC use identified by physicians").

211. *See* Michael Migden, Arianne Chavez-Frazier & Tri Nguyen, *The Use of High Definition Video Modules for Delivery of Informed Consent and Wound Care Education in the Mohs Surgery Unit*, 27 SEMINARS CUTANEOUS MED. & SURGERY 89, 92 (2008) ("Increased patient understanding was demonstrated in our assessment of the wound care video group, with patients scoring 91.6% on the multiple-choice quiz compared with a score of 84% in the group with only nurse demonstration of wound care."); E. Tompsett, R. Afifi & S. Tawfeek, *Can Video Aids Increase the Validity of Patient Consent*, 32 J. OBSTETRICS & GYNAECOLOGY, 680, 680–82 (2012) (offering evidence that patient understanding of methods and purpose of treatment was significantly enhanced by using videos).

Some states provide legal safe harbor protections that immunize physicians who follow "stock" disclosures about the risks of a particular treatment, an approach that could be used here to reduce the transaction costs of providing informed consent (as well as liability risks). Texas provides one example of such a safe harbor protection.[212] Texas physicians may use off-the-rack disclosure forms to provide information to patients about risks inherent in particular procedures.[213] One form is very general and may be adapted to any procedure.[214] Other forms have been developed for specific procedures, listing their particular risks and unique concerns.[215] The patient signs the form prior to undergoing treatment. The patient's signature triggers a legal presumption that the duty of informed consent was satisfied.[216] The form supplements, but does not replace, the discussion that must occur between physician and patient to otherwise fulfill the doctor's disclosure obligations.[217]

The safe harbor approach, like good office procedures, can significantly reduce the burden on physicians of meeting their legal duties to empower women to decide for themselves.

VI. Conclusion

Like so much of the country's continuing clash over abortion, the dispute over whether Plan B and *ella* act as ordinary contraceptives, before fertilization—or whether they "violate[] the

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212. For a general discussion of Texas's safe harbor protections, see generally *Informed Consent*, TEXAS MED. ASS'N (Feb. 2012), http://www.texmed.org/Template.aspx?id=6049#Proper (last visited Feb. 8, 2014) (on file with the Washington and Lee Law Review).

213. *See id.* (explaining how and when disclosure forms are used); *see also* 22 TEX. ADMIN. CODE § 165.6 (2014); 25 TEX. ADMIN. CODE §§ 601.4, 601.5, 601.7, 601.8, 601.9 (2014) (discussing consents and disclosures required in various procedures).

214. 25 TEX. ADMIN. CODE §§ 601.4, 601.5, 601.7.

215. 22 TEX. ADMIN. CODE § 165.6; *see also* 25 TEX. ADMIN. CODE §§ 601.4, 601.5, 601.7, 601.8, 601.9 (discussing consents and disclosures required in various procedures).

216. *See Informed Consent*, *supra* note 212 (stating that once risks are disclosed and consent is given, a legal presumption is established).

217. *Id.*

Commandment against murder"[218]—generates more heat than light.

Clearly, "women should be informed that the best available evidence is that the ability of [both to] prevent pregnancy can be fully accounted for by mechanisms that do not involve interference with post-fertilization events."[219] While hundreds of studies over fifteen years demonstrate that the chances that Plan B ever acts after fertilization are vanishingly small, the same cannot be said of *ella*.

While many women have no moral qualms about using EC, whether it acts before or after fertilization, others do. For them, the fact that a drug may act after fertilization means that it is morally off limits. Equipping women with the factual information necessary for them to make their own moral judgments falls squarely within the commitment we have made to patients in matters affecting their bodies and health: *patients* decide.

218. Complaint at 10, Geneva Coll. v. Sebelius, 929 F. Supp. 2d 402 (W.D. Penn. 2013) (No. 2:12-cv-00207).

219. Trussell, Raymond & Cleland, *supra* note 73, at 7.