Too High a Price for Some Drugs?: The FDA Burdens Reproductive Choice

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TABLE OF CONTENTS

I. INTRODUCTION

For a relatively small agency in the federal establishment, the U.S. Food and Drug Administration (FDA) attracts a good deal of notoriety. In part, this stems from the fact that it routinely makes judgments affecting human reproduction, including matters such as the over-the-counter availability of emergency contraceptives,[1] approval of the

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1. *See* Lars Noah, *Treat Yourself: Is Self-Medication the Prescription for What Ails American Health Care?*, 19 HARV. J.L. & TECH. 359, 374–76 (2006); Rob Stein, *FDA Approves Plan B's Over-the-Counter Sale: No Prescription Will Be Required for Women 18 or Older*, WASH. POST, Aug. 25, 2006, at A4 ("The announcement was aimed at resolving one of the longest and highest-profile health controversies of the Bush

abortifacient drug mifepristone (also known as RU-486),[2] regulation of fertility treatments,[3] and oversight of embryonic stem cell research.[4] Not surprisingly, the political branches have become increasingly interested in the FDA's decisions in these areas. One recent agency policy has, however, largely escaped notice, even though it raises peculiar questions that I have posed elsewhere:

> [D]oes the FDA cross a constitutional line when it purports to require that patients undergo periodic pregnancy testing and use contraceptives as a condition of access to a drug known to cause birth defects? If such conditions fail to reduce the number of birth defects, could the agency go one step further and, at least in the case of teratogens indicated for chronic use, urge sellers to require that patients first undergo a sterilization procedure if they wish to use the drug?[5]

This Article tackles that puzzle. Part II elaborates on the history behind the FDA's distribution restrictions, and Part III finds parallels in other contexts where policymakers have considered conditioning access to a benefit on the waiver of reproductive rights. Part IV offers an extended analysis of possible constitutional objections to the FDA's policy.

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administration, but opponents said they are considering plans to block the decision, either in court or in Congress.").

2. *See* Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics*, 36 WAKE FOREST L. REV. 571 (2001); Marc Kaufman, *Abortion Foes Want RU-486 Pill Pulled*, WASH. POST, May 17, 2006, at A3 (reporting that opponents have lobbied Congress and petitioned the FDA to withdraw the approval).

3. *See* Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 648–59 (2003); *see also* FDA, Human Cells, Tissues, and Cellular and Tissue-Based Products: Donor Screening and Testing, and Related Labeling, 70 Fed. Reg. 29,949 (May 25, 2005) (codified at 21 C.F.R. § 1271.90 (2006)) (amending rules to cover cryopreserved embryos later donated to someone else).

4. *See* Lars Noah, *A Postmodernist Take on the Human Embryo Research Debate*, 36 CONN. L. REV. 1133, 1144–47 (2004); *see also* Richard A. Merrill & Bryan J. Rose, *FDA Regulation of Human Cloning: Usurpation or Statesmanship?*, 15 HARV. J.L. & TECH. 85 (2001).

5. LARS NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY 119 (2d ed. 2007); *see also* Noah, *supra* note 3, at 664 ("[G]iven the [Supreme] Court's clear recognition of a right to privacy in the context of contraception, one has to wonder about FDA distribution restrictions that require patients to use two methods of birth control as a condition of access to the teratogens Accutane and Thalomid."). The lack of attention to this issue strikes me as especially odd given the current administration's apparent antipathy toward promoting the wider use of contraceptives. *See* Noah, *supra* note 4, at 1145–52; Christopher Lee, *Bush Choice for Family-Planning Post Criticized*, WASH. POST, Nov. 17, 2006, at A1 ("The Bush administration has appointed a new chief of family-planning programs at the Department of Health and Human Services who worked at a Christian pregnancy-counseling organization that regards the distribution of contraceptives as 'demeaning to women.'").

II. RESTRICTING ACCESS TO TERATOGENIC DRUGS

In 1982, the FDA approved Hoffmann-La Roche's application to market isotretinoin (Accutane®) for use in patients with severe recalcitrant nodular acne.[6] Although no one doubts its efficacy in treating this disfiguring (though otherwise nonserious) condition,[7] the drug is a potent teratogen: it carries a significant (more than 25%) risk of miscarriage and major birth defects such as facial deformities, severe mental retardation, and lethal cardiac abnormalities.[8] As further details about the teratogenic potential of isotretinoin have emerged over the course of the last quarter of a century, the FDA and the manufacturer adopted increasingly aggressive mechanisms designed to prevent its use by pregnant women.[9]

The original labeling revealed that the drug caused fetal abnormalities in animals, recommended that physicians not prescribe the drug to female patients of childbearing age unless they used an effective form of contraception, and suggested that patients who nonetheless become pregnant while using the drug receive counseling about the desirability of continuing their pregnancies.[10] Within one year of approval, after reports began to emerge of serious birth defects in humans, Hoffmann-La Roche revised the drug's labeling (and took other steps) to draw this

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6. *See* Penny Chorlton, *FDA Outpaced Firm on Acne Drug*, WASH. POST, Sept. 14, 1982, at A17. For the current version of the package insert, see Roche Lab., Inc., Accutane® Package Insert (Aug. 12, 2005), http://www.rocheusa.com/products/accutane/pi.pdf. For more background on the drug's regulatory milestones, including a history of its many labeling revisions, see FDA, Isotretinoin (Marketed as Accutane) Capsule Information (Oct. 6, 2006), http://www.fda.gov/cder/drug/infopage/accutane/default.htm. Starting in 2002, generic versions of the drug became available (sold under the tradenames Amnesteem®, Claravis®, and Sotret®). *See* Gideon Koren et al., *Generic Isotretinoin: A New Risk for Unborn Children*, 170 CAN. MED. ASS'N J. 1567 (2004).

7. *See* Aamir Haider & James C. Shaw, *Treatment of Acne Vulgaris*, 292 JAMA 726, 731 (2004); William D. James, *Acne*, 352 NEW ENG. J. MED. 1463, 1469–70 (2005).

8. *See* Edward J. Lammer et al., *Retinoic Acid Embryopathy*, 313 NEW ENG. J. MED. 837, 839–40 (1985). David Graham, the FDA whistleblower who attracted attention after the withdrawal of Vioxx® (rofecoxib), reiterated in congressional testimony his longstanding views that the agency should withdraw approval of isotretinoin. *See* Marc Kaufman, *Attempt to Discredit Whistle-Blower Alleged*, WASH. POST, Nov. 24, 2004, at A19.

9. *See* Ami E. Doshi, Comment, *The Cost of Clear Skin: Balancing the Social and Safety Costs of iPLEDGE with the Efficacy of Accutane (Isotretinoin)*, 37 SETON HALL L. REV. 625, 630–45 (2007); *see also id*. at 659–60 (concluding that the FDA should withdraw approval).

10. *See* Joan H. Krause, *Accutane: Has Drug Regulation in the United States Reached Its Limits?*, 6 J.L. & HEALTH 1, 17 (1991).

information to the attention of physicians.[11] In 1988, because these enhanced warnings did not entirely prevent prescribing of the drug to women who became pregnant,[12] the FDA persuaded the manufacturer to develop a "Pregnancy Prevention Program" (PPP) that supplied physicians with kits containing patient informed consent forms and other educational materials.[13] Revised labeling urged physicians to perform pregnancy tests before prescribing the drug to their female patients, but this and other aspects of the program lacked any mechanism for ensuring compliance.

In 2000, after receiving reports of gestational exposures caused by failures in using hormonal contraceptives, the manufacturer revised the labeling to recommend the use of two different forms of contraception.[14] In 2001, when the FDA realized that these additional warnings and related voluntary measures had still not prevented all use by pregnant women,[15] the agency approved SMART™ (System to Manage Accutane-

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11. *See* Paul J. Benke, *The Isotretinoin Teratogen Syndrome*, 251 JAMA 3267, 3267 (1984); Roche Labs., *Accutane Contraindicated in Pregnancy*, 252 JAMA 2623 (1984).

12. *See* CDC, *Birth Defects Caused by Isotretinoin—New Jersey*, 37 MORBIDITY & MORTALITY WKLY. REP. 171 (1988); Robert S. Stern, *When a Uniquely Effective Drug Is Teratogenic: The Case of Isotretinoin*, 320 NEW ENG. J. MED. 1007, 1008 (1989); Michael Abramowitz & Philip J. Hilts, *FDA Eyes Ban on Acne Drug: Study Links Use by Pregnant Women to Birth Defects*, WASH. POST, Apr. 23, 1988, at A1; Michael Waldholz, *FDA Panel Suggests Strict Limits on Use of Acne Drug That Causes Birth Defects*, WALL ST. J., Apr. 27, 1988, at A3. Enhanced warnings of belatedly discovered drug risks often have little impact on prescribing behavior. *See* Lars Noah, *Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 438–40 (2002).

13. *See* Lawrence K. Altman, *U.S. Orders Curbs on Drug Linked to Birth Defects*, N.Y. TIMES, May 27, 1988, at A1 (adding that "Roche was taking another unusual step in offering to pay the costs of counseling for contraception and pregnancy tests for any woman for whom Accutane is prescribed"); Judith Willis, *New Warning About Accutane and Birth Defects*, FDA CONSUMER, Oct. 1988, at 26. Within a couple of years, questions surfaced about the PPP's effectiveness, but the FDA declined to order more drastic restrictions at that time. *See* Charles Marwick, *Additional Steps Proposed to Ensure Antiacne Drug Used Only in Appropriate Patient Population*, 263 JAMA 3125 (1990); William Booth, *Education Drive on Risks of Accutane Said to Fail*, WASH. POST, May 22, 1990, at A9. The manufacturer had included an enrollment form for patients to send to the Slone Epidemiology Unit at Boston University's School of Public Health that facilitated the tracking of patient compliance and adverse outcomes. *See* Allen A. Mitchell et al., *A Pregnancy-Prevention Program in Women of Childbearing Age Receiving Isotretinoin*, 333 NEW ENG. J. MED. 101, 104–05 (1995) (concluding that the PPP worked fairly well).

14. *See* Michelle Meadows, *The Power of Accutane: The Benefits and Risks of a Breakthrough Acne Drug*, FDA CONSUMER, Mar.–Apr. 2001, at 18, 20. As lower dosage formulations of hormonal contraceptives have become more popular, their failure rates have increased. *See* Anna Wilde Mathews, *FDA Mulls Birth-Control Standards*, WALL ST. J., Jan. 19, 2007, at B5.

15. *See, e.g.*, CDC, *Accutane®-Exposed Pregnancies—California, 1999*, 49 MORBIDITY & MORTALITY WKLY. REP. 28 (2000); Kenneth Lyons Jones et al., Letter to the Editor, *Isotretinoin and Pregnancy*, 285 JAMA 2079 (2001).

Related Teratogenicity), a still more aggressive risk management program developed by Hoffmann-La Roche. SMART attempted to require (through physician registration with the manufacturer and use of special qualification stickers as a prerequisite for dispensing by pharmacists) a negative pregnancy test before prescribing a nonrefillable one month supply in addition to an agreement by patients to use two methods of contraception or abstain from sexual activity.[16] The agency modeled this program on a similar effort undertaken by the manufacturer of Thalomid® (thalidomide), which the FDA had approved for the treatment of Hansen's disease (leprosy): STEPS™ (System for Thalidomide Education and Prescribing Safety) sought to ensure that this infamous teratogen stay out of the hands of persons who might become pregnant.[17] Because semen could carry residues of thalidomide, male patients also had to agree to use contraceptives.[18]

In 2005, because SMART had not entirely lived up to expectations, the FDA approved the iPLEDGE™ risk management program established by the manufacturers of isotretinoin, which required prescribers, distributors, and patients to register (on-line or by using a toll-free number) and attest to their understanding of the risks and commitment to abide by the pregnancy testing and contraception requirements.[19] Physicians and

16. *See* Diane Knich, *Accutane: New Rules Debut*, WASH. POST, Apr. 9, 2002, at F1; *see also* Margaret A. Honein et al., *Can We Ensure the Safe Use of Known Human Teratogens?: Introduction of Generic Isotretinoin in the US As an Example*, 27 DRUG SAFETY 1069, 1072 (2004); *id*. at 1075 (explaining that each generic version uses a parallel risk management program).

17. *See* Sheryl Gay Stolberg, *Thalidomide Approved to Treat Leprosy, with Other Uses Seen*, N.Y. TIMES, July 17, 1998, at A1 ("If any doctors or pharmacists refuse to comply with the distribution rules, their privileges to prescribe or dispense the drug might be revoked."); Jamie Talan, *Thalidomide's Legacy*, WASH. POST, Jan. 4, 2000, at F10; *cf*. Michael E. Weinblatt, Editorial, *Methotrexate for Chronic Diseases in Adults*, 332 NEW ENG. J. MED. 330, 331 (1995) (explaining that low doses of this chemotherapy agent may help treat autoimmune diseases, but warning that its teratogenicity means that female patients should not become pregnant). Celgene also sells Revlimid® (lenalidomide), a thalidomide derivate for multiple myeloma subject to the same distribution restrictions (under the RevAssist™ program). *See* Revlimid Homepage, http://www.revlimid.com (last visited June 14, 2007).

18. *See* Rita Rubin, *Thalidomide Could Guide Use of Drugs That Risk Birth Defects*, USA TODAY, July 22, 1998, at 7D. Given the far more limited range of options and lower reliability of contraceptives for men, male patients would have to ensure that their female partners use contraceptives (otherwise, one wonders whether the FDA might have called for vasectomies as a condition for access).

19. *See* Laurel Naversen Geraghty, *Doctors Fear Acne Drug Rules Go Too Far*, N.Y. TIMES, Jan. 12, 2006, at G3; Gardiner Harris, *F.D.A. Imposes Tougher Rules for Acne Drug*, N.Y. TIMES, Aug. 13, 2005, at A1 ("The new program is the latest and by far

patients have expressed frustration about the sometimes cumbersome barriers to access erected by iPLEDGE, but at least initially the program has succeeded where its predecessors had failed—namely, in preventing pregnancies among users of the drug.[20] In contrast with the gradual adoption of ever tighter access requirements for isotretinoin in this country, British regulators long ago imposed even more stringent distribution restrictions, including a requirement that patients agree to undergo an immediate abortion in case they become pregnant while using the drug.[21]

Over the last two decades, and in parallel with the FDA's incremental approach to addressing Accutane's teratogenicity, victims have pursued tort litigation against Hoffmann-La Roche. For the most part, courts have rejected inadequate warning claims.[22] In one recent case, a woman

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most drastic of more than 40 efforts by the agency in the last 22 years to reduce harm from Accutane . . . while allowing its continued use.").

20. *See* Sandra G. Boodman, *Too Hard to Take: A Strict New Acne Drug Program May Prevent Birth Defects, but Many Complain It Also Drives People Away from a Potentially Life-Transforming Treatment*, WASH. POST, Sept. 5, 2006, at F1 ("Public health officials say such strict regulation is necessary because years of progressively stronger voluntary programs failed to prevent pregnancy in users of the medicine . . . ."); *id*. ("Between 1982 and 2005, 2,796 pregnancies among women who used Accutane were reported to the FDA . . . . Most ended in abortion or miscarriage, but the birth of 194 babies with defects caused by the drug were reported to the FDA. The actual numbers are believed to be far higher . . . ."). The latest figures are, however, far less encouraging. *See Anti-Pregnancy Effort Fails*, WASH. POST, July 31, 2007, at A10 ("The new figures show the 122 pregnancies reported in the first year of the iPledge program are about the same as the number reported annually before the FDA tightened restrictions on the drug . . . .").

21. *See* Gina Kolata, *Europeans Placed Stiffer Curbs on Acne Drug*, N.Y. TIMES, Apr. 28, 1988, at A1 (adding that only three pregnancies had been reported in isotretinoin users outside of North America). These sorts of marketing restrictions, though imposed by the government, represent a type of "precommitment strategy" that some commentators have endorsed as a mechanism for resolving disputes in connection with reproductive decisionmaking. *See* John A. Robertson, *Precommitment Strategies for Disposition of Frozen Embryos*, 50 EMORY L.J. 989, 1046 (2001); *cf*. *id*. at 1022–23, 1041 (recognizing that precommitments requiring bodily intrusions at a future time might be difficult to enforce); John A. Robertson, *Liberalism and the Limits of Procreative Liberty: A Response to My Critics*, 52 WASH. & LEE L. REV. 233, 259 n.95 (1995) ("In very extreme circumstances of compelling interest, forced abortion or contraception might be appropriate, but such cases will be extremely rare."); John A. Robertson, *Precommitment Issues in Bioethics*, 81 TEX. L. REV. 1849, 1869 (2003) ("[A gestational surrogate] should not be specifically ordered to abort or undergo prenatal tests. However, she could still be required to pay damages for the loss caused the couple from violating her promise that she would screen . . . the fetus prior to birth and continue (or terminate) the pregnancy . . . .").

22. *See, e.g.*, Gerber v. Hoffmann-La Roche Inc., 392 F. Supp. 2d 907, 916–20 (S.D. Tex. 2005) (holding that the 1983 warning was adequate as a matter of law notwithstanding the failure to recommend the use of more than one form of contraception); Hunt v. Hoffmann-La Roche, Inc., 785 F. Supp. 547, 550 (D. Md. 1992) (holding that the 1984 warning was adequate as a matter of law notwithstanding the failure to recommend an initial pregnancy test); Bealer v. Hoffman-La Roche, Inc., 729 F. Supp. 43, 44–45 (E.D. La. 1990) (holding, in a case where the patient underwent a

who received a prescription for Accutane in 1995 (under the terms of the PPP, including the completion of a detailed patient informed consent form) sued for an alleged failure to warn after she had opted for abstinence rather than contraception but then failed to remain celibate and subsequently gave birth to a profoundly disabled child.[23] In affirming the trial judge's decision to dismiss the complaint, the court explained: "We cannot conclude that Roche had a duty to withhold from Ms. Banner a medication her doctor determined was an appropriate treatment for her unless she agreed to the use of contraceptive techniques that may have violated her religious principles."[24] In another case, however, a child born with birth defects recovered damages from a physician who negligently had prescribed Accutane to an already pregnant woman and failed to secure the patient's written consent or follow other aspects of the PPP.[25]

The FDA has approved a number of teratogenic drugs other than isotretinoin and thalidomide, but it generally has not subjected these drugs to the same distribution restrictions.[26] For instance, a topical

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therapeutic abortion after becoming pregnant, that the 1987 warning was adequate as a matter of law); Felix v. Hoffmann–LaRoche, Inc., 540 So. 2d 102, 103–05 (Fla. 1989) (holding that the 1982 warning was adequate as a matter of law).

23. *See* Banner v. Hoffmann-La Roche Inc., 891 A.2d 1229, 1231–33 (N.J. Super. Ct. App. Div. 2006). "According to plaintiffs, Roche should have warned that all women of child-bearing age who were married or sexually active should use two forms of birth control, even if they indicated an intent not to engage in sexual activity while taking Accutane." *Id*. at 1234 ("Plaintiffs assert that Roche knew or should have known that women of child-bearing age who were married or sexually active were unlikely to remain abstinent."); *id*. ("Plaintiffs also asserted that Roche was at fault for not restricting the physicians authorized to prescribe Accutane. They pointed to a registry program instituted by another pharmaceutical company, Celgene, in connection with that company's distribution of thalidomide . . . .").

24. *Id*. at 1241; *see also id*. at 1237–40 (explaining that the warnings used in 1995 were adequate as a matter of law notwithstanding the inclusion of abstinence as an alternative to using two forms of contraception).

25. *See* Hogle v. Hall, 916 P.2d 814, 816–17 (Nev. 1996) (noting that the medical defendants had impleaded the mother as a joint tortfeasor and that the jury had allocated 40% of the responsibility to her for incorrectly informing the physician that she had just experienced a menstrual period).

26. *See* Kathleen Uhl et al., *Risk Management Strategies in the Physicians' Desk Reference Product Labels for Pregnancy Category X Drugs*, 25 DRUG SAFETY 885, 887–91 (2002) (reviewing the package inserts of more than 100 drugs contraindicated for use during pregnancy, and finding that only thirteen included recommendations that physicians conduct pregnancy testing, encourage the use of contraception, or both). In addition, the FDA authorized the sale of a class of mild teratogens (nicotine replacement products) without requiring either a prescription or consumer labeling that fully describes the risk of use during pregnancy. *See* Dowhal v. SmithKline Beecham Consumer Healthcare,

retinoid for the treatment of acne and psoriasis (tazarotene) carries a similar risk of birth defects (as revealed in its labeling) and recommendations for pregnancy testing and contraceptive use, but it does not include any special limitations on access.[27] Tegison® (etretinate), another vitamin A derivative for treating severe psoriasis, carried an even higher risk of causing birth defects—in part because (unlike isotretinoin) it persists long after a patient discontinues use, which would necessitate long-acting contraception or sterilization—but faced no distribution restrictions.[28] The labeling for Tegison's successor Soriatane® (acitretin) does, however, include a risk management program similar to that used for isotretinoin and thalidomide.[29] The labeling for the antiviral Rebetol® (ribavirin) recommends a negative pregnancy test as well as the use of two contraceptives (and for both male and female patients) continuing for six months after the cessation of this therapy for hepatitis C.[30]

The FDA also imposed restrictions on access when it approved the controversial abortifacient Mifeprex® (mifepristone). Concerns existed about birth defects in the event of product failure (which could, for instance, happen if a pregnant woman ingested only the initial dose of the drug but then changed her mind), so patients had to abide by a protocol that included a follow-up visit for the administration of a second drug (misoprostol) to complete the abortion.[31] In effect, the

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88 P.3d 1, 4–5, 15 (Cal. 2004) (holding that this decision preempted a contrary warning requirement imposed under state law).

27. *See* Allergan, Tazorac® Package Insert (May 2004), http://www.tazorac. com/PDFs/Tazorac_Cream_Full_PI.pdf. Similar recommendations appear in the labeling for Tracleer® (bosentan), a treatment for primary pulmonary hypertension. *See* Actelion, Tracleer® Package Insert (Feb. 15, 2007), http://www.tracleer.com/pdf%5CPI_4pg_ TR2454_032707_FINAL.pdf.

28. *See* Gina Kolata, *A Second Skin Drug Is Called Major Threat for Birth Defects*, N.Y. TIMES, May 1, 1988, § 1, at 1. In 1999, after introducing Soriatane® (acitretin), the manufacturer ceased marketing the drug and asked the FDA to withdraw approval, which the agency did four years later. *See* FDA, Notice, Hoffmann-La Roche, Inc.: Withdrawal of Approval of a New Drug Application, 68 Fed. Reg. 53,384, 53,385 (Sept. 10, 2003).

29. *See* Uhl et al., *supra* note 26, at 888–90.

30. *See* Schering Corp., Rebetol® Package Insert (July 2004), http://www.spfiles.com/pirebetol.pdf.

31. *See* Noah, *supra* note 2, at 574–75 & n.12, 585–86; Gina Kolata, *U.S. Approves Abortion Pill*, N.Y. TIMES, Sept. 29, 2000, at A1 ("A woman will be given written instructions . . . , and her doctor must sign a statement saying they have read the instructions and will comply with them exactly."); John Leland, *Abortion Might Outgrow Its Need for* Roe v. Wade, N.Y. TIMES, Oct. 2, 2005, § 4, at 14 (reporting that the off-label use of the ulcer drug Cytotec® (misoprostol) alone may cause birth defects if it fails to induce a miscarriage). The Patient Agreement for Mifeprex includes the following statement: "I understand that if my pregnancy continues after any part of the treatment [as happens in 5–8% of cases], there is a chance that there may be birth defects. . . . I will talk with my provider about my choices, which may include a surgical procedure to end my pregnancy." Patient Agreement, Mifeprex (Mifepristone) Tablets

agency decided that patients had to use these drugs in tandem. Along similar lines, perhaps it makes sense to view hormonal contraceptives as necessary concomitant treatments for women using other teratogens.[32] Could the FDA go further still and, taking a cue from its British counterpart, insist that women who become pregnant while using a teratogen take an abortifacient drug?[33] Or, instead of relying on agreements by patients and physicians, could the agency demand that the manufacturer sell a bundled product (for example, a single pill that combined a teratogen with a hormonal contraceptive),[34] at least when indicated for use by female patients?[35]

(July 19, 2005), http://www.fda.gov/cder/drug/infopage/mifepristone/patientAgreement 20050719.pdf; *cf*. Sheppard-Mobley v. King, 830 N.E.2d 301, 303 (N.Y. 2005) (summarizing tort claims brought on behalf of an infant whose mother declined to undergo a surgical abortion after a nonsurgical abortion using the drug methotrexate failed and caused serious birth defects).

32. *Cf*. Noah, *supra* note 3, at 644 ("[O]ne might view selective reduction as a necessary adjunct to ARTs that may result in the implantation of multiple embryos."). Similar questions might arise in connection with other medical interventions (for example, radiation and chemotherapy) that may cause permanent chromosomal damage to a patient's germ cells, which would make any subsequent efforts at procreation inadvisable. Because these interventions also create a risk of infertility, patients sometimes store reproductive tissues for future use before undergoing such treatments. *See* Anne Reichman Schiff, *Arising from the Dead: Challenges of Posthumous Procreation*, 75 N.C. L. REV. 901, 905 & n.16 (1997). Assuming that a treatment did not cause infertility but might adversely affect a patient's future children, could the government insist on permanent contraception (that is, sterilization) as a condition of access to the intervention?

33. *Cf*. Noah, *supra* note 2, at 576 (describing the range of abortifacient drugs available in the United States); *id*. at 589 (explaining that "the labeling for one drug may direct physicians to make use of another drug in order to counteract a particular side effect"). Would-be fathers have no right to insist that a pregnant woman undergo an abortion or, conversely, prevent her from doing so. *See* Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 896 (1992) (plurality opinion); Planned Parenthood of Cent. Mo. v. Danforth, 428 U.S. 52, 71 (1976). In one publicized case, biological parents unsuccessfully sought to insist that their surrogate comply with a contractual provision for selective reduction when she developed a twin pregnancy. *See New Parents Found for Surrogate's Twins*, L.A. TIMES, Aug. 14, 2001, at B7. *See generally supra* note 21 (discussing precommitment strategies).

34. For instance, under government pressure to reduce the rampant abuse of OxyContin® (oxycodone), the manufacturer announced plans to add an ingredient (naltrexone) that could deactivate the opioid analgesic when crushed. *See* Lars Noah, *Challenges in the Federal Regulation of Pain Management Technologies*, 31 J.L. MED. & ETHICS 55, 62 (2003); *see also* Sandra Blakeslee, *Drug Makers Hope to Kill the Kick in Pain Relief*, N.Y. TIMES, Apr. 20, 2004, at F1 (reporting that another approach involves adding a chemical irritant such as capsaicin); Marc Kaufman, *Drug Firms Trying to Make Painkillers Less Abusable*, WASH. POST, June 14, 2004, at A7 (noting

III. CONDITIONS ON PROCREATION IN OTHER CONTEXTS

Two decades ago, in order to prevent perinatal transmission of the AIDS virus, the U.S. Centers for Disease Control (CDC) announced that HIV-positive women should not become pregnant.[36] Recognizing that this recommendation would have only a limited impact, a few commentators went further in suggesting mandatory screening of already pregnant women,[37] while some physicians evidently insisted that their infected female patients remain abstinent:

> Comments by health professionals to the effect that they will not provide prenatal or other medical care to [HIV-positive] women who decide to bear children constitute a more aggressive influence strategy. Although nowhere advocated in print, such pressure may have been endemic in clinical practice. . . . The reproductive forbearance requested might range from a promise not to become pregnant to the use of a particular contraceptive method or even consent to abortion. In addition, some have expressed concern about a more extreme prospect—that providers could condition their services upon consent to sterilization.[38]

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that "some combination drugs that might reduce the abuse potential of painkillers are also likely to reduce their effectiveness").

35. Although rare, the FDA has approved certain drugs for use by only members of one sex. *See, e.g.*, FDA, Avodart Consumer Information (Nov. 22, 2002), http://www.fda.gov/cder/consumerinfo/druginfo/avodart.htm ("Dutasteride is for men only. . . . [W]omen who are pregnant or may be pregnant should not touch Avodart because it can pass through their skin and may cause a birth defect in their male baby."); Uhl et al., *supra* note 26, at 887 (finding that almost a dozen drugs contraindicated during pregnancy are intended for use only in males); Marc Kaufman, *FDA Reapproves Bowel Drug After Pulling It for Safety*, WASH. POST, June 8, 2002, at A4 (reporting that Lotronex is only approved for use by women). At least in the case of isotretinoin, such a combination product would make additional sense because hormonal contraceptives also help to treat acne in women. *See* Jane E. Brody, *The Pill at 40: New Uses for a Drug That Changed Society*, N.Y. TIMES, May 9, 2000, at F1 ("[O]ne product, Ortho Tri-Cyclen, has received F.D.A. approval to treat moderate cystic acne in women 15 or older who desire contraception and who have not been helped by topical acne remedies.").

36. *See* CDC, *Recommendations for Assisting in the Prevention of Perinatal Transmission of Human T-Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus and Acquired Immunodeficiency Syndrome*, 34 MORBIDITY & MORTALITY WKLY. REP. 721, 724–25 (1985); *see also* CDC, *Childbearing and Contraceptive-Use Plans Among Women at High Risk for HIV Infection*, 41 MORBIDITY & MORTALITY WKLY. REP. 135, 144 (1992).

37. *See, e.g.*, Carole A. Campbell, *Women and AIDS*, 30 SOC. SCI. & MED. 407, 410 (1990). In 1995, the government recommended the testing of all pregnant women. *See U.S. Public Health Service Recommendations for Human Immunodeficiency Virus Counseling and Voluntary Testing for Pregnant Women*, 44 MORBIDITY & MORTALITY WKLY. REP. RR-7 (1995).

38. M. Gregg Bloche, *Beyond Autonomy: Coercion and Morality in Clinical Relationships*, 6 HEALTH MATRIX 229, 239 (1996) (footnotes omitted); *see also id*. at 250–51, 255–56, 262–63, 300–01 (evaluating the legitimacy of such conditions); *id*. at 239–40 ("Additional influence strategies are possible at the public health level. These range from the public promotion of reproductive abstinence via mass media campaigns

In the face of suggestions that the government codify restrictions of this sort, critics assailed such proposals as threatening an unconstitutional interference with procreative liberties and intrusion upon bodily integrity.[39]

Could the FDA instead have made contraceptive use a condition of access to AIDS drugs by women of childbearing years? Unlike proposals for mandatory screening and sterilization of HIV-positive women, patients theoretically would remain free to decline, but such a condition on access seems more attenuated than in the case of teratogens because the AIDS drugs themselves do not pose any risk of fetal injury.[40] In any event, with the advent of new treatments, including methods for reducing the risk of perinatal transmission,[41] the original reasons for discouraging pregnancy in HIV-positive patients largely have disappeared.

Fifteen years ago, shortly after the FDA approved the long-acting contraceptive implant Norplant® (levonorgestrel),[42] controversy erupted over proposed incentives designed to encourage its use by welfare

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to the creation of financial and other material incentives to refrain from childbearing." (footnotes omitted)).

39. *See* John D. Arras, *AIDS and Reproductive Decisions: Having Children in Fear and Trembling*, 68 MILBANK Q. 353, 373 (1990); Suzanne Sangree, *Control of Childbearing by HIV Positive Women: Some Responses to Emerging Legal Policies*, 41 BUFF. L. REV. 309, 395–414, 424–35 (1993) (assuming that "only" 30% of children delivered by HIV-positive women would become infected in this manner); *id*. at 429 (predicting that, because of risks associated with intrauterine devices, "neither the[ir] manufacturers nor the FDA would sanction the compulsory use of IUDs" by HIV-positive women); *see also id*. at 414–23, 435–41 (raising similar objections to proposals for HIV screening of pregnant women).

40. *Cf*. Heather S. Dixon, *Pelvic Exam Prerequisite to Hormonal Contraceptives: Unjustified Infringement on Constitutional Rights, Governmental Coercion, and Bad Public Policy*, 27 HARV. WOMEN'S L.J. 177, 209–17 (2004) (arguing that publicly funded family planning clinics cannot condition access to oral contraceptives on intrusive exams that serve only collateral purposes); *id*. at 216 (recognizing the peculiarity that "both the right being exercised [bodily integrity] and the subject of the subsidy itself [access to effective contraception] are constitutional entitlements"); *id*. at 231–32 (concluding that, while physicians should discuss risks and separately might encourage a pelvic exam, women retain the right to make an informed choice to use oral contraceptives without first undergoing such an exam); Felicia H. Stewart et al., *Clinical Breast and Pelvic Examination Requirements for Hormonal Contraception*, 285 JAMA 2232, 2236 (2001).

41. *See* Marc Santora, *U.S. Is Close to Eliminating AIDS in Infants, Officials Say*, N.Y. TIMES, Jan. 30, 2005, § 1, at 1.

42. Products liability litigation ultimately helped to drive Norplant from the marketplace. *See* Lars Noah, *Triage in the Nation's Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 S.C. L. REV. 741, 760 n.87 (2003). Nonetheless, manufacturers continue to introduce new long-acting contraceptive drugs and devices. *See* Shari Roan, *Now, a Birth Control Bonanza*, L.A. TIMES, July 10, 2006, at F1.

recipients.[43] A number of commentators assailed such plans as amounting to unconstitutional conditions.[44] After states failed to adopt proposals to encourage contraceptive use by persons on welfare, a private organization sponsored an initiative to reduce unwanted or hazardous pregnancies: Project Prevention offered $200 to any substance abusers who opted for a long-acting contraceptive.[45] Although widely denounced for its methods and message,[46] no one seriously suggested that the program violated any existing laws.

Separately, a few judges tried to make the implantation of Norplant a condition of probation.[47] Again, several commentators criticized such

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43. *See* Tamar Lewin, *5-Year Contraceptive Implant Seems Headed for Wide Use*, N.Y. TIMES, Nov. 29, 1991, at A1 (describing proposals in Kansas and Louisiana); Adam Pertman, *Long-lasting Contraceptive Comes Under Fire*, BOSTON GLOBE, Aug. 3, 1994, at A3 ("Lawmakers have tried unsuccessfully in many states, including Maryland and Connecticut, to provide monetary incentives for women on welfare to receive Norplant.").

44. *See, e.g.*, David S. Coale, Note, *Norplant Bonuses and the Unconstitutional Conditions Doctrine*, 71 TEX. L. REV. 189, 204–15 (1992) (arguing that such programs would intrude upon the constitutional rights to privacy, bodily integrity, and the free exercise of religion); John Robert Hand, Note, *Buying Fertility: The Constitutionality of Welfare Bonuses for Welfare Mothers Who Submit to Norplant Insertion*, 46 VAND. L. REV. 715, 718–23, 744–50 (1993) (focusing on the privacy objections, but cautioning that the unconstitutional conditions doctrine may not come into play here); *see also* AMA Bd. of Trustees, *Requirements or Incentives by Government for the Use of Long-Acting Contraceptives*, 267 JAMA 1818, 1821 (1992). *But see* Kimberly A. Smith, Note, *Conceivable Sterilization: A Constitutional Analysis of a Norplant/Depo-Provera Welfare Condition*, 77 IND. L.J. 389 (2002) (defending the constitutionality of supplemental payments to encourage the use of long-acting contraceptives, distinguishing between temporary and permanent sterilization).

45. *See* Jane Gilbert Mauldon, *Providing Subsidies and Incentives for Norplant, Sterilization and Other Contraception: Allowing Economic Theory to Inform Ethical Analysis*, 31 J.L. MED. & ETHICS 351, 354–55, 358–61 (2003) (describing and defending this effort); Jennifer Mott Johnson, Note, *Reproductive Ability for Sale, Do I Hear $200?: Private Cash-for-Contraception Agreements As an Alternative to Maternal Substance Abuse*, 43 ARIZ. L. REV. 205, 223–43 (2001) (same, and distinguishing the public policy concerns that have led to restrictions on surrogacy agreements between private parties).

46. *See* Adam B. Wolf, Note, *What Money Cannot Buy: A Legislative Response to C.R.A.C.K.*, 33 U. MICH. J.L. REFORM 173 (2000); Avram Goldstein, *Group to Pay Addicts to Take Birth Control*, WASH. POST, June 26, 2000, at B1; Cecilia M. Vega, *Sterilization Offer to Addicts Reopens Ethics Issue*, N.Y. TIMES, Jan. 6, 2003, at B1. In contrast, evidently no one has criticized an incentive program created by Planned Parenthood to discourage second pregnancies by teenage girls. *See* Bonnie Steinbock, *Coercion and Long-Term Contraceptives*, HASTINGS CENTER REP., Jan.–Feb. 1995, at S19, S21–22 (applauding the "Dollar-a-Day" program in Denver); Dyan Zaslowsky, *Denver Program Curbs Teen-Agers' Pregnancy*, N.Y. TIMES, Jan. 16, 1989, at A8.

47. *See* People v. Walsh, 593 N.W.2d 558, 558 (Mich. 1999) (Corrigan, J., concurring); Sally Jacobs, *Norplant Draws Concerns over Risks, Coercion*, BOSTON GLOBE, Dec. 21, 1992, at A1; Tamar Lewin, *Implanted Birth Control Device Renews Debate over Forced Contraception*, N.Y. TIMES, Jan. 10, 1991, at A20; John Makeig, *Surgical Deterrent: Mom Convicted of Child Abuse Picks Birth-Control Implant over Prison*, HOUS. CHRON., Mar. 6, 1992, at A1; *see also* Dee McAree, *Deadbeat Dads Face Ban on Procreation*, NAT'L L.J., May 31, 2004, at 4 (reporting that a family court judge

conditions on constitutional grounds.[48] On those occasions where probationers have challenged similar conditions (barring pregnancy though without specifying a particular method of birth control), appellate courts generally have rejected them as improper.[49] In one case involving a mother prosecuted for child endangerment based on her severe dietary restrictions, the court accepted the need to prevent another pregnancy because of the risk of prenatal injury, but it still invalidated the condition because other less restrictive means existed to prevent injury in the event of a subsequent pregnancy.[50]

IV. CONSTITUTIONAL ANALYSIS

If the constitutional objections lodged against other attempts to limit procreation might have some merit, then the FDA's conditions on access to teratogenic drugs deserve closer scrutiny. Historically, this agency has not paid much attention to statutory or constitutional obstacles that

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in Kentucky had offered some fathers who were in contempt of child support orders the option of vasectomies in lieu of spending a month in jail).

48. *See, e.g.*, Janet F. Ginzberg, Note, *Compulsory Contraception as a Condition of Probation: The Use and Abuse of Norplant*, 58 BROOK. L. REV. 979, 1001–18 (1992) (arguing that, notwithstanding the diminished constitutional protections afforded to probationers, such a condition on probation for persons convicted of child abuse unreasonably infringes upon rights related to privacy, procreation, and bodily integrity); James H. Taylor, Note, *Court-Ordered Contraception: Norplant as a Probation Condition in Child Abuse*, 44 FLA. L. REV. 379, 406–16 (1992); Kristyn M. Walker, Note, *Judicial Control of Reproductive Freedom: The Use of Norplant as a Condition of Probation*, 78 IOWA L. REV. 779, 797–807 (1993). *But see* Thomas E. Bartrum, Note, *Birth Control as a Condition of Probation—A New Weapon in the War Against Child Abuse*, 80 KY. L.J. 1037, 1047–53 (1992) (defending their constitutionality).

49. *See, e.g.*, People v. Ferrell, 659 N.E.2d 992 (Ill. App. Ct. 1995); State v. Mosburg, 768 P.2d 313, 315 (Kan. Ct. App. 1989); State v. Richard, 680 N.E.2d 667, 670 (Ohio Ct. App. 1996); *see also* State v. Talty, 814 N.E.2d 1201 (Ohio 2004) (invalidating probation condition for a deadbeat dad). *But cf. In re* Bobbijean P., No. 03626-03, 2004 WL 834480, at *2–3 (N.Y. Fam. Ct. 2004) (ordering the parents of several crack babies to stop procreating); State v. Kline, 963 P.2d 697, 698–99 (Or. Ct. App. 1998) (involving a father convicted of child abuse); State v. Oakley, 629 N.W.2d 200, 201–02 (Wis. 2001) (involving a father who refused to pay child support).

50. *See* People v. Pointer, 199 Cal. Rptr. 357, 364–65 & n.9 (Ct. App. 1984); *see also* Stacey L. Arthur, *The Norplant Prescription: Birth Control, Woman Control, or Crime Control?*, 40 UCLA L. REV. 1, 69–83 (1992) (questioning the latter aspect of the court's decision, and documenting subsequent acts of child endangerment that would not have occurred had the defendant used contraceptives during her probationary period); *cf.* People v. Zaring, 10 Cal. Rptr. 2d 263, 265, 271 (Ct. App. 1992) (invalidating a condition designed to prevent a heroin abuser from having an addicted baby); Trammell v. State, 751 N.E.2d 283, 285–86, 290–91 (Ind. Ct. App. 2001) (vacating condition imposed after neglect by mentally retarded mother caused child's death).

stand in the way of pursuing its mission to protect the public health,[51] and perhaps no one would ever actually try to test the validity of these distribution restrictions, but their lawfulness remains very much in doubt.

A. Finding State Action

Would a requirement making contraception a prerequisite for access to a prescription drug survive a constitutional challenge? As a threshold matter, anyone wishing to mount such a challenge would have to find some "state action" underlying the condition.[52] If a nongovernmental entity imposed the condition, then constitutional constraints become inapplicable, though statutes may impose parallel limitations on private actors.[53] In other words, the Constitution would not prevent a physician in private practice from adopting a policy of prescribing Accutane (or some other teratogen) only if a patient first agreed to use contraceptives (or to undergo an abortion in the event of a pregnancy).[54] Similarly, the

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51. *See* Lars Noah, *Interpreting Agency Enabling Acts: Misplaced Metaphors in Administrative Law*, 41 WM. & MARY L. REV. 1463, 1488 (2000); Lars Noah, *What's Wrong with "Constitutionalizing Food and Drug Law"?*, 75 TUL. L. REV. 137, 144 & n.39, 148 (2000).

52. *See* Brentwood Acad. v. Tenn. Secondary Sch. Athletic Ass'n, 531 U.S. 288, 295–96 (2001) (summarizing the factors considered by the Court); Blum v. Yaretsky, 457 U.S. 991, 1004 (1982) ("[O]ur precedents indicate that a State normally can be held responsible for a private decision only when it has exercised coercive power or has provided such significant encouragement, either overt or covert, that the choice must in law be deemed to be that of the State."); *id*. at 1005–12 (holding that decisions made by private nursing homes to discharge or transfer Medicaid patients did not qualify as state action even though subject to extensive regulation); Gilliam E. Metzger, *Privatization as Delegation*, 103 COLUM. L. REV. 1367, 1410–21, 1446–52 (2003); *id*. at 1417 (noting "the Court's prime insistence on government involvement in specific challenged acts"); *id*. at 1420 ("No doubt, the Supreme Court will clamp down when it perceives an effort by government to evade its constitutional obligations.").

53. For example, Title VII of the Civil Rights Act of 1964, as amended by the Pregnancy Discrimination Act, would apply. *See* UAW v. Johnson Controls, Inc., 499 U.S. 187, 190, 192, 199, 211 (1991) (holding that a private employer could not exclude non-sterile female employees from work involving exposure to lead because of possible fetal harms); Erickson v. Bartell Drug Co., 141 F. Supp. 2d 1266, 1268, 1271–72, 1276–77 (W.D. Wash. 2001) (holding that a health insurer could not exclude coverage for contraceptives); Mary E. Becker, *Can Employers Exclude Women to Protect Children?*, 264 JAMA 2113 (1990). *But see In re* Union Pac. R.R. Employ. Prac. Litig., 479 F.3d 936 (8th Cir. 2007) (disagreeing with the holding in *Erickson*).

54. *See* Walker v. Pierce, 560 F.2d 609, 611, 613 (4th Cir. 1977) (no state action where a physician insisted on sterilizing patients); *see also* Lawrence K. Altman, *Medical Dilemma: Necessary Drugs with Intolerable Dangers*, N.Y. TIMES, May 3, 1988, at C3 ("Many doctors also demand agreement from a patient before prescribing the drug that she would terminate a pregnancy that occurred while using it, although, of course, this could not be enforced."); *cf*. *supra* note 38 and accompanying text (discussing a similar practice in connection with HIV-positive female patients). At least one state statute governing fertility procedures prohibits such conditions. *See* N.M. STAT. ANN. § 24-9A-1(D) (Supp. 2006) (providing that "no physician may stipulate that

Constitution would not prevent a pharmaceutical company from adopting a policy of supplying Accutane (or some other teratogen) only if a physician first agreed to adopt and enforce such a policy.[55] If, however, a government agency directed a pharmaceutical company to proceed in such a fashion, then constitutional constraints would come into play.[56]

Although it appears that the FDA ordered the manufacturers of isotretinoin and thalidomide to implement restrictive distribution systems, the agency undoubtedly would argue that the companies took the initiative and "voluntarily" created the programs in question. After all, the FDA lacks any delegated statutory authority to impose such conditions. Nonetheless, it enjoys plenty of leverage to secure concessions from sponsors of new drugs when they apply for a marketing license,[57] and courts might look beneath the surface to find state action in these cases. The long history behind the Accutane restrictions, for instance, clearly indicates that the FDA pressured the manufacturer to adopt the increasingly burdensome conditions on access.[58]

In the alternative, the agency might take the position that, even if it effectively had ordered the companies to adopt these restrictions, it has no direct power to enforce them. In the event of widespread noncompliance by physicians, pharmacists, or patients, the FDA could threaten to

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a woman must abort in the event the pregnancy should produce a deformed or handicapped child").

55. *Cf.* Jamison v. Purdue Pharma Co., 251 F. Supp. 2d 1315, 1326–27 (S.D. Miss. 2003) (rejecting drug manufacturers' effort to remove tort claims to federal court on the theory that they acted under the direction of federal officers); *id*. at 1326 ("[D]efendants have established only that they are participants in a highly regulated industry. . . . [T]hey are for-profit corporations that do not derive their primary income from federal funding . . . [, and they] do not operate as a public utility under the direct control of the federal government."). *But cf.* Watson v. Philip Morris Cos., 420 F.3d 852 (8th Cir. 2005) (allowing removal on such a theory), *rev'd*, 127 S. Ct. 2301 (2007).

56. *Cf.* Skinner v. Ry. Labor Executives' Ass'n, 489 U.S. 602, 614–15 (1989) (holding that federal rules specifying when and how private railroads must test their employees for substance abuse qualified as state action); Doe v. Charleston Area Med. Ctr., Inc., 529 F.2d 638, 642–44 (4th Cir. 1975) (holding that a private hospital's policy against performing abortions satisfied state action requirements insofar as it was derived from a now unconstitutional state criminal statute).

57. *See* Lars Noah, *Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority*, 1997 WIS. L. REV. 873, 881–82. In a recent op-ed piece, a former FDA official who had just left his post as deputy commissioner explained that risk management plans "already guide the use of about 30 marketed drugs as part of 'voluntary' arrangements with drug companies." Scott Gottlieb, *Prescription for Trouble*, WALL ST. J., Mar. 6, 2007, at A19.

58. *See supra* notes 6–20 and accompanying text.

withdraw the manufacturer's license to sell the drug, but it could take no action against noncompliant providers or users.[59] Once again, however, courts may find state action based on the agency's indirect power to encourage the private manufacturer to take steps to enforce the conditions on access. Otherwise, nothing other than a pharmaceutical manufacturer's willingness to resist the FDA's pressure would stand as an obstacle to the government's ability to impose arguably unreasonable restrictions on patient access to drugs.

These questions also may arise in connection with restrictive enrollment criteria for clinical trials of investigational products. Putting aside research initiated or sponsored by federal funding agencies (which would simplify the state action issue), when a private entity (pharmaceutical company or academic institution) undertakes clinical trials of a potential teratogen, it may insist that women of childbearing age agree to undergo an abortion in the event of contraceptive failure. Apparently this had happened in the testing of isotretinoin.[60] Although the FDA first must grant an application for an investigational new drug (IND) exemption, it plays a largely passive role at this stage of the research and development process, so any such restrictions would have originated with the sponsor.[61] In

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59. *See* Noah, *supra* note 2, at 586, 592 n.99, 594; Marc Kaufman, *Death After Abortion Pill Reignites Safety Debate*, WASH. POST, Nov. 3, 2003, at A3 (reporting that the distribution restrictions for mifepristone have not been enforced); *see also* Planned Parenthood Cincinnati Region v. Taft, 444 F.3d 502 (6th Cir. 2006) (invalidating a state law that attempted to prevent the off-label use of mifepristone at lower dosages or later in pregnancy). *But cf*. Doshi, *supra* note 9, at 659, 660 (assuming incorrectly that the FDA could sanction isotretinoin users who failed to comply with the restrictions). This stands in stark contrast to the powers exercised by the Drug Enforcement Administration over controlled substances. *See* Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149, 177–85 (2004).

60. *See* Nancy Blodgett, *Acne Control vs. Birth Defects: Accutane Spurs Lawsuits, Called Thalidomide of the '80s*, A.B.A. J., July 1, 1988, at 17, 18 (reporting that some research sites had excluded women while others insisted that female subjects agree to undergo an abortion in the event of contraceptive failure).

61. *See* FDA, Investigational New Drug Applications; Amendment to Clinical Hold Regulations for Products Intended for Life-Threatening Diseases and Conditions, 65 Fed. Reg. 34,963, 34,965 (June 1, 2000). The agency has issued guidelines that address the inclusion of women who might become pregnant. *See* FDA, Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs, 58 Fed. Reg. 39,406, 39,407–08 (July 22, 1993) (discussing its 1977 policy that had called for the exclusion of women of childbearing age from early phases of studies with investigational drugs); *id*. at 39,410 (rescinding this policy); *id*. at 39,411 ("[C]linical protocols should also include measures that will minimize the possibility of fetal exposure to the investigational drug. These would ordinarily include providing for the use of a reliable method of contraception (or abstinence) for the duration of drug exposure (which may exceed the length of the study) . . . ."). The agency's guidelines have no binding effect, however. *See id*. at 39,409; *id*. at 39,408 ("The agency recognizes that this change in FDA's policy will not, by itself, cause drug companies or IRBs to alter restrictions they might impose on the participation of women of childbearing potential."). In contrast, the Department of Health and Human Services

addition, local institutional review boards (IRBs) must approve an experimental protocol before a clinical trial gets under way, but these entities generally also do not qualify as state actors.[62] Thus, notwithstanding legitimate objections to the tradition of excluding women of childbearing age from clinical trials,[63] persons denied the opportunity to enroll as subjects in privately sponsored research presumably could not invoke constitutional protections against discrimination.[64]

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revised its regulations governing federally-funded biomedical research to encourage greater inclusion of women in clinical trials. *See* HHS, Protection of Human Research Subjects, 66 Fed. Reg. 3878 (Jan. 17, 2001) (amending 45 C.F.R. pt. 46(B)). *See generally* Karen H. Rothenberg, *Gender Matters: Implications for Clinical Research and Women's Health Care*, 32 HOUS. L. REV. 1201, 1222–41, 1267–70 (1996).

62. *See* Missert v. Trs. of Boston Univ., 73 F. Supp. 2d 68, 70–73 (D. Mass. 1999) (dismissing constitutional claims asserted by a graduate student who was dismissed from a dentistry program where he premised state action solely on the federal requirements for IRB review of research that he had done for his thesis); Lars Noah, *Deputizing Institutional Review Boards to Police (Audit?) Biomedical Research*, 25 J. LEGAL MED. 267, 276–79 & n.43 (2004). For the most part, private health care facilities also need not fear constitutional claims. *See* Annotation, *Action of Private Hospital as State Action Under 42 USCS § 1983 or Fourteenth Amendment*, 42 A.L.R. FED. 463, § 18(b) (1979 & Supp. 2006).

63. *See* Rebecca Dresser, *Wanted: Single, White Male for Medical Research*, HASTINGS CENTER REP., Jan.–Feb. 1992, at 24, 25 ("The possibility that a few women might become pregnant [after contraceptive failure], might choose against abortion, and might have a child who is harmed by exposure to an experimental intervention is too small to justify the current exclusionary practices."); *id*. at 26 (arguing that, even if it made sense to exclude women of childbearing age from clinical trials involving potential teratogens that offer little promise of therapeutic benefit, fertile men should be excluded as well given the possibility of birth defects transmitted by sperm); Vanessa Merton, *The Exclusion of Pregnant, Pregnable, and Once-Pregnable People (a.k.a. Women) from Biomedical Research*, 19 AM. J.L. & MED. 369 (1993); L. Elizabeth Bowles, Note, *The Disenfranchisement of Fertile Women in Clinical Trials: The Legal Ramifications of and Solutions for Rectifying the Knowledge Gap*, 45 VAND. L. REV. 877, 895–907 (1992) (emphasizing this same point about the differential treatment of fertile male and female subjects in the course of trying to craft an Equal Protection objection to the FDA's previous policy); *id*. at 909–10 (favoring a policy that would make contraception a condition of participation); Kathy George, *UW to Study Prenatal Drug Use: Safety of Medicines for Pregnant Women a Neglected Research Area*, SEATTLE POST-INTELLIGENCER, July 26, 2004, at B1.

64. *See* R. Alta Charo, *Protecting Us to Death: Women, Pregnancy, and Clinical Research Trials*, 38 ST. LOUIS U. L.J. 135, 166–67 (1993). *But see* Rothenberg, *supra* note 61, at 1246 n.296, 1251–52 n.328; *cf*. Elaine W. v. Joint Diseases N. Gen. Hosp., Inc., 613 N.E.2d 523 (N.Y. 1993) (holding that a private hospital would have to establish a medical justification for its policy of excluding pregnant women from a drug treatment program to sustain it against a gender discrimination charge asserted under state statute); Megan R. Golden, Note, *When Pregnancy Discrimination Is Gender Discrimination: The Constitutionality of Excluding Pregnant Women from Drug Treatment Programs*, 66

B. Identifying the Rights at Stake

After satisfying the state action prerequisite for invoking the Constitution, someone seeking to challenge the FDA's access restrictions would need to identify the right(s) at stake. Until recently, courts consistently had rejected claims that persons had any special right of access to pharmaceutical products. Although patients enjoyed an interest in making choices about their medical care, the government could decline to allow the sale of drugs until the manufacturer proved their safety and effectiveness. In 2006, however, the U.S. Court of Appeals for the D.C. Circuit held that terminally ill patients sufficiently alleged that they enjoyed a fundamental right of access to promising therapeutic agents in advance of final approval, which meant that the FDA would have to demonstrate that its contrary policy represented the least restrictive means for serving a compelling governmental interest.[65] As suggested in the accompanying dissent,[66] the court's astonishing decision represents a departure from the Supreme Court's cautionary guidance about discovering new fundamental rights imbedded in the penumbra of the Bill of Rights.[67]

In contrast, the courts repeatedly have recognized fundamental rights involving procreative choices.[68] Although normally framed as rights of access to contraceptives or abortions,[69] the right to decline such interventions

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N.Y.U. L. REV. 1832, 1867–68 (1991) (arguing that the policy challenged in *Elaine W.* grew from state action for purposes of bringing a federal constitutional challenge).

65. *See* Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, 445 F.3d 470 (D.C. Cir. 2006), *vacated*, No. 04-5350, 2006 U.S. App. LEXIS 28974 (D.C. Cir. Nov. 21, 2006) (granting rehearing en banc).

66. *See id*. at 486 (Griffith, J., dissenting); *see also* Raich v. Gonzales, No. 03-15481, 2007 WL 754759, at *8-12 (9th Cir. Mar. 14, 2007) (rejecting due process claim for access to medical marijuana); Cass R. Sunstein, *Is There a Constitutional Right to Clone?*, 53 HASTINGS L.J. 987, 994 (2002) ("[W]henever the government imposes barriers on the use of some medicine or medical technology, there is a disproportionate burden on those who believe that they need it. By itself that burden is not enough to create a serious constitutional issue."). Shortly after the court granted a motion for rehearing en banc, the agency proposed amendments to liberalize its rules. *See* FDA, Expanded Access to Investigational Drugs for Treatment Use, 71 Fed. Reg. 75,147 (Dec. 14, 2006); FDA, Charging for Investigational Drugs, 71 Fed. Reg. 75,168 (Dec. 14, 2006); Rob Stein, *FDA Reveals Plan for Wider Access to Experimental Drugs*, WASH. POST, Dec. 12, 2006, at A10.

67. *See, e.g.*, Washington v. Glucksberg, 521 U.S. 702, 720–21 (1997). *See generally* Daniel O. Conkle, *Three Theories of Substantive Due Process*, 85 N.C. L. REV. 63 (2006); Brian Hawkins, Note, *The* Glucksberg *Renaissance: Substantive Due Process Since* Lawrence v. Texas, 105 MICH. L. REV. 409 (2006).

68. *See, e.g.*, Lawrence v. Texas, 539 U.S. 558, 564–66, 573–74 (2003); Hodgson v. Minnesota, 497 U.S. 417, 434 (1990) ("A woman's decision to conceive or to bear a child is a component of her liberty that is protected by the Due Process Clause of the Fourteenth Amendment to the Constitution."); Stanley v. Illinois, 405 U.S. 645, 651 (1972).

69. *See, e.g.*, Eisenstadt v. Baird, 405 U.S. 438, 453 (1972) ("If the right to privacy means anything, it is the right of the *individual*, married or single, to be free from

seems even more straightforward and far less controversial.[70] The issue becomes clearer still if the contraceptive method requires implantation and functions over a relatively long period of time, which would represent a form of temporary sterilization. Notwithstanding the failure to overrule some of the older decisions upholding early twentieth century eugenics legislation, most observers doubt that state-mandated sterilization programs would survive today.[71] After all, even without any procreative overtones,

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unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."); Griswold v. Connecticut, 381 U.S. 479 (1965). For this reason, some commentators have questioned predictions that the Court would extend the right to include novel reproductive strategies. *See* Marsha Garrison, *Law Making for Baby Making: An Interpretive Approach to the Determination of Legal Parentage*, 113 HARV. L. REV. 835, 854–59 (2000); Note, *Human Cloning and Substantive Due Process*, 111 HARV. L. REV. 2348, 2354 (1998) ("Despite the Court's occasional references to a broader principle of reproductive freedom, the Court has not truly tested a right to procreate." (footnote omitted)).

70. *See* Carey v. Population Servs. Int'l, 431 U.S. 678, 685 (1977) ("The decision whether or not to beget or bear a child . . . holds a particularly important place in the history of the right of privacy. . . . [The] decision whether to accomplish or prevent conception [is] among the most private and sensitive."); *Griswold*, 381 U.S. at 497 (Goldberg, J., concurring) ("[If] a law outlawing voluntary birth control by married persons is valid, then, by the same reasoning, a law requiring compulsory birth control also would seem to be valid. In my view, however, both types of law would unjustifiably intrude upon rights of marital privacy which are constitutionally protected."). As the Court later explained:

> The soundness of this [procreative liberty] prong of the *Roe* analysis is apparent from a consideration of the alternative. If indeed the woman's interest in deciding whether to bear and beget a child had not been recognized as in *Roe,* the State might as readily restrict a woman's right to choose to carry a pregnancy to term as to terminate it, to further asserted state interests in population control, or eugenics, for example. Yet *Roe* has been sensibly relied upon to counter any such suggestions.

Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 859 (1992).

71. *See* Michael G. Silver, Note, *Eugenics and Compulsory Sterilization Laws: Providing Redress for the Victims of a Shameful Era in United States History*, 72 GEO. WASH. L. REV. 862, 866–84 (2004) (tracing the judiciary's failure to overrule *Buck v. Bell*, 274 U.S. 200 (1927), which had upheld a state's authority to sterilize the "feeble-minded," but arguing that such laws unconstitutionally interfere with fundamental rights associated with procreation subsequently recognized by the Court); *see also* Skinner v. Oklahoma, 316 U.S. 535, 539–41 (1942) (invalidating a statute authorizing sterilization of habitual offenders, recognizing a fundamental right to procreate but basing the decision on Equal Protection grounds because it drew arbitrary distinctions among crimes that could lead to this sanction); Paul A. Lombardo, *Medicine, Eugenics, and the Supreme Court: From Coercive Sterilization to Reproductive Freedom*, 13 J. CONTEMP. HEALTH L. & POL'Y 1, 7–8, 24 (1996); Mike Anton, *Forced Sterilization Once Seen as Path to a Better World*, L.A. TIMES, July 16, 2003, at A1. After all, persons may qualify for political asylum in the U.S. when they flee other countries (such as China) because of population control policies that include state-ordered abortion and sterilization. *See* 8

persons enjoy rights of bodily integrity that would allow them to decline unwanted medical interventions unless the state had some powerful justification.[72] Even if a pregnancy might imperil a woman's life, it would be hard to imagine the state having any compelling reason for mandating the use of contraception in the face of a competent patient's refusal.[73]

The First Amendment also might come into play. After all, objections to contraception and abortion often spring from strongly held religious beliefs. Nonetheless, the FDA's access restrictions offer patients the alternative of agreeing to remain abstinent, and, even if the government decided to eliminate that option (or, to pose the issue in starker terms, insisted on an abortion in the event of pregnancy), the Free Exercise Clause does not require state actors to craft special exceptions to laws of general application.[74] Separately, some physicians and pharmacists may object on First Amendment grounds, complaining that the government compels them to distribute information recommending the use of contraceptives (which might offend their religious scruples even if abstinence remains an alternative) or else lose the opportunity to prescribe and dispense certain teratogenic drugs. The coerced speech argument has not, however, succeeded in similar medical settings (though lacking the overlay of the provider's or recipient's religious objections).[75]

U.S.C. § 1101(a)(42)(B) (2000); Megan C. Dempsey, Note, *A Misplaced Bright-Line Rule: Coercive Population Control in China and Asylum for Unmarried Partners*, 92 IOWA L. REV. 213, 216–20 (2006).

72. *See* Washington v. Glucksberg, 521 U.S. 702 (1997); *cf.* Washington v. Harper, 494 U.S. 210 (1990) (recognizing, however, that the state may have a valid competing interest where the patient is in its custody as a prison inmate).

73. *Cf.* Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261 (1990) (recognizing that the state may have a valid competing interest where the patient lacks the capacity to decide whether to refuse life-sustaining care).

74. *See* Employment Div. v. Smith, 494 U.S. 872, 879 (1990) (rejecting a free exercise claim by a Native American employee fired after ingesting peyote, a Schedule I hallucinogenic substance); *see also* Carol M. Kaplan, Note, *The Devil Is in the Details: Neutral, Generally Applicable Laws and Exceptions from* Smith, 75 N.Y.U. L. REV. 1045 (2000). Congress enacted the Religious Freedom Restoration Act in an effort to resurrect the strict scrutiny previously recognized under the free exercise clause. *See, e.g.*, Gonzales v. O Centro Espírita Beneficente União do Vegetal, 546 U.S. 418 (2006) (holding that the government had failed to demonstrate that its asserted interest in the uniform application of the Controlled Substances Act was sufficiently compelling to justify a prohibition on the sacramental use of hoasca, a tea containing the Schedule I hallucinogen dimethyltryptamine, in part because the federal government has long made an exception for the use of peyote by Native Americans).

75. *See* Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 884 (1992) (plurality opinion) ("All that is left of petitioners' argument is an asserted First Amendment right of a physician not to provide information about the risks of abortion, and childbirth, in a manner mandated by the State. . . . We see no constitutional infirmity in the requirement that the physician provide the information mandated by the State here."). Scholars have critiqued the Court's analysis. *See, e.g.*, Paula Berg,

In the past few years, "conscientious objection" by pharmacists in refusing to dispense contraceptives has attracted a great deal of attention. Some state legislatures have protected such choices while others have attempted to prohibit this sort of behavior.[76] Other health care professionals undoubtedly can decline to prescribe contraceptives or assist with abortions,[77] and patients who share in these views may find such environments more appealing, while other patients would remain free to seek out family planning services elsewhere.[78] The FDA's access restrictions might, however, effectively prevent such conscientious objectors from

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Toward a First Amendment Theory of Doctor-Patient Discourse and the Right to Receive Unbiased Medical Advice, 74 B.U. L. REV. 201, 224–25, 235–43, 247–50, 256–65 (1994); *id*. at 266 ("[R]egulations that compel physician speech may subvert patients' audience-based interests if they . . . advance a particular viewpoint regarding medical treatment or how a patient should respond to a certain diagnosis . . . ."); *id*. at 250 n.242 ("For example, patients who oppose the use of artificial contraception would likely feel trapped and offended if forced to listen to their physician deliver a speech expressing the government's view that women ought to practice artificial birth control.").

76. *See, e.g.*, Rob Stein, *A Medical Crisis of Conscience: Faith Drives Some to Refuse Patients Medication or Care*, WASH. POST, July 16, 2006, at A1; Rob Stein, *Health Workers' Choice Debated: Proposals Back Right Not to Treat*, WASH. POST, Jan. 30, 2006, at A1; *see also* Menges v. Blagojevich, 451 F. Supp. 2d 992 (C.D. Ill. 2006) (allowing pharmacists to challenge a state regulation requiring them to dispense emergency contraceptives). *See generally* Julie Cantor & Ken Baum, *The Limits of Conscientious Objection—May Pharmacists Refuse to Fill Prescriptions for Emergency Contraception?*, 351 NEW ENG. J. MED. 2008 (2004); Melissa Duvall, Comment, *Pharmacy Conscience Clause Statutes: Constitutional Religious "Accommodations" or Unconstitutional "Substantial Burdens" on Women?*, 55 AM. U. L. REV. 1485 (2006); Jed Miller, Note, *The Unconscionability of Conscience Clauses: Pharmacists' Consciences and Women's Access to Contraception*, 16 HEALTH MATRIX 237 (2006).

77. *See* Lynn D. Wardle, *Protecting the Rights of Conscience of Health Care Providers*, 14 J. LEGAL MED. 177 (1993) (surveying "conscience clauses" enacted in the states, and editorializing that these laws generally do not go far enough in securing the rights of conscientious objectors); *id*. at 180 (finding that "45 American jurisdictions provide at least some protection for some health care providers to decline to provide or perform some abortions, 10 states cover contraception, [and] seven jurisdictions include sterilization"); Natalie Langlois, Note, *Life-Sustaining Treatment Law: A Model for Balancing a Woman's Reproductive Rights with a Pharmacist's Conscientious Objection*, 47 B.C. L. REV. 815, 825–32 (2006); Katherine A. White, Note, *Crisis of Conscience: Reconciling Religious Health Care Providers' Beliefs and Patients' Rights*, 51 STAN. L. REV. 1703, 1707–17 (1999).

78. *See* Rob Stein, *Medical Practices Blend Health and Faith: Doctors, Patients Distance Themselves from Care They Consider Immoral*, WASH. POST, Aug. 31, 2006, at A1 (describing the emergence of "natural family planning" clinics that reject any use of contraceptives); *see also* Rob Stein, *Institute Practices Reproductive Medicine—and Catholicism*, WASH. POST, Oct. 31, 2006, at A14.

ever selecting—and perhaps their patients from ever even learning about[79]—teratogenic drugs available to treat a disease or other condition.

C. Unconstitutional Conditions Doctrine

Even if someone seeking to challenge the access restrictions succeeded in asserting that they enjoyed some fundamental right, they would still have to establish that state action threatened to deprive them of the opportunity to exercise this right. The state has not, for instance, ordered contraception for (or sterilization of) persons likely to transmit infectious or genetic diseases.[80] Moreover, the FDA has not told women of childbearing age that they can never use these teratogenic drugs; instead, it has insisted that they promise to avoid becoming pregnant before using such drugs. A person seeking to challenge such a requirement would have to invoke the unconstitutional conditions doctrine, which asks whether the government inappropriately demands that an individual forego exercising a constitutionally protected right in order to secure access to a benefit.

The doctrine recognizes that, even without coercion, persons often face seriously constrained choices and that the government's offer of some benefit may encourage waivers of their rights without valid consent. The U.S. Supreme Court has employed the unconstitutional conditions doctrine in resolving challenges to state denials of unemployment benefits to individuals who decline to work on their sabbath,[81] state

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79. *See* Farr A. Curlin et al., *Religion, Conscience, and Controversial Clinical Practices*, 356 NEW ENG. J. MED. 593, 597 (2007) ("If physicians' ideas translate into their practices, then 14% of patients—more than 40 million Americans—may be cared for by physicians who do not believe they are obligated to disclose information about medically available treatments they consider objectionable.").

80. *See* John A. Robertson, *Norplant and Irresponsible Reproduction*, HASTINGS CENTER REP., Jan.–Feb. 1995, at S23, S25 ("At present this discussion is largely hypothetical, because no one has proposed that HIV-positive women or those at genetic risk should be penalized for reproduction or failure to accept Norplant."); *see also* John A. Robertson, *Procreative Liberty and Human Genetics*, 39 EMORY L.J. 697, 716 (1990) (doubting that the government could mandate genetic screening); Sonia Mateu Suter, *The Routinization of Prenatal Testing*, 28 AM. J.L. & MED. 233, 269 (2002) (arguing that, as voluntary genetic screening has become routine, "a new, more subtle form of eugenics is currently emerging at the individual level"); *cf.* Elisabeth Rosenthal, *Scientists Debate China's Law on Sterilizing the Carriers of Genetic Defects*, N.Y. TIMES, Aug. 16, 1998, § 1, at 14. If screening for homozygous recessive conditions such as cystic fibrosis, Tay Sachs disease, or sickle-cell anemia revealed that both potential parents were carriers, then they would have a 25% chance of bearing a child suffering from such a disease, which does not differ appreciably from the risk of serious birth defects that the FDA thought necessitated contraception when using certain teratogenic drugs.

81. *See, e.g.*, Hobbie v. Unemployment Appeals Comm'n, 480 U.S. 136, 146 (1987); Sherbert v. Verner, 374 U.S. 398, 404 (1963); *see also* Speiser v. Randall, 357

prohibitions on office-holding by ministers,[82] and federal restrictions on editorializing as a condition for receiving public broadcasting subsidies.[83] Because of its inconsistent application by the Court, the unconstitutional conditions doctrine has attracted a great deal of scholarly attention.[84] Commentators have suggested a number of competing formulations,[85] but the Supreme Court has not explicitly embraced any of these approaches.[86]

What if the government demanded contraceptive use as a condition of Medicaid reimbursement for drugs that create a risk of birth defects?[87] In fact, Medicare has begun to insist that beneficiaries seeking coverage of certain medical devices agree to participate in post-approval safety and efficacy studies.[88] The Medicaid condition hypothesized here

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U.S. 513, 518–19 (1958) (holding that the denial of a state tax exemption to persons advocating the overthrow of the government represented an unconstitutional condition).

82. *See* McDaniel v. Paty, 435 U.S. 618, 626–29 (1978) (plurality opinion).

83. *See* FCC v. League of Women Voters, 468 U.S. 364, 399–401 (1984).

84. *See, e.g.*, Mitchell N. Berman, *Coercion Without Baselines: Unconstitutional Conditions in Three Dimensions*, 90 GEO. L.J. 1 (2001); Daniel A. Farber, *Another View of the Quagmire: Unconstitutional Conditions and Contract Theory*, 33 FLA. ST. U. L. REV. 913 (2006).

85. *See* Kathleen M. Sullivan, *Unconstitutional Conditions*, 102 HARV. L. REV. 1413 (1989) (canvassing several different theories based on notions of coercion, corruption, and commodification, and offering instead a "systemic" theory calling for strict scrutiny of rights-pressuring conditions on government benefits because they skew the distribution of power between and among the government and the governed).

86. *See* Lynn A. Baker, *The Prices of Rights: Toward A Positive Theory of Unconstitutional Conditions*, 75 CORNELL L. REV. 1185, 1195 (1990) (noting that all recent commentators concede that "the Court has yet to arrive, explicitly or implicitly, at a clear limiting principle for deciding challenges to conditions on government benefits").

87. *Cf.* Judy Berlfein, *Genetic Testing: Health Care Trap*, L.A. TIMES, Apr. 30, 1990, at B2 (reporting that an HMO threatened to drop a pregnant woman's coverage after she received a positive prenatal test for cystic fibrosis unless she underwent an abortion).

88. *See* Gina Kolata, *Medicare Covering New Treatments, but with a Catch*, N.Y. TIMES, Nov. 5, 2004, at A1; Rick Weiss, *Medicare to Cover Cardiac Device: Plan Raises Issue of Line Between Care and Research*, WASH. POST, Jan. 20, 2005, at A1 (explaining that this "represents the most aggressive effort yet to use the federal insurance plan for the elderly as a backdoor way to learn more about what works and what does not in medicine"); *see also* Steven D. Pearson et al., *Medicare's Requirement for Research Participation as a Condition of Coverage: Is It Ethical?*, 296 JAMA 988 (2006) (defending this approach). In fact, the isotretinoin and thalidomide registration requirements operate in much the same fashion by enrolling patients in an epidemiological study of pregnancy rates and outcomes. *See* Michael Kranish, *New Use Is Found for Thalidomide: Fighting Cancer*, BOSTON GLOBE, Oct. 20, 2002, at A28 (reporting objections that BU's initial policing role under STEPS was unduly coercive); *supra* note 13; *see also* FDA, General Information About Pregnancy Exposure Registries, http://www.fda.gov/womens/registries (last visited Apr. 30, 2007); Honein et

unmistakably involves state action, though it looks more like a nonsubsidy than a penalty because a woman receiving public assistance for drug coverage would remain free (in theory) to refuse contraception and pay for the drug out of pocket.[89] The actual condition of access imposed by the FDA operates more strongly, however, than a simple government decision not to subsidize use of a particular drug.

If courts began to view access to therapeutic agents as protected by the Constitution, then contraception requirements would amount to a double whammy, forcing patients to choose which of two fundamental rights to sacrifice in order to secure the other right.[90] Furthermore, if access to therapeutic agents qualified as a fundamental right, then the differential impact of contraception as a condition of access might pose Equal Protection questions.[91] The concern becomes even clearer if the agency adopted a broader restriction linked to the patient's sex (for example, altogether prohibiting use by women of childbearing years, as often happens in clinical trials with investigational new drugs that may cause birth defects).[92] Because gender only qualifies as a quasi-suspect classification triggering heightened scrutiny, however, the government probably would manage to justify such restrictions.[93]

D. Applying Strict Scrutiny

Lastly, even if (indirect) state action (indirectly) threatens to infringe upon some fundamental right(s), the constitutional inquiry allows the government to try and justify its action. If strict scrutiny applied, the

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al., *supra* note 16, at 1073 (discussing a pregnancy registry for antiepileptic drugs); Uhl et al., *supra* note 26, at 890.

89. *Cf.* Mem'l Hosp. v. Maricopa County, 415 U.S. 250 (1974) (holding that the state cannot deny a benefit (for example, access to medical care) because an otherwise eligible person had exercised a fundamental right (to travel, for example)).

90. *See supra* note 40 (making a similar point in connection with pelvic exams as a condition for access to contraceptives).

91. For instance, women with cystic acne would face a difficult choice not forced on men with the same disease (even if the patient's male partner might have to use a contraceptive in order to satisfy the condition). In contrast, for drugs such as thalidomide that have teratogenic potential whether used by a male or female patient, the government would have drawn no classification based on sex.

92. *Cf.* January W. Payne, *Forever Pregnant: Guidelines—Treat Nearly All Women as Pre-Pregnant*, WASH. POST, May 16, 2006, at F1 (discussing new CDC recommendations for "preconception care" designed to ensure that all women who might become pregnant adhere to prenatal care guidelines during the window of time before confirmation of pregnancy).

93. *Cf.* Nguyen v. INS, 533 U.S. 53 (2001); United States v. Virginia, 518 U.S. 515, 533–34 (1996) ("The heightened review standard our precedent establishes does not make sex a proscribed classification. . . . But such classifications may not be used . . . to create or perpetuate the legal, social, and economic inferiority of women."); Bray v. Alexandria Women's Health Clinic, 506 U.S. 263, 271 (1993).

agency would need to demonstrate that its conditions on access represented the least restrictive means for achieving a compelling governmental interest.[94] State actors rarely prevail once a court decides to use strict scrutiny,[95] though usually because they struggle to satisfy the least restrictive means requirement. In the case of teratogenic drugs, however (and somewhat counterintuitively), the ends prong may be trickier: even though the state may seek to minimize the risks of in utero exposure to teratogens, the state may not have a compelling interest in *preventing* the birth of a child so exposed.[96] If it did, then the least restrictive means prong should not pose much of a problem. After all, at least in the case of Accutane, the FDA proceeded deliberately (some would say too slowly), incrementally adding ever more burdensome conditions on access after it realized that the previous effort had not worked as well as hoped.

Some scholars have taken the position that safeguarding unconceived offspring from the risk of fetal injuries would not qualify as a compelling interest because children born with unavoidable birth defects are still better off alive.[97] This view coincides with the judicial hostility

94. *See, e.g.*, Carey v. Population Servs. Int'l, 431 U.S. 678, 686 (1977) ("[W]here a decision as fundamental as that whether to bear or beget a child is involved, regulations imposing a burden on it may be justified only by compelling state interests, and must be narrowly drawn to express only those interests.").

95. *See* Adam Winkler, *Fatal in Theory and Strict in Fact: An Empirical Analysis of Strict Scrutiny in the Federal Courts*, 59 VAND. L. REV. 793, 800–09, 869–71 (2006) (summarizing the conventional wisdom about strict scrutiny, but finding that in recent years, depending on various circumstances, some laws survive the test).

96. *Cf.* Charo, *supra* note 64, at 154 ("Even if excluding pregnant women intending to go to term from all nontherapeutic research can be justified on the grounds of fetal protection, excluding all fertile but not currently pregnant women certainly cannot . . . .").

97. *See* Jan C. Heller, *Religious Perspectives on Human Cloning: Revisiting Safety as a Moral Constraint*, 32 VAL. U. L. REV. 661, 663–69, 676–77 (1998) (referring to this paradox as the problem of the "contingent future person"); John A. Robertson, *Embryos, Families, and Procreative Liberty: The Legal Structure of the New Reproduction*, 59 S. CAL. L. REV. 939, 987–93 (1986); John A. Robertson, *Liberty, Identity, and Human Cloning*, 76 TEX. L. REV. 1371, 1405–08 (1998); John A. Robertson, *Procreative Liberty and the Control of Conception, Pregnancy, and Childbirth*, 69 VA. L. REV. 405, 435 (1983); Michael H. Shapiro, *How (Not) to Think About Surrogacy and Other Reproductive Innovations*, 28 U.S.F. L. REV. 647, 672–73 (1994). In an article that proposed restricting access to fertility drugs, I argued that this premise did not apply to avoidable prenatal injuries caused by multifetal pregnancies. *See* Noah, *supra* note 3, at 659–65; *see also* Dan W. Brock, *Procreative Liberty*, 74 TEX. L. REV. 187, 202–05 (1995) (book review) (criticizing Professor Robertson's claim that any harm done to children born through assisted reproductive technologies would not justify state

to "wrongful life" claims brought on behalf of such children.[98] A physician may face liability for neglecting to disclose the teratogenic potential of a prescribed drug, but the courts in such cases assume that the risk information would have caused the patient to avoid using the drug rather than to avoid becoming pregnant (hence, an avoidable birth defect).[99] Thus, if a physician prescribed isotretinoin to a woman of childbearing years without revealing the risk of congenital abnormalities, then the physician has breached the duty to secure informed consent and may face liability for the resulting injuries to the child. If, however, the physician fully disclosed the risk but allegedly failed to take reasonable steps to ensure that the patient would not become pregnant, then courts would not allow recovery for any injuries to the child.[100]

Under that view, the FDA has a legitimate interest in ensuring that pharmaceutical manufacturers accurately disclose the teratogenic potential of drug products but does not have a compelling interest that would justify taking additional steps designed to prevent the conception and birth of children by a woman after she has decided to use such a drug. In making risk-benefit judgments and labeling decisions, the FDA routinely takes into account the possibility of adverse impacts on the

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interference); Ronald M. Green, *Parental Autonomy and the Obligation Not to Harm One's Child Genetically*, 25 J.L. MED. & ETHICS 5, 10 (1997); Philip G. Peters, Jr., *Protecting the Unconceived: Nonexistence, Avoidability, and Reproductive Technology*, 31 ARIZ. L. REV. 487, 508–19, 524, 546–48 (1989).

98. *See, e.g.*, Grubbs v. Barbourville Family Health Ctr., 120 S.W.3d 682 (Ky. 2003); Kassama v. Magat, 792 A.2d 1102, 1115–23 (Md. 2002); *id*. at 1116–17 (explaining that twenty-eight other states had rejected wrongful life claims while only three had allowed limited recovery in such cases); Hester v. Dwivedi, 733 N.E.2d 1161 (Ohio 2000); Willis v. Wu, 607 S.E.2d 63 (S.C. 2004). *But cf*. Harbeson v. Parke Davis, Inc., 746 F.2d 517, 523–25 & n.4 (9th Cir. 1984) (affirming judgment for plaintiffs on an informed consent claim where the physicians had failed to advise an epilepsy patient of the teratogenicity of Dilantin after she specifically had inquired about such risks in order to decide whether to attempt to conceive).

99. *See, e.g.*, Hogle v. Hall, 916 P.2d 814, 816–17 (Nev. 1996) (Accutane).

100. In one recent Accutane case, the court drew precisely this distinction:

> Given that Mr. Gerber cannot recover on a theory that, had Roche provided certain precautions, he would not have been born, Mr. Gerber can only argue that Shirley Gerber would not have taken Accutane in the first place if Roche's warning had been adequate. In order to prove causation under the circumstances presented in this case, Plaintiff must demonstrate that an alternative warning would have changed the physician's decision to prescribe Accutane *or* would have altered Shirley Gerber's decision to take the drug for her severe acne condition.

Gerber v. Hoffmann-La Roche Inc., 392 F. Supp. 2d 907, 920 (S.D. Tex. 2005); *id*. at 921 ("A different warning may have altered Shirley Gerber's birth control plan to better avoid pregnancy, but, as noted above, the net result of this argument is that Plaintiff would not have been born, a 'wrongful life' theory which is not cognizable in Texas."); *see also* Walker v. Mart, 790 P.2d 735, 740 (Ariz. 1990) ("If her parents had decided to conceive, despite knowledge of probable congenital defects, the law would recognize no action on Christy's behalf against them.").

unborn.[101] Thus, if the agency decided to withdraw its approval of a teratogen, then (putting aside the possibility of a constitutional right of drug access) disappointed patients probably would have no constitutional grounds for objecting.[102] The greater power does not, however, invariably include the lesser power to condition access on the forfeiture of a patient's constitutional rights.[103] If preventing the birth of injured children does not qualify as a compelling interest, then the FDA's access restrictions would amount to unconstitutional conditions.[104]

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101. *See* Gail H. Javitt & Kathy Hudson, *Regulating (for the Benefit of) Future Persons: A Different Perspective on the FDA's Jurisdiction to Regulate Human Reproductive Cloning*, 2003 UTAH L. REV. 1201, 1222–27; *id*. at 1221–22 ("[A]s far back as 1962, there has been a tacit presumption that the FDA's regulatory jurisdiction over articles intended 'for use in man' includes both current and future persons, and that its mandate extends to protecting the safety of future persons who may be exposed to a regulated product . . . ."); Noah, *supra* note 3, at 662–63 ("The FDA routinely regulates pharmaceutical products in ways designed to minimize the risks of fetal injuries and malformations. . . . [T]he FDA clearly—even if some would say unreflectively—views harms to the unborn as relevant hazards of an intervention."); Peters, *supra* note 97, at 488, 537–38 (explaining that the FDA applies a more stringent standard for measuring risks and benefits of drugs that may affect the unborn); *see also* Berg, *supra* note 75, at 263 (arguing that the First Amendment would not prevent the government from directing physicians to discuss risks that drugs may pose to the fetus); David Brown, *Blood-Pressure Drugs Linked to Birth Defects*, WASH. POST, June 8, 2006, at A12 (reporting that the FDA will consider expanded pregnancy warnings for ACE inhibitors after a review of one state's Medicaid records uncovered a significant increase in the risk of birth defects when taken during the first trimester); *Pregnant Women Warned About Paxil*, WASH. POST, Dec. 1, 2006, at A8.

102. *See* Peters, *supra* note 97, at 544–45 ("Drug disapproval is certainly a lesser violation of parental privacy and bodily integrity than forced sterilization or abortion."); *id*. at 519 ("Is there any doubt that the [FDA] would disapprove a fertility drug that produced birth defects similar to those associated with thalidomide even if the alternative for the affected children was nonexistence?").

103. *See* Brooks R. Fudenberg, *Unconstitutional Conditions and Greater Powers: A Separability Approach*, 43 UCLA L. REV. 371, 519 (1995) (concluding that, although the greater-includes-the-lesser argument makes sense, heightened judicial scrutiny is appropriate in those cases where a lesser power is separated from the greater power along a constitutionally protected dimension); John H. Garvey, *The Powers and the Duties of Government*, 26 SAN DIEGO L. REV. 209, 215–19 (1989) (discussing the limitations of this argument); Michael Herz, *Justice Byron White and the Argument that the Greater Includes the Lesser*, 1994 BYU L. REV. 227, 238–49 (same).

104. *Cf.* Andrew Zoltan, Comment, Jacobson *Revisited: Mandatory Polio Vaccination as an Unconstitutional Condition*, 13 GEO. MASON L. REV. 735 (2005) (arguing that, once an infectious disease such as smallpox has been eradicated, mandatory immunizations no longer serve a public health purpose and, if made a prerequisite for access to public education, would violate the unconstitutional conditions doctrine). The requirement for a negative pregnancy test should, however, survive because it does not involve sacrificing any fundamental right and, even if it did, the condition appears to serve the compelling interest of preventing avoidable birth defects insofar as a positive

V. CONCLUSION

Who can argue with the goal of avoiding prenatal injuries, and who can fail to appreciate the FDA's frustration over the seeming inability of users to guard against becoming pregnant when taking a drug that poses a serious risk of teratogenicity? Even so, the agency may have crossed a constitutional line when it in effect required that patients first agree to use contraceptives as a condition of access to one of these drugs. If anyone ever challenged this risk management strategy, a court would have to decide whether the policy grew out of state action, involved the exercise of a fundamental right, inappropriately conditioned access to a benefit on the waiver of one of these rights, and failed to serve a compelling governmental interest. Each of these steps in the analysis has undoubted weaknesses, and perhaps in the aggregate they would defeat an effort to challenge the distribution restrictions on constitutional grounds. Nonetheless, the FDA's recent efforts to impose such conditions raise serious enough questions about burdening procreative rights that these initiatives deserve closer attention than they have received to this point.

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test would deprive the patient of access to the drug rather than force the patient to forego the right to become pregnant once on the drug. Conversely, labeling that urged patients to consider an abortion in the event of exposure, which conflicts with the professional norm of "non-directive" counseling in connection with prenatal testing for genetic defects, might fail strict scrutiny (for example, if conscientious objectors declined to supply teratogens accompanied by such patient labeling).