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## Abortion, Equality, and Administrative Regulation

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## **ABORTION, EQUALITY, AND ADMINISTRATIVE REGULATION**

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## **ABORTION, EQUALITY, AND ADMINISTRATIVE REGULATION**

Gillian E. Metzger<sup>1</sup>

Abortion and equality are a common pairing; courts as well as legal scholars have noted the importance of abortion and a woman's ability to control whether and when she has children to her ability to participate fully and equally in society. Abortion and administrative regulation, on the other hand, are a more unusual combination. Most restrictions on abortion are legislatively imposed, while guarantees of reproductive freedom are constitutionally-derived, so administrative law does not frequently figure in debates about access to abortion.

I think administrative regulation of abortion merits closer study. Fights over reproductive rights are increasingly occurring in administrative contexts. The current struggle over the federal Food and Drug Administration (FDA)'s refusal to grant over-the-counter access to emergency contraception is a prime example, with recent expansions in state licensing requirements for abortion clinics being another. Such licensing requirements are often quite onerous, forcing clinics to undertake costly renovations or imposing conditions that clinics are unable to meet. Yet instances also exist of administrative regulation being used affirmatively to foster women's reproductive rights, such as Illinois' recent rule requiring pharmacists to dispense emergency contraception if they dispense other forms of contraception.<sup>2</sup>

This trend towards increasing administrative control is reason enough to pay greater attention to the interaction of administrative law and reproductive rights. Perhaps more relevantly to this symposium, however, focusing on administrative abortion regulation is useful because it demonstrates unexpected obstacles to successfully challenging abortion restrictions as unconstitutional gender discrimination. Numerous grounds exist on which to conclude that measures singling out abortion for regulation should constitute sex-based classifications for purposes of equal protection analysis. As Reva Siegal has argued, abortion restrictions were and are often animated by traditional—and constitutionally

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<sup>2</sup> See Monica Davey, *Illinois Pharmacies Ordered to Provide Birth Control*, N.Y. Times, Apr. 2, 2005 at 10.

illegitimate—views concerning women’s proper roles.<sup>3</sup> In addition, the ability to control their reproductive capacity is central to women becoming “full and equal members of society.”<sup>4</sup> But on the most basic level, abortion-specific regulation is sex-based regulation because it exclusively targets women: “Only women become pregnant; only women have abortions.”<sup>5</sup> Further, as Cass Sunstein has argued, this means that abortion regulations represent facial or de jure sex classifications, making any additional demonstration of discriminatory purpose unnecessary.<sup>6</sup>

Of course, these arguments failed to persuade the Supreme Court, which in its 1974 *Geduldig v. Aiello* decision insisted that not every pregnancy classification was in fact sex-based. In *Geduldig* the Court rejected a gender equal protection challenge to a government disability program that denied benefits for disabilities connected to pregnancy, famously concluding that the program did not distinguish between men and women but instead between “pregnant women and nonpregnant persons.”<sup>7</sup> The Court has also upheld abortion-specific restrictions without seeming to find it necessary to subject such measures to gender equal protection scrutiny. Yet more recently, the Court has indicated greater awareness of the relationship between regulation of reproduction and sex discrimination. Most notably, *Planned Parenthood v. Casey* invoked women’s equality concerns in concluding that access

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<sup>3</sup> Reva Siegel, Reasoning from the Body: A Historical Perspective on Abortion Regulation and Questions of Equal Protection, 44 Stan. L. Rev. 261, 277, 348–80 (1992); see also Cass R. Sunstein, Neutrality in Constitutional Law (with Special Reference to Pornography, Abortion, and Surrogacy), 92 Colum. L. Rev. 1, 36 (1992); see also Kristin Luker, Abortion and the Politics of Motherhood 192–215 (1984) describing different views of motherhood and women’s roles that dominate pro-life and pro-choice movements).

<sup>4</sup>Anita Allen, The Proposed Equal Protection Fix for Abortion Law: Reflections on Citizenship, Gender, and the Constitution, 18 Harv. J. L. & Pub. Pol’y 419, 424–28, 435–39 (1994); Ruth Bader Ginsburg, Some Thoughts on Autonomy and Equality in Relation to *Roe v. Wade*, 63 N.C. L. Rev. 375,382–83 (1985); Kenneth Karst, The Supreme Court—1976 Term, Foreword: Equal Citizenship Under the Fourteenth Amendment, 91 Harv. L. Rev. 1, 57–59 (1977); Sylvia A. Law, Rethinking Sex and the Constitution, 132 U. Pa. L. Rev. 955, 1016–19 (1984); Catharine A. MacKinnon, Reflections on Sex Equality Under Law, 100 Yale L. J. 1281, 1308–13, 1319–20 (1991).

<sup>5</sup> Law, supra note ?, at 1016; see also Donald H. Regan, Rewriting *Roe v. Wade*, 77 Mich. L. Rev. 1569, 1618–23, 1630–35 (1979) (describing the equal protection problem with an anti-abortion statute as being that “[w]omen who want abortions are required to give aid in circumstances where closely analogous potential samaritans are not. And they are required to give aid of a *kind* and an *extent* that is required of no other potential samaritan.”). Congress accepted this reasoning in the Pregnancy Discrimination Act of 1978 (PDA), which amended Title VII to grant protection against employment discrimination based on pregnancy. The PDA states that “‘because of sex’ or ‘on the basis of sex’ include. . . because of or on the basis of pregnancy, childbirth, or related medical conditions.” 42 U.S.C. § 2000e-(k).

<sup>6</sup> See Sunstein, supra note ?, at 32–33; see also Personnel Administrator v. Feeney, 442 U.S. 256, 279 (1979) (“‘Discriminatory purpose’ . . . implies that the decisionmaker . . . selected or reaffirmed a particular course of action at least in part ‘because of’ not merely ‘in spite of’ its adverse effects upon an identifiable group.”).

<sup>7</sup> 417 U.S. 484, 496 n. 20 (1974).

to abortion should continue to receive constitutional protection under the Due Process Clause.<sup>8</sup> On other occasions, the Court has reinforced constitutional prohibitions on sex-role stereotyping, as well as underscored how stereotypes based on women's roles as mothers and caregivers restrict their employment opportunities.<sup>9</sup>

These recent decisions might suggest the time has come to try to recast abortion rights in equality terms, as many scholars have long argued.<sup>10</sup> An additional impetus is the diminished protection for abortion rights under due process that resulted from *Casey*'s replacing the trimester framework of *Roe v. Wade* with the undue burden standard.<sup>11</sup> Moreover, administrative abortion measures might appear particularly susceptible to gender equal protection challenge. Administrative regulation of abortion is overwhelmingly health regulation; the focus is on abortion as a medical procedure, and the government's only stated interest is protecting the health of women obtaining abortions—as opposed to that of preserving fetal life, the other recognized government interest in this area. This health focus is not coincidental; administrative agencies typically play a major role in health regulatory schemes, reflecting the medical, scientific, and technical expertise often involved. But this focus means that the unique aspects of abortion—its impact on the fetus and the social, moral, and psychological effects of terminating potential life—are largely absent in regard to administrative abortion regulations. Although abortion involves women's reproductive organs, that does not distinguish it under a health perspective. Instead, the question is what risks and complications are associated with abortion compared to other forms of surgery (or, in the case of medical abortion, compared to other prescription drugs). And widespread agreement on the minimal risks associated with first and early second trimester abortions provides an objective basis for concluding that regulations targeting such abortions represent instances where medical procedures sought by women are being singled out for unwarranted burdens.

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<sup>8</sup> See 505 U.S. 833, 852, 856 (1992).

<sup>9</sup> See *Nevada Department of Human Resources v. Hibbs*, 538 U.S. 721, 730-31 (2003); *United States v. Virginia*, 518 U.S. 515, 531, 533 (1996). But see *Nguyen v. United States*, 533 U.S. 53, 61-70 (2001).

<sup>10</sup> See sources cited *supra* notes 3-5.

<sup>11</sup> See *infra* note ?.

What this line of argument fails to account for, however, is the regulatory and administrative character of abortion health measures. Paradoxically, rather than underscoring their gendered nature, emphasizing these measures' health focus serves to immunize them against constitutional challenge. Doing so makes these measures appear as a species of ordinary regulation, with the effect that courts assess their constitutionality against the background of the government's broad power to regulate in the name of health as well as doctrines of deference to administrative expertise. Framed in this fashion, regulations targeting abortion on health grounds become simply a manifestation of the government's leeway to regulate in a case-by-case incrementalist fashion, instead of grounds for suspicion.

The net result is that erasing abortion's uniqueness to foster a gender equal protection challenge serves actually to undermine the claim that it is illegitimate to target abortion for regulation. Put differently, the perception of abortion as unique has a dual-edged character; it allows abortion to be singled out for regulation, but also simultaneously singles out abortion for protection against regulation. This suggests that equal protection analysis is unlikely to offer greater prohibitions on abortion targeting than are available under abortion-specific jurisprudence rooted in due process. More generally, while courts may come to recognize the importance of reproductive rights to women's equality, that recognition is more likely to come by integrating equality concerns into current due process frameworks than by independent equal protection challenges.

Yet at the same time, the perception of abortion health measures as ordinary regulation opens up the possibility of challenging these measures in more straightforward administrative law terms. Administrative law does not offer the permanent protections of constitutional law, and can be quite deferential to administrative determinations. Nonetheless, administrative law's requirements of explanation and reasoned decisionmaking may in the end offer the greatest protection against regulations that single out abortion for disfavored treatment.

#### I. RECENT INSTANCES OF ADMINISTRATIVE ABORTION REGULATION: TARGETED REGULATION OF ABORTION PROVIDERS AND FDA REGULATION OF ABORTION-RELATED DRUGS

Administrative regulation of abortion is not a new phenomenon. Although triggering criminal penalties, abortion bans pre-*Roe* were also administratively implemented, through license revocation proceedings for doctors who provided abortions.<sup>12</sup> Post-*Roe*, states and local governments imposed numerous requirements on abortion in the name of protecting women's health. Many of these measures were legislatively imposed; indeed, abortion and reproduction generally appear singular in the extent to which the substantive details of health regulation are legislatively

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<sup>12</sup> See, e.g., *Withrow v. Larkin*, 421 U.S. 35 (1975); *Epstein v. Bd. of Regents*, 65 N.E. 2d 756 (N.Y. 1946); *Missouri ex rel Hurwitz v. North*, 271 U.S. 40 (1926); *Kemp v. Board of Medical Supervisors*, 46 App. D.C. 173 (D.C. Cir. 1917).

determined, rather than left for administrative discretion.<sup>13</sup> Nonetheless, in the post-*Roe* period abortion providers were occasionally subjected to administrative restrictions as well.<sup>14</sup> Recently, however, abortion regulation justified on health grounds—and even more specifically, abortion health regulations promulgated by administrative agencies—seem to be growing more prevalent. Two particular instances of such administrative regulation deserve special note. One is state and local regulatory schemes imposing a variety of detailed requirements on abortion providers and facilities; the other, federal regulation of drugs connected to abortion and to reproduction more generally. Some background on these two instances is helpful for understanding the difficulties involved in challenging administrative abortion regulation in equal protection terms.

#### A. *Targeted Regulation of Abortion Providers and Facilities*

In the years between *Roe* and *Casey*, numerous jurisdictions adopted detailed regulatory schemes subjecting abortion providers to a wide variety of requirements not imposed on those performing comparable medical practices.<sup>15</sup> Such targeted regulation of abortion providers, often referred to by pro-choice advocates as TRAP laws, has expanded significantly post-*Casey*.<sup>16</sup> This expansion is not unique to

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<sup>13</sup> See, e.g., *Planned Parenthood v. Casey*, 505 U.S. 833, 900 (1992) (statutory reporting requirements justified on health grounds); *Thornburgh v. American College of Obstetricians & Gynecologists*, 476 U.S. 747, 756–58 (1986) (same); *City of Akron v. Akron Ctr for Reprod. Health*, 462 U.S. 416, 431–39 (1983) (second-trimester hospitalization requirement imposed by city ordinance); *Mahoning Women’s Center v. Huner*, 610 F.2d 456 (6th Cir. 1979) (detailed requirements on abortion providers by city ordinance, including requirement that abortion facilities must be licensed by the city Board of Health).

<sup>14</sup> See, e.g., *Ragsdale v. Turnock*, 841 F.2d 1358 (7th Cir. 1988) (invalidating Illinois statutory and regulatory scheme imposing numerous requirements on abortion providers and facilities, including requirement that abortions be performed in licensed surgical centers and the state Department of Public Health hold public hearings on license applications); *Birth Control Centers, Inc. v. Reizen*, 743 F.2d 352 (6th Cir. 1984) (upholding and invalidating parts of Michigan’s statutory and regulatory scheme applicable to abortion clinics); *Friendship Med. Ctr. v. Chicago Bd. of Health*, 505 F.2d 1141 (7th Cir. 1974) (invalidating regulations adopted by city board of health addressing a variety of aspects of abortion provision); *Florida Women’s Med. Clinic v. Smith*, 478 F. Supp. 233, 235–36 (S.D. Fla. 1976) (invalidating detailed implementing regulations but not statutory abortion-specific licensure requirement as unconstitutional under *Roe*).

<sup>15</sup> See *supra* cases cited nn. 1–3; see also *Sendak v. Arnold*, 429 U.S. 968 (1976) (sum. aff) (invalidating pre-*Roe* requirement that first trimester abortions be performed by a physician in a hospital or licensed health facility); *Connecticut v. Menillo*, 423 U.S. 9, 10–11 (1975) (per curiam) (upholding prohibition on abortions by non-physicians because first trimester abortion only safe if performed by competent personnel).

<sup>16</sup> See Amalia W. Jorns, Note, *Challenging Warrantless Inspections of Abortion Providers: A New Constitutional Strategy*, 105 Colum. L. Rev. 1563, 1565 (2005); see also [http://www.prochoiceamerica.org/choice-action-center/in\\_your\\_state/who-decides/nationwide-trends/issues-trap.html](http://www.prochoiceamerica.org/choice-action-center/in_your_state/who-decides/nationwide-trends/issues-trap.html) (website of NARAL/Pro-Choice America providing links to different states’ TRAP laws). Disagreement exists on the number of states which currently have TRAP laws. See

TRAP laws; other forms of abortion restrictions have also increased, reflecting *Casey*'s greater tolerance of such measures and that decision's identification of the government's interests in potential life and women's health as legitimate from the beginning of pregnancy.<sup>17</sup>

The content of different states' TRAP laws varies, but in general they impose licensing requirements, authorize state inspections, regulate wide-ranging aspects of abortion providers' operations—including, for example, staff qualifications and minimum hallway dimensions—and impose civil and criminal penalties for noncompliance.<sup>18</sup> Although the adoption of such abortion regulations is frequently mandated by statute, the specific content of the resultant requirements (often quite detailed) is set by state agencies.<sup>19</sup> Moreover, the resultant regulatory schemes themselves expand administrative oversight and control of abortion providers by mandating periodic licensing and inspection of abortion facilities, which can lead to frequent interaction with health department officials as well as adjudicatory hearings or other administrative proceedings.<sup>20</sup>

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Jorns, *supra*, at 1568 & n.20.

<sup>17</sup> See *Casey*, 505 U.S. at 869–76; Caitlin Borgmann, Winter Count: Taking Stock of Abortion Rights After *Casey* and *Carhart*, 31 Fordham Urb. L. J. 675, 688 (2004); see also Gillian E. Metzger, Note, Unburdening the Undue Burden Standard: Orienting *Casey* in Constitutional Jurisprudence, 94 Colum. L. Rev. 2025 (1994) (analyzing implications of the undue burden standard for challenges to abortion restrictions). According to the organization NARAL/Pro-Choice America, between 1995 and 2005 the states enacted 467 anti-choice measures. See Key Findings, in *Who Decides: The Status of Women's Reproductive Rights in America* (15th ed. 2006), available at: [http://www.prochoiceamerica.org/choice-action-center/in\\_your\\_state/who-decides/nationwide-trends/key-findings-risk.html](http://www.prochoiceamerica.org/choice-action-center/in_your_state/who-decides/nationwide-trends/key-findings-risk.html). The expansion in TRAP laws in particular also reflects pro-life activists' recognition that efforts to ban abortion outright would not succeed post-*Casey*. This led to “a shift in strategy” to focus on “regulation at the outskirts of abortion” and efforts to “[c]ouch the issue in terms of women's health.” Barry Yeoman, *The Quiet War on Abortion*, *Mother Jones*, Sept. 1, 2001, at 46 (quoting a staff counsel at Americans United for Life).

<sup>18</sup> See Jorns, *supra* note ?, at 1568–69; Center for Reproductive Rights, Targeted Regulation of Abortion Providers: Avoiding the “TRAP” 2–4 (Apr. 2004), at [http://www.crlp.org/pub\\_fac\\_trap.html](http://www.crlp.org/pub_fac_trap.html) (detailing typical TRAP requirements with illustrations from different states' regulatory codes).

<sup>19</sup> Compare, e.g., Ark. Code Ann. § 20-9-302(a) (requiring abortion facilities be licensed and inspected by the state health department and authorizing that department to promulgate regulations addressing “facilities, equipment, procedures, techniques, and conditions” of such facilities) with Ark. State Bd. of Health, Rules and Regulations for Abortion Facilities, §§1–12 (detailed regulations); S.C. Code Ann. §§ 44-41-75 (imposing licensing requirement on facility performing more than five abortions per month and requiring state health department to issue regulations on a variety of specific subjects) with S.C. Code Ann. Regs. 61-12 (2005) (detailed regulations).

<sup>20</sup> See, e.g., *Women's Medical Professional Corp. v. Baird*, 438 F.3d 595, 598–601 (6th Cir. 2006) (describing clinic's lengthy interactions with state department of health over license); *Planned Parenthood v. Atchinson*, 126 F.3d 1042, 1044–45 (6th Cir. 1997) (same); *Founder's Women's Health Ctr. v. Ohio State Dept't of Health*, Nos. 01AP-872, 01AP-873, 2002 WL 1933886 at \*5, \*7–\*10 (Ohio Ct. App. Aug. 15, 2002) (upholding state hearing examiner's conclusion that abortion providers are subject to statutory licensure requirements).



Litigation challenging TRAP measures pre-*Casey* was often, though not always, successful. An important factor for judicial willingness to invalidate such measures was whether abortion providers and facilities actually were singled out for special treatment.<sup>21</sup> But rather than invalidating regulations targeted at abortion on gender equal protection grounds, courts instead largely emphasized the constitutionally-protected status of abortion rights under due process.<sup>22</sup> Indeed, in some cases concern about burden on access to abortion led courts to uphold constitutional challenges even where the regulatory schemes did not single out abortion but instead applied more generally to all outpatient surgical facilities.<sup>23</sup>

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<sup>21</sup> General applicability and evenhandedness was frequently emphasized in decisions sustaining regulations. See, e.g., *Planned Parenthood v. Ashcroft*, 462 U.S. 476, 487–90 (1983) (upholding requirement that a pathologist review and report on tissue removed during abortions, characterizing the requirement as in accord with generally accepted medical practice, as imposing a “comparatively small additional cost,” and as applying to almost all surgeries); *Simopoulos v. Virginia*, 462 U.S. 506, 511–19 (1983) (upholding requirement that second trimester abortions be performed in licensed outpatient surgical facilities, where same regulatory requirements applied to all such facilities, including those not performing abortions, and concluding no reason existed “to doubt that an adequately equipped [abortion] clinic could, upon proper application, obtain an outpatient hospital license”); *Baird v. Dep’t of Pub. Health*, 599 F.2d 1098, 1101–02 (1st Cir. 1979) (emphasizing that licensing requirement applied to all clinics in rejecting claim that applying requirement to abortion clinic was unconstitutional); *Hodgson v. Lawson*, 542 F.2d 1350, 1357–58 (8th Cir. 1976) (stating “a state can impose the same regulations on a[n abortion] clinic . . . that are imposed on other clinics that person surgical procedures requiring approximately the same degree of skill and care” in upholding state’s power to regulate first trimester abortions); see also *Planned Parenthood v. Danforth*, 428 U.S. 52, 65–67 (1976) (upholding government’s power to require written consent for abortion, arguing that states could impose a written consent requirement for any surgery, although noting Missouri had done so only for abortion).

<sup>22</sup> See *Mahoning Women’s Center v. Huner*, 610 F.2d 456, 460 (6th Cir. 1979) (emphasizing abortion singled out for restrictive measures and that regulations would significantly burden fundamental right), vacated and remanded on other grounds, 447 U.S. 918 (1980); *Friendship Med. Ctr. v. Chicago Bd. of Health*, 505 F.2d 1141, 1152–54 (7th Cir. 1974); *Word v. Poelker*, 495 F.2d 1349, 1351–52 (8th Cir. 1974) (invalidating St. Louis measure targeting abortion, emphasizing that in “no other single surgical procedure . . . [are] doctors . . . required to ‘prove up’ their overall fitness as they are here,” and concluding that the measure was unreasonable and penalized women seeking abortion as well as their physicians); *Hallmark Clinic v. North Car. Dep’t of Human Res.*, 380 F. Supp. 1153, 1157–58 (E.D. N. Car. 1974) (three-judge court) (“Under *Roe* and *Doe*, if North Carolina may regulate the performance of first trimester abortions at all, it may do so only to the extent that it regulates tonsillectomies and other relatively minor operations.”); see also *Reizen*, 743 F.2d at 358–60 (emphasizing Michigan regulations applied to all freestanding surgical facilities and lack of evidence of selective enforcement in rejecting equal protection claims).

<sup>23</sup> See, e.g., *Ragsdale v. Turnock*, 841 F.2d 1358, 1369–72, 1373–75 (rejecting licensing, physical plant, staffing, and certificate of need requirements for ambulatory surgical facilities as applied to facilities performing first trimester abortions, emphasizing burden of greater cost on access to abortion as well as that desire to regulate abortion clinics motivated adoption of general regulatory scheme); *Reizen*, 743 F.2d at 362–63, 364–66 (sustaining due process challenges to general regulations found to result in significant cost increases but not to regulations found not to have a significant impact). Other decisions rejected challenges to generally applicable laws, such as licensing requirements, but in doing so noted lack of evidence that the requirements imposed a burden. See, e.g., *Baird*, 599 F.2d at 1102–03.

Few decisions exist, particularly at the federal appellate level, addressing the constitutional challenges to TRAP measures post-*Casey*. The two main decisions are by the Fourth Circuit, in *Greenville Women's Clinic v. Bryant*,<sup>24</sup> and by the Ninth Circuit, in *Tucson Woman's Clinic v. Eden*.<sup>25</sup> In *Greenville Women's Clinic*, the Fourth Circuit upheld the challenged regulations in their entirety, suggesting that the undue burden standard did not even apply because the regulations did not strike “directly at the ability to make a decision to have an abortion as distinct from the financial cost of procuring an abortion.”<sup>26</sup> In *Tucson Woman's Clinic*, by contrast, the Ninth Circuit ruled that even indirect imposition of costs conceivably could

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<sup>24</sup> 222 F.3d 157 (4th Cir. 2000).

<sup>25</sup> 379 F.3d 531 (9th Cir. 2004). Other post-*Casey* federal decisions addressing laws targeting abortion for health regulation include *Women's Med. Ctr. v. Bell*, 248 F.3d 411 (5th Cir. 2001) (rejecting equal protection challenge to licensing level of 300 abortions per year but affirming preliminary injunction based on plaintiffs' likely success on vagueness challenge); *Springfield Healthcare Center v. Nixon*, No. 05-4296-CV-C-NLL (W.D. Mo. Sept. 16, 2005) (concluding enforcement of Missouri requirement that abortion providers have clinical privileges at a hospital within thirty miles likely to create an undue burden on abortion access and granting TRO), vacated, No. 05-4296-CV-C-NKL (W.D. Mo. Oct. 25, 2005); *Jackson Women's Health Org'n Inc. v. Amy*, 330 F. Supp.2d 820 (S.D. Miss. 2004) (preliminarily enjoining requirement that second-trimester abortions be performed only in licensed surgical facilities or hospitals, when no surgical facility or hospital in state provided second-trimester abortions except in rare circumstances and existing abortion provider ineligible to become license under regulatory scheme); *Reproductive Servs. v. Keating*, 35 F.Supp.2d 1332 (N.D. Okla. 1998) (preliminarily enjoining second trimester requirement for abortions); see also *Planned Parenthood v. Rounds*, 372 F.3d 969 (8th Cir. 2004) (concluding that by its terms South Dakota statute did not require hospitalization for second-trimester abortions because hospitals in South Dakota are not available to perform abortions and thus reversing district court determination that second-trimester hospitalization requirement was unconstitutional). In addition, some state court decisions address TRAP measures. See *Tenn. Dep't of Health v. Boyle*, No. M2001-01738-COA-R3-CV (Tenn. Ct. App. Dec. 19, 2002) (holding state statute requiring a private clinic that performs a substantial number of abortions to obtain a certificate of need creates an undue burden on abortion and also violated the right to privacy under the Tennessee Constitution); *Founder's Women's Health Ctr. v. Ohio State Dept't of Health*, Nos. 01AP-872, 01AP-873, 2002 WL 1933886 (Ohio Ct. App. Aug. 15, 2002) (interpreting licensing requirement for ambulatory surgical facilities to apply to facilities primarily performing abortions and holding subjecting abortion providers to licensure requirement did not create an undue burden); *Davis v. Fieker*, 952 P.2d 505 (Okla. 1997) (holding evidence insufficient to show second trimester hospitalization requirement imposed an undue burden and that *Akron's* determination that such hospitalization requirements are unconstitutional was no longer valid).

<sup>26</sup> 222 F.3d at 170; see also *id.* at 166-67 (arguing that Court has distinguished between regulations that “reach into the heart” of protected liberty and those that “merely have an incidental effect on the women's decision, but noting the Court had invalidated even health regulations found to impose a “prohibitive” cost increase). The Fourth Circuit subsequently rejected additional challenges to the regulations as violating due process (on standardless delegations and vagueness grounds) the First Amendment, and informational privacy rights. See *Greenville Women's Clinic v. Commissioner*, 317 F.3d 357 (4th Cir. 2002).

create an undue burden and remanded for a determination of whether Arizona's abortion regulations in fact did so.<sup>27</sup>

The two opinions were united, however, in rejecting equal protection challenges to the regulations.<sup>28</sup> Both ruled physicians performing abortions were not a suspect class and thus their being singled out for special regulation triggered only rationality review, which both courts found satisfied.<sup>29</sup> In *Greenville Women's Clinic*, the Fourth Circuit concluded that "the particular gravitas of the moral, psychological, and familial aspects of the abortion decision" made abortion "rationally distinct from other routine medical services."<sup>30</sup> The court never expressly addressed whether regulations targeting abortion are gender classifications, not surprising as the plaintiffs did not challenge the regulations on gender equal protection grounds.<sup>31</sup> Perhaps the most notable feature of the Fourth Circuit's equal protection analysis was its claim that post-*Casey* the right to choose abortion may no longer qualify as a fundamental constitutional right.<sup>32</sup>

While the Ninth Circuit in *Tucson Woman's Clinic* rejected that extreme view,<sup>33</sup> it agreed that equal protection offered no additional safeguard for the abortion right than that found in the due process undue burden inquiry.<sup>34</sup> Most significantly, the Ninth Circuit did address and seemed somewhat sympathetic to the claim that the abortion regulations at issue represented unconstitutional gender discrimination. Nonetheless, it ultimately rejected the argument, concluding that "even if laws singling out abortion can be judicially recognized as not gender-neutral, where such laws facially promote maternal health or fetal life, *Casey* replaces the intermediate

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<sup>27</sup> 379 F.3d at 541–43. The Ninth Circuit further held that disclosure and warrantless search provisions in the regulations violated the Fourth Amendment and patient's informational privacy rights, and that other provisions were unconstitutionally vague. *Id.* at 549–55. For a discussion of the Fourth Amendment issue, see Jorns, *supra* note ?.

<sup>28</sup> The district court in *Greenville Women's Clinic*, by contrast, did invalidate South Carolina's regulations on equal protection grounds, both because the regulations singled out and burdened a fundamental right and because they were unreasonable. 66 F.Supp.2d 691, 739–43 (D. S. Car. 1999); compare *Tucson Woman's Clinic v. Eden*, No. CV 00-141-TUC-RCC, 2002 WL 32595282 \*3–\*5 (D. Ariz. Oct. 1, 2002) (rejecting equal protection claims).

<sup>29</sup> See *Greenville Women's Clinic*, 222 F.3d at 173–75; *Tucson Woman's Clinic*, 379 F.3d at 545–47.

<sup>30</sup> 222 F.3d at 173.

<sup>31</sup> Instead, they challenged the regulations' singling out of abortion as an unconstitutional targeting of fundamental rights, a claim the Fourth Circuit ruled it did not need to address having determined that the regulations did not create an undue burden on abortion access. See *id.* at 173.

<sup>32</sup> *Id.* at 172–73.

<sup>33</sup> 379 F.3d at 544 ("The right to abortion is a fundamental constitutional right.").

<sup>34</sup> *Id.* at 544–45.

scrutiny such a law would normally receive under the equal protection clause with the undue burden standard.”<sup>35</sup>

In addition to such targeted regulation of abortion, evidence exists of generally-applicable health regulations, in particular licensing requirements, being applied against abortion clinics in a discriminatory fashion. In *Planned Parenthood of Iowa v. Atchinson*, the Sixth Circuit held that Iowa’s effort to enforce its certificate of need statute against a proposed abortion clinic was unconstitutional. Central to the court’s ruling was its determination that Iowa’s Department of Health had an established practice of not requiring medical offices structured similarly to the proposed clinic to obtain a certificate. From this, however, the appellate court concluded that the health officials were motivated by an illegitimate purpose to impede abortions, not that they had violated equal protection.<sup>36</sup> More recently, the Sixth Circuit rejected the claim that requiring an abortion clinic to obtain a written transfer agreement with a local hospital as a condition for a license was unconstitutional as applied to an abortion clinic—notwithstanding that the state health department had deviated from its usual procedures in reviewing and denying the clinic’s waiver application, and that no hospital would enter such an agreement with the clinic in question.<sup>37</sup>

### B. *Federal Regulation of Abortion-Related Drugs*

Like TRAP laws, significant government regulation of abortion-related drugs and procedures is largely a recent phenomenon. Although in the years immediately post-*Roe* some states restricted certain methods of abortion, in particular saline amniocentesis,<sup>38</sup> regulation of abortion procedures became far more prevalent in the mid-1990s with widespread adoption of statutes prohibiting use of the dilation and

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<sup>35</sup> *Id.* at 549.

<sup>36</sup> 126 F.3d 1042, 1048–49 (6th Cir. 1997).

<sup>37</sup> See *Women’s Medical Prof. Corp. v. Baird*, 438 F.2d 595 (6th Cir. 2006), reversing 277 F.Supp.2d 862 (S.D. Ohio 2003) (permanently enjoining requirement that ambulatory surgical facilities must have written transfer agreement with hospital as applied to abortion provider). The Court emphasized that the Director of Ohio’s Department of Health had granted waivers to abortion clinics in the past, concluding from this that despite the deviations from standard procedures evidenced regarding this clinic—including numerous communications between the Department’s chief counsel and right-to-life groups—the Director did not act with an illegitimate purpose in denying the waiver application. See *id.* at 608–09. The clinic’s application for a waiver triggered substantial public opposition in part because it was the only provider of late second-trimester abortions in southern Ohio and the corporation that operated the clinic was owned by Dr. Martin Haskell, a physician closely associated with development of the dilation and extraction or “partial birth abortion” technique.

<sup>38</sup> See, e.g., *Planned Parenthood v. Danforth*, 428 U.S. 52, 75–79 (1976); *Wynn v. Scott*, 449 F. Supp. 1302, 1324–1326 (N.D. Ill. 1978) (three-judge court), app. dismissed on different grounds, 599 F.2d 193 (1979). Some states also imposed two-physician requirements on post-viability abortions. See *Planned Parenthood v. Ashcroft*, 462 U.S. 476, 482–86 (1983) (upholding such a requirement).

extraction (D&X) procedure, commonly known as partial birth abortion bans.<sup>39</sup> These bans differ significantly from the type of abortion regulations that are the focus here, however, in that they are legislatively adopted and intended to advance the state's interest in preserving life.<sup>40</sup>

More relevant to consideration of administrative health regulation are the FDA's decisions regarding access to mifepristone, more popularly known as RU-486, and the Plan B form of emergency contraception. Although both are used to prevent reproduction, RU-486 and emergency contraception differ significantly in their operation. RU-486 is effective at preventing implantation of a fertilized egg and thus pregnancy, but it is also used for medical (i.e. nonsurgical) abortion up to forty-nine days gestation. It is taken in combination with another drug, misoprostol,<sup>41</sup> and operates by interfering with the flow of progesterone to the uterus, essentially resulting in a miscarriage.<sup>42</sup> Plan B, by contrast, has no effect on an embryo or fetus, nor—contrary to popular perception—does it appear to impede implantation of a fertilized egg. Instead, progestin-only emergency contraceptives such as Plan B operate by impeding ovulation and in other ways making fertilization

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<sup>39</sup> A paper outlining the D&X method brought the technique to the attention of the National Right-to-Life Committee in early 1993, which began a national campaign to encourage states and the federal government to adopt statutes banning the procedure. See Debra Rosenberg, Chipping Away at Roe, *Newsweek*, Mar. 17, 2003 at 40. Currently, 31 states have adopted partial birth abortion bans, although nearly all of these are nonenforceable after the Supreme Court's decision in *Stenberg v. Carhart*, 530 U.S. 914 (2000), holding Nebraska's partial-birth abortion ban unconstitutional. See Center for Reproductive Rights, Briefing Paper: So-Called "Partial Birth Abortion" Ban Legislation: By State 1 (February 2004), available at: [http://www.crlp.org/pdf/pub\\_bp\\_pba\\_bystate.pdf](http://www.crlp.org/pdf/pub_bp_pba_bystate.pdf). The Supreme Court will revisit the constitutionality of partial-birth abortion bans next Term, in the context of ruling on challenges to the federal ban. See *Gonzales v. Carhart*, 126 S. Ct. 1314 (2006).

<sup>40</sup> See, e.g., An Act Relating to Abortion, 1997 Neb. Laws LB 23, § 3 (describing act as an expression of the will of the people of the State of Nebraska and the members of the Legislature to provide protection for the life of the unborn child whenever possible"); Ohio Rev. Code Ann. §2919.15(A) § 2919.15 Note, Uncodified Law, ("The General Assembly declares that its intent in enacting [partial-birth measure] is to prevent the unnecessary use of a specific procedure used in performing an abortion. This intent is based on a state interest in preventing unnecessary cruelty to the human fetus."); see also *Stenberg v. Carhart*, 530 U.S. 914, 951–52 (2000) (Ginsburg, J., concurring) (purpose of partial birth bans is to "chip away at the private choice shielded by *Roe v. Wade*"). Congress justified the federal Partial-Birth Abortion Ban Act of 2003 on its interest in promoting maternal health, as well as in "preserv[ing] the integrity of the medical profession," "promot[ing] respect for human life," and "protecting the life of the partially-born child." Pub. L. 108-105, § 2(14)(G)-(H), Nov. 5, 2003, 117 Stat. 1206, codified at 18 U.S.C. § 1531, Historical and Statutory Notes.

<sup>41</sup> The combination of the two drugs is known as mifeprex, and is the form of RU-486 approved for use in the United States.

<sup>42</sup> RU-486 is used in combination with misoprostol to ensure complete abortion. See Margaret Talbot, *The Little White Bombshell*, *N.Y. Times Mag.*, July 11, 1999, at 39. Medical abortions are also performed using misoprostol and methotrexate, a cancer drug. See *id.*; see generally James G. Kahn, *The Efficacy of Medical Abortion: A Meta-Analysis*, 61 *Contraception* 29, 36–38 (2000) (concluding that both methods are effective at terminating pregnancy up to 49 days gestation and listing differences).

less likely if taken a short time after intercourse.<sup>43</sup> RU-486 and Plan B also came before the FDA in very different postures. The FDA reviewed RU-486 pursuant to its authority under the federal Food and Drug Act (FDCA) to approve new drugs; the FDCA bans sale of any new drug absent such approval.<sup>44</sup> In reviewing a new drug application, the FDA is charged with determining if the product is safe and effective.<sup>45</sup> Plan B, by contrast, was already available by prescription, and the issue before the FDA was whether it should be available over-the-counter (OTC) and thus without a prescription. Under governing statutory and regulatory provisions, drugs that are safe for use without medical supervision are generally available OTC.<sup>46</sup>

What RU-486 and Plan B have in common, however, is that both were very controversial FDA decisions because of their connection (or perceived connection, in the case of Plan B) to abortion. A second similarity is that the FDA appears to have deviated from its standard procedures in regard to both. RU-486 was developed in France in 1980 and approved for use there in 1988, but did not become available

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<sup>43</sup> Knowledge of the mechanisms by which different methods of emergency contraception prevent pregnancy is incomplete, and difficulties in conducting research on implantation mean that a post-fertility effect cannot be definitely excluded. Nonetheless, studies so far only indicate pre-fertilization effects from Plan B (and levonorgestrel generally). By contrast, Preven, another form of emergency contraception that involves a combination of estrogen and progestin, may have an effect on implantation, although studies suggest it primarily acts to inhibit ovulation. In addition, some evidence suggests that RU-486 may have both pre-fertilization and post-fertilization effects. See, e.g., Horacio B. Croxatto et al, Mechanisms of Action of Emergency Contraception, 68 *Steroids* 1095, 1095–98 (2003); K. Gemzell-Danielsson & L. Marions, Mechanisms of Action of Mifepristone and Levonorgestrel When Used for Emergency Contraception, 10 *Human Reprod. Update* 341, 346 (2004); Lena Marions et al., Emergency Contraception with Mifepristone and Levonorgestrel: Mechanism of Action, 100 *Obstetrics & Gynecology* 65, 70 (2002); Russell Shorto, *Contraception*, N.Y. Times Mag., May 7, 2006, at 48. The increasing evidence that at least the Plan B form of emergency contraception has no effect post-fertilization supports some commentators' suggestion that what is at stake in the fight over Plan B is opposition to contraception and non-procreative sex as much as opposition to abortion. See Edward L. Rubin, *Sex, Politics, and Morality*, 47 *Wm. & Mary L. Rev.* 1, 24–25 (2005); Shorto, *supra*.

<sup>44</sup> 21 U.S.C. §§ 321(g)(1), 321(p), 355.

<sup>45</sup> 21 U.S.C. § 355(d) (setting out conditions for approval or denial of a new drug application); 21 U.S.C. § 321(p) (defining a "new drug" as a drug "not generally recognized among experts ... as safe and effective for use").

<sup>46</sup> 21 U.S.C. § 353(b)(1) (setting out when drugs are available only by prescription). Under FDA regulations, the FDA will authorize a drug's availability OTC if the FDA "finds such requirements are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and . . . that the drug is safe and effective for use in self-medication as directed in proposed labeling." 21 C.F.R. § 310.20(b); see also U.S. Gov't Accountability Office, No. GAO-06-109, *Food and Drug Administration: Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B Was Unusual at 7-11* (Nov. 2005), available at: <http://www.gao.gov/new.items/d06109.pdf>; [hereinafter, GAO Report](describing OTC switch process).

in the United States until twelve years later.<sup>47</sup> In the intervening period, the FDA's response to the drug varied considerably with shifts in presidential administration.<sup>48</sup>

In 1989, under the first President Bush and in response to congressional pressure, the FDA put RU-486 on an import alert list, which made it ineligible for the FDA's personal use exemption; that exemption allows individuals to import a three-month supply of a nonapproved drug for personal use.<sup>49</sup> Under President Clinton, by contrast, the FDA strongly encouraged RU-486's manufacturer to submit a new drug approval application, which was a highly unusual action for the FDA to take. The manufacturer had resisted doing so for fear of a boycott of its other products, but eventually such an application was filed by a nonprofit organization to which the manufacturer donated its license, and approved by the FDA under special accelerated review procedures. These procedures, however, are intended for use in approving new drugs used in treating serious or life-threatening illnesses, which pregnancy is not, and thus were not clearly applicable to RU-486.<sup>50</sup>

Finally, the FDA's approval of RU-486 in September 2000 differed from its standard approach in several ways, including an effort to require physicians to adhere to the FDA's approved regimen as to how RU-486 is prescribed and used. Ordinarily, deviations from the approved regimen—known as “off-label” uses—are permitted.<sup>51</sup> Ultimately, the FDA did not mandate compliance with its approved regimen, which advocates opposed because it required two physician visits, and many providers use an alternative protocol that avoids a follow-up visit for oral administration of misoprostol.<sup>52</sup> Recently, however, some providers have switched to an approach closer to the FDA protocol or stopped providing medical abortions at all after several publicized deaths connected to the alternative regimen for RU-486

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<sup>47</sup> For a description of RU-486's development and the controversy surrounding it in France, see Steven Greenhouse, *A New Pill, A Fierce Battle*, *N.Y. Times Mag.*, Feb. 12, 1989, at 23.

<sup>48</sup> See Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifestone Embroils the FDA in Abortion Politics*, 36 *Wake Forest L. Rev.* 571, 575–79 (2001); Talbot, *supra* note ?, at 39.

<sup>49</sup> See Noah, *supra* note ?, at 576–79; *Benton v. Kessler*, 799 F. Supp. 281, 284–86, 288–91 (E.D.N.Y. 1992) (discussing regulatory framework and granting preliminary injunction ordering return of RU-486 seized by U.S. Customs, concluding that a substantial likelihood existed FDA violated the Administrative Procedure Act in issuing import alert on RU-486); see also *Benton v. Kessler*, 505 U.S. 1084, 1085 (1992) (*per curiam*) (declining to vacate stay of preliminary injunction on grounds that no substantial likelihood of success existed).

<sup>50</sup> See Noah, *supra* note ?, at 577–84.

<sup>51</sup> See 21 U.S.C. § 396 (“Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.”); James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 *Food & Drug L.J.* 71, 76–80 (1998).

<sup>52</sup> See *id.*, at 584–90; *Planned Parenthood v. Taft*, 444 F.3d 502, 505–06 (6th Cir. 2006).

abortions.<sup>53</sup> In addition, several states have enacted or proposed limits on off-label uses of RU-486, and a proposal to ban its use is pending in Congress.<sup>54</sup>

Plan B was approved for prescription use in 1999; another form of emergency contraception had been approved for prescription use the prior year.<sup>55</sup> In truth, as both of these drugs consist of standard oral contraceptives taken at high doses, they were available even before these dates because of physicians' ability to prescribe approved drugs for off-label uses.<sup>56</sup> In 2001, a group of women's health and medical associations submitted a citizen's petition seeking to have Plan B and Preven switched to OTC status, but the FDA delayed acting on the petition for over five years.<sup>57</sup> In 2003, the manufacturer of Plan B submitted an application seeking to have Plan B switched to OTC status. Two FDA advisory committees meeting jointly voted 23 to 4 to approve the switch, and directors of the two FDA offices assigned to review the application similarly recommended approval. Nonetheless, the Acting Director of the FDA's Center for Drug Evaluation Research issued a not-approvable letter to Barr Laboratories, which had purchased the marketing rights to Plan B.<sup>58</sup>

The FDA's decision to reject the recommendations of both its advisory committees and the directors and staff of the offices reviewing the application was

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<sup>53</sup> See Gardiner Harris, *Some Doctors Voice Worry Over Abortion Pills' Safety*, N.Y. Times, Apr. 1, 2006, at A11 [hereinafter *Harris, Some Doctors*]; Gardiner Harris, *After 2 More Deaths, Planned Parenthood Alters Method for Abortion Pill*, N.Y. Times, Mar. 18, 2006, at A10.

<sup>54</sup> On state measures, see Taft, 444 F.3d at 506 (describing Ohio's statute); Center for Reproductive Rights, *Laws and Regulations Affecting Medical Abortion 3* (July 2003), available at: [http://reproductiverights.org/tools/print\\_page.jsp](http://reproductiverights.org/tools/print_page.jsp) (last visited May 17, 2006) [hereinafter *CRR, Medical Abortions*] (noting new state legislation to restrict medical abortion had been proposed in at least 12 states in 2003); see also Hilary Guenther, *The Development of the Undue Burden Standard in Stenberg v. Carhart: Will Proposed RU-486 Legislation Survive*, 35 Ind. L. Rev. 1021, 1041-43 (2002) (describing a proposed Oklahoma measure banning use of RU-486). On federal measures, see RU-486 Suspension and Review Act of 2005, H.R. 1079, S. 511, 109th Cong., 1st Sess. (2005); see also RU-486 Patient Health and Safety Act, H.R. 489, 108th Cong., 1st Sess. (2003) (requiring the FDA to impose additional restrictions on access to mifepristone).

<sup>55</sup> The other form of emergency contraception is known as Preven. Its production was stopped in 2004. See GAO Report, *supra* note ?, at 11 n.22; see also *supra* note 43.

<sup>56</sup> See GAO Report, *supra* note ?, at 11-12 (noting prior off-label use of standard birth control pills as emergency contraception).

<sup>57</sup> See Citizen's Petition on Behalf of the American Public Health Association et al., available at: [http://www.crlp.org/pdf/EC\\_petition.pdf](http://www.crlp.org/pdf/EC_petition.pdf); Tummino v. Crawford, Complaint at ¶ 39, available at: [http://www.crlp.org/pdf/crt\\_012105\\_fdacomplaint.pdf](http://www.crlp.org/pdf/crt_012105_fdacomplaint.pdf). The FDA eventually denied the citizen petition on June 9, 2006, in the midst of discovery in the Tummino litigation. See Letter from Randall W. Lutter, Assoc. Comm'r for Policy & Planning, FDA, to Bonnie Scott Jones & Simon Heller (on file with Emory Law Journal).

<sup>58</sup> See GAO Report, *supra* note ?, at 38-40 (Appendix II) (reproducing FDA's not approvable letter to Barr Labs); *id.* at 13-19 (describing FDA's actions on Plan B); see also *id.* at 3 n. 8 (describing non-approvable letters as meaning additional data needed, whereas approvable letters mean sufficient data exists but some concerns persist).



a deviation from its usual practice regarding OTC applications.<sup>59</sup> The Government Accountability Office (GAO), asked by members of Congress to investigate the FDA's decision, concluded the FDA's treatment of the Plan B application was "unusual" in other ways as well. Most notably, the reason cited by the FDA—lack of data on use of Plan B by younger adolescents and concern that its OTC availability would encourage them to engage in unsafe sexual practices—was not one the FDA had previously considered in approving products.<sup>60</sup> The GAO also noted evidence suggesting high-level FDA officials had reached a decision before the FDA's review was complete and were unusually involved in Plan B's review.<sup>61</sup> In response to the FDA's not-approvable letter, Barr Labs submitted a revised application, seeking to have Plan B be switched to OTC status only for women 16 and older. Rather than approving the revised application, in September 2005 the FDA issued an advanced notice of proposed rulemaking addressing the question of whether a drug can be approved for prescription and OTC access simultaneously for different groups.<sup>62</sup>

The FDA's decision approving RU-486, and the conditions imposed on its use, were never subject to legal challenge.<sup>63</sup> Its refusal to approve Plan B for OTC status, however, has ended up in the courts. In January 2005, a lawsuit was filed in federal district court in New York, challenging the nonapproval decision on gender equal protection, right to privacy, and administrative law grounds.<sup>64</sup> In lieu of

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<sup>59</sup> According to the GAO, in only one other case in the period 1994-2004 did the FDA's decision on an OTC switch application differ from the recommendation of the advisory committee, and in that case the FDA granted approval where advisory committee had recommended denial. In addition, of the 67 OTC switch applications filed during this period (resulting in 98 action letters), Plan B represented the only instance in which the letter was signed by the Director of the Center for Drug Evaluation Research rather than by the directors of the FDA offices that reviewed the application. See *id.*, at 5, 19-20, 29-30.

<sup>60</sup> See *id.* at 22-29, 30-31; see also *id.* at 51-52 (letter from the director of the FDA's Office of New Drugs arguing that the FDA had not previously distinguished between women of childbearing potential based on their age in assessing the safety and efficacy of contraceptives and suggesting that concerns were rooted in "views and attitudes about the morality of adolescent sexual behavior" and "concerns about the role for parents").

<sup>61</sup> See *id.* at 20-22.

<sup>62</sup> See *id.* at 3 & n.11, see also FDA, Drug Approvals; Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug product, 70 Fed. Reg. 52050 (2005).

<sup>63</sup> The FDA's initial issuing of an import alert on RU-486, however, was challenged, ultimately unsuccessfully, in *Benton v. Kessler*, 505 U.S. 1084, 1085 (1992) (*per curiam*). In addition, litigation has been brought challenging state measures limiting off-label use of RU-486, see *Planned Parenthood v. Taft*, 337 F. Supp. 2d 1040 (S.D. Ohio 2004), and a petition was filed in 2003 seeking to have the FDA stop distribution of the drug, see CRR, Medical Abortions, *supra* note 48, at 3.

<sup>64</sup> See *Tummino v Crawford* (filed January 21, 2005), available at: [http://www.crlp.org/pdf/crt\\_012105\\_fdacomplaint.pdf](http://www.crlp.org/pdf/crt_012105_fdacomplaint.pdf). The District Court denied the FDA's motions to dismiss and allowed discovery to proceed, including depositions of top FDA personnel. See

federal action, some states have enacted measures to provide mechanisms by which pharmacists are authorized to dispense emergency contraception without a prescription and in other ways expand access to Plan B.<sup>65</sup>

## II. OBSTACLES TO EQUAL PROTECTION ANALYSIS OF ADMINISTRATIVE ABORTION REGULATIONS

These two examples demonstrate the diversity among measures in the category I am labeling administrative abortion regulations, despite their shared focus on women's health. Regulations targeting abortion providers and facilities are promulgated at the state or local level, include a variety of substantive requirements, and usually are adopted in response to legislation specifically mandating greater regulation of abortion providers.<sup>66</sup> Regulation of abortion-related drugs, by contrast, generally occurs at the federal level, involves a single drug at a time with decisions focused on a specific regulatory issue, and is undertaken pursuant to non-abortion-specific federal legislation.

Yet from the perspective of equal protection, both share several notable features. In particular, both represent instances in which the government acting pursuant to a neutral interest, protecting health, has singled out drugs and procedures used only by women for distinct and disfavored treatment. As a result, both types of regulation might appear particularly suitable for challenge as unconstitutional on gender equality grounds. In fact, however, their health focus and administrative aspect obscures their character as sex-based classifications. Moreover, substantial obstacles also exist to other possible equal protection claims, such as that these measures unconstitutionally single out fundamental rights for regulation or are irrational.

### A. *The Power of Framing: Illegitimate Targeting or Justified One-Step-At-A-Time Regulation?*

At first glance, it might seem that abortion health regulations are particularly vulnerable to equal protection challenges. As Justice Jackson argued in *Railway Express v. People of New York*, illegitimate targeting is the danger that equal

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Tummino v. von Eschenbach, No.CV-05-366, Transcript at 78–80, 91–92 (E.D.N.Y. Dec. 22, 2005) (Korman, J.); Tummino v. von Eschenbach, No.CV-05-366, Order Denying Partial Reconsideration (E.D.N.Y. Jan. 17, 2006) (Korman, J.). In addition, a magistrate judge denied the FDA's motion to prevent depositions of FDA officials, concluding that "a strong preliminary showing of 'bad faith' or improper behavior' has been made." Tummino v. von Eschenbach, No. CV-05-366, Decision and Order at 30-34 (E.D.N.Y. Feb. 24, 2006) (Pohorelsky, M.J.).

<sup>65</sup> See Center for Reproductive Rights, 2005 Mid-Year Legislative Summary at 6–7. Numerous states have also proposed measures that would authorized pharmacists and others to refuse to dispense plan B and other contraceptives. See id. at 7–8.

<sup>66</sup> But see RU-486 Patient Health and Safety Act, H.R. 489, 108th Cong., 1st Sess. (2003) (proposed measure representing federal regulation of abortion providers).

protection guards against,<sup>67</sup> and targeting is the essence of the complaint against these measures. To be sure, if burdensome enough, even generally applicable regulations could significantly restrict access to abortion.<sup>68</sup> But the claim that abortion's constitutionally protected status entitles it to special exemption from generally applicable requirements is less intuitively powerful than the claim it should not be singled out for special burdens. Plausible claims of substantive due process protection could be made regarding a wide variety of medical procedures, such as organ transplants or experimental treatments. That fact, in and of itself, is rarely enough to prevent substantial governmental regulation, even all-out prohibitions, provided the government's protective interests are seen as legitimately implicated.<sup>69</sup>

Targeting of course is present in regard to most abortion regulation, and the Court has countenanced such targeting by characterizing abortion as "unique."<sup>70</sup> Yet what makes abortion unique in the Court's eyes is not its medical aspect but its impact on the fetus and on the state's interest in potential life. As *Casey* put it:

Abortion is a unique act. It is an act fraught with consequences for others: for the woman who must live with the implications of her decision; for the persons who perform and assist; for the spouse, family and society which must confront the knowledge that these procedures exist, procedures some deem nothing short of an act of violence against innocent human life; and, depending on one's beliefs, for the life or potential life that is aborted.<sup>71</sup>

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<sup>67</sup> 336 U.S. 106, 112–13 (1949).

<sup>68</sup> See, e.g., cases cited *supra* in note ?.

<sup>69</sup> Cf. *Washington v. Glucksberg*, 521 U.S. 702 (1997) (denying substantive due process claim to assistance in committing suicide, emphasizing states' legitimate concerns about abuse of vulnerable individuals). In a recent decision, the D.C. Circuit held that the FDA's refusal to allow access to investigational drugs violated substantive due process rights of terminally ill, mentally competent patients when an investigational drug is potentially life-saving, no alternative government-approved treatment options exist, and the FDA has deemed the drug sufficiently safe for expanded human trials. 445 F.3d 470, 486 (D. C. Cir. 2006). While the appellate court thus upheld a challenge to generally applicable requirements on due process grounds, it emphasized the narrow terms of its holding, see *id.* 478 & n.9, and argued that the FDA's having determined that a drug is safe for expanded human trials undermined the government's claimed safety interest, see *id.* at 486.

<sup>70</sup> See *Planned Parenthood v. Casey*, 505 U.S. 833, 871–873, 878–79 (1992).

<sup>71</sup> 505 U.S. 833, 852 (1992); see also *Harris v. McRae*, 448 U.S. 297, 325 (1980) ("Abortion is inherently different from other medical procedures, because no other procedure involves the purposeful termination of a potential life."); *Roe v. Wade*, 410 U.S. 159 (1973) ("The pregnant woman cannot be isolated in her privacy. She carries an embryo and, later, a fetus, . . . The situation is therefore inherently different from marital intimacy, or bedroom possession of obscene material, or marriage, or procreation, or education" with which previous liberty and privacy cases were concerned).

But these administrative regulations are not intended to further the state's interest in protecting fetal life. Instead, they are justified solely as measures advancing the state's interest in protecting maternal health.<sup>72</sup>

Viewed simply through a health lens, however, abortion is hardly unique. At least within the medical community, broad consensus exists that the physical risks of first and many second trimester abortions are relatively minor.<sup>73</sup> The most common methods used, suction curettage and dilation and evacuation, are surgical procedures comparable in risks and other aspects to many surgical procedures performed in physician offices—procedures not similarly subject to special regulations in the name of health. These include both gynecological and nongynecological procedures, such as minor nose, mouth, and ear surgeries, drainage of neck abscesses, liposuction, and endoscopy.<sup>74</sup> So too with medical abortions; despite the recent deaths of a few women who had undergone abortions using RU-486 and misoprostol, the risks associated with medical abortion remain very low.<sup>75</sup>

As a result, if a gender equal protection perspective were ever going to be successfully injected into abortion analysis, arguably it would be here, where abortion is being regulated solely as a medical procedure and an objective basis—professional practices and empirical data on health risks—exists for discerning dissimilar treatment. Viewed from the health perspective, abortion becomes a type of procedure with regard to which men and women actually are

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<sup>72</sup> See, e.g., *Tucson Woman's Clinic*, 379 F.3d at 536, 539–4, 546–47 & n.2; *Greenville Women's Clinic*, 222 F.3d at 163, 166–69; GAO Report, *supra* note ?, at 38–39 (reproducing FDA nonapprovable letter on Plan B, which states that Barr Labs had “not yet provided adequate data to support a conclusion that Plan B can be used safely by young adolescent women for emergency contraception without . . . professional supervision”).

<sup>73</sup> See, e.g., *Akron v. Akron Ctr. for Reprod. Health*, 462 U.S. 416, 435–49 (1983) (striking down hospitalization requirement for second trimester abortions based on safety gains from the dilation and evacuation (D&E) procedure and evidence demonstrating that second trimester D&E abortions can be performed as safely in outpatient clinics as in hospitals); *Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 175–76 (4th Cir. 2000) (accepting that abortion involves “often relatively simple medical procedures”); *Greenville Women's Clinic v. Bryant*, 66 F.Supp.2d 691, 717–18 (D. S. Car. 1999) (finding that abortion is one of the safest surgical procedures that can be performed”); see also David A. Grimes, *Induced Abortion: An Overview for Internists*, 140 *Annals of Internal Medicine* 620, 623–24 (2004) (describing safety data on abortion). More debate exists over the psychological effects of abortion. But see Grimes, *supra* note ?, at 624 (arguing data demonstrates improved psychological health post-abortion). The focus of these regulations, however, is on protecting women's physical health. For example, although some TRAP measures address counseling, for the most part they focus on qualifications of providers, ability to access hospitals were emergencies to occur, practice protocols, supplies required to be on hand and the like—all of which are keyed to protecting women's physical health (and thus affect psychological health only derivatively).

<sup>74</sup> See *Women's Health Ctr. of West Houston v. Archer*, 159 F. Supp.2d 414, 461–62 (S.D. Tex. 1999); *Greenville*, 66 F.Supp.2d at 704–05, 712, 714, 718; *Opening Br. of Plaintiffs-Appellants/Cross-Appellees, Tucson Woman's Clinic v. Eden*, 2003 WL 22670260 at \*6–\*15 (Feb. 20, 2003).

<sup>75</sup> See *Harris, Some Doctors*, *supra* note ??*Greenville*, 66 F. Supp.2d at 718.

similarly situated; although men will never have abortions, they frequently have minor surgeries posing a similar degree and kind of medical danger. Moreover, claims that surgeries and drugs of particular relevance to men and of comparable health risk, such as vasectomies or Viagra, are not subject to similar burdens, reinforce the facially gender discriminatory character of such abortion regulation.<sup>76</sup> So does the paternalistic aura of extensively regulating abortion—thereby substantially increasing its costs and limiting its availability—in women’s own interests. And while the Court’s protection of access to abortion has weakened over the years, its enforcement of constitutional prohibitions on gender discrimination has remained strong; the Court consistently at least invokes intermediate scrutiny, demanding that sex-based classifications “serve important governmental objectives” and be “substantially related to the achievement of those objectives.”<sup>77</sup>

Yet courts do not seem drawn to gender equality arguments against abortion health regulations. This was true before *Casey*, when courts regularly invalidated health regulations for unconstitutionally targeting abortion, but did so under the fundamental rights prong of gender equal protection analysis. It remains true today. Rarely do courts discuss whether an abortion health regulation represents an unconstitutional sex-based classification, let alone invalidate it on this ground; the Ninth Circuit’s *Tucson Woman’s Clinic* decision is remarkable for expressly considering gender equality in connection with abortion at all. Why are the courts not more receptive?

Obviously, one major reason is precedent. In sustaining the benefits exclusion for pregnancy at issue in *Geduldig*, the Court insisted that “[w]hile it is true that only women can get pregnant it does not follow that every classification concerning pregnancy is a sex-based classification.”<sup>78</sup> Perhaps more importantly, the Court’s increased tolerance for regulation of abortion, now sanctioning restrictions on pre-viability abortions that do not rise to the level of an “undue burden,” seems incompatible with subjecting abortion regulations to more searching scrutiny on gender equal protection grounds.<sup>79</sup> Nor has the Court shown much interest in developing different analytic frameworks for assessing abortion regulation

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<sup>76</sup> Such claims were made in *Tucson Woman’s Clinic*. See Br. of Plaintiffs-Appellants/Cross-Appellees, supra note ?, at \*11, \*13 n.8, \*40–\*44.

<sup>77</sup> *Nevada Department of Human Resources v. Hibbs*, 538 U.S. 721, 730-31 (2003) (alterations and internal quotations omitted); *United States v. Virginia*, 518 U.S. 515, 531, 533 (1996). Some argue the Court has intensified its scrutiny of sex-based classifications, with the Court’s insistence that sex-based classifications require an “extremely persuasive justification” making the Court’s stated intermediate scrutiny standard more akin to strict scrutiny. See, e.g., *Virginia*, 518 U.S. at 571 (Scalia, J., dissenting).

<sup>78</sup> 417 U.S. 484, 496 n. 20 (1974).

<sup>79</sup> See *Tucson Woman’s Clinic v. Eden*, 379 F.3d 531, 548–49 (9th Cir. 2004) (“[E]ven if laws singling out abortion can be judicially recognized as not gender-neutral, where such laws facially promote maternal health or fetal life, *Casey* replaces the intermediate scrutiny such a law would normally receive with the undue burden standard.”).

depending on the government interest—fetal life or women’s health—claimed to be at stake.<sup>80</sup>

Invocation of precedent, however, is not a completely satisfying answer. While the Court has never overruled *Geduldig*, it has since acknowledged the gender equality concerns raised by measures targeting reproduction and abortion.<sup>81</sup> In *Nevada Department of Human Resources v. Hibbs*, the Court argued that gender differences in parental leave policies reflected “pervasive sex role stereotype[s]” that justified invocation of heightened equal protection scrutiny.<sup>82</sup> Even more pertinently, *Casey* itself invoked women’s equality concerns in concluding that access to abortion should continue to receive constitutional protection. In marked contrast to *Geduldig*’s casual dismissal of the relationship between reproduction and gender equality, the *Casey* Court emphasized that “[t]he ability of women to participate equally in the economic and social life of the Nation has been facilitated by their ability to control their reproductive lives.”<sup>83</sup> The Court then returned to the gender equal protection theme in invalidating Pennsylvania’s spousal notice requirement, which it argued embodied “a view of marriage consonant with the common-law status of married women but repugnant to our present understanding of marriage. . . . Women do not lose their constitutionally protected liberty when they marry.”<sup>84</sup>

This is not to say that subsequent precedent is univocal, or that the Court has to come to view regulations differentiating among the sexes because of their different

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<sup>80</sup> See, e.g., *Casey*, 505 U.S. at 877–78, 900–01 (analyzing health-based regulations as well as fetal life regulations under the undue burden framework); *Mazurek v. Armstrong*, 520 U.S. 968, 971–72 (1997) (analyzing physician-only requirement under undue burden test and concluding no basis exists for inferring illegitimate purpose).

<sup>81</sup> In addition, *Geduldig*’s refusal to treat pregnancy as a sex-based classification arose in the context of a benefits program, and thus may not extend to contexts, such as abortion restrictions, where pregnancy is singled out for regulatory burdens. See *Tucson Woman’s Clinic*, 379 F.3d at 548. *Geduldig* is even more distinguishable from instances involving regulation of female contraceptives, such as the FDA’s decision on Plan B; not only are the women taking Plan B not yet pregnant, but the possibility exists of contrasting this regulation with regulatory treatment of contraceptive methods used by men.

<sup>82</sup> 538 U.S. 721, 730–31 (2003). In addition, the Court has occasionally suggested *Geduldig*’s rejection of pregnancy as a sex-based classification be viewed narrowly. See *Newport News Shipbuilding & Dry Dock Co. v. EEOC*, 462 U.S. 669, 676–77, nn. 12–13 (1983) (emphasizing that the focus of *Geduldig* was on the reasonableness of the exclusion of pregnancy on cost grounds); *Turner v. Dep’t of Employment Security*, 423 U.S. 44, 45 n.\* (1975)(per curiam)(rejecting analogy to *Geduldig* and invalidating statute making women ineligible for unemployment benefits for 18 weeks surrounding the birth of a child).

<sup>83</sup> 505 U.S. 833, 856 (1992); see also *id.*, at 852 (arguing that a pregnant woman’s “suffering is too intimate and personal for the State to insist, without more, upon its own vision of the woman’s role, however dominant that vision has been in the course of our history and culture.”); *id.* at 896–98 (invalidating spousal notice rule in part on the ground that it embodies “a common-law understanding of a woman’s role within the family” that is no longer “consistent with our understanding of the family, the individual, or the Constitution.”).

<sup>84</sup> *Id.* at 896–98.

roles in reproduction as unconstitutional. On the contrary, in its recent *Nguyen v. INS* decision, the Court invoked the biological reality that women are necessarily present at birth to uphold greater limitations on the ability of unmarried male citizens to pass U.S. citizenship to their children born abroad than apply to unmarried female citizens.<sup>85</sup> Yet at the same time, *Nguyen* could be read to support viewing abortion regulations as sex-based classifications, for it demonstrates that much existing abortion jurisprudence can fit within the gender equal protection rubric.<sup>86</sup> In particular, the biological reasoning of *Nguyen* supports sustaining many measures that single out abortion for restrictions in the aim of preserving potential life as simply reflecting “real differences” between the sexes.<sup>87</sup> This move is more difficult regarding abortion health regulations, given abortion’s ordinariness as a medical procedure, as is demonstrating that health regulations are closely related to the government’s acknowledged legitimate interest in women’s health.<sup>88</sup> But even here the conflict between gender equal protection and abortion jurisprudence is still fairly minimal, as most Supreme Court decisions addressing health regulations predate *Casey* and subject health regulations to more searching scrutiny.<sup>89</sup>

To be fair, another major factor contributing to the courts’ failure to discuss gender equality concerns in the abortion context is the limited extent to which advocates have raised such arguments. Advocates initially attacked abortion restrictions on substantive due process rather than equal protection grounds and continued with that approach—perhaps not surprisingly, given their success in *Roe*

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<sup>85</sup> 533 U.S. 53, 61–70 (2001). In addition, in *Bray v. Alexandria Health Clinic*, the Court relied on *Geduldig* to reject the claim that opposition to abortion represented invidious discrimination against women because only women obtain abortions. 506 U.S. 263, 271 (1993).

<sup>86</sup> See also Siegel, *supra* note ?, at 267–77 (noting that Court’s gender equal protection and abortion jurisprudence share a physiological focus that hides the role played by stereotypes and other social constructions of gender).

<sup>87</sup> See *Harris v. McRae*, 448 U.S. 297, 325 (1980) (emphasizing that “no other procedure involves the purposeful termination of potential life”); see also *Nguyen*, 533 U.S. at 73 (The difference between men and women in relation to the birth process is a real one.”); *Michael M. v. Superior Ct.*, 450 U.S. 464, 469–75 (1981) (upholding statutory rape law which punished only the male involved justified by differences between “young men and young women . . . with respect to the problems and the risks of sexual intercourse”). For the claim that *Nguyen*’s diminished scrutiny rests more on the immigration context than the real differences line of gender equal protection jurisprudence, see Nina Pillard, *Plenary Power Underground in Nguyen v. INS: A Response to Professor Spiro*, 16 *Geo. Immigr. L. J.* 835 (2002).

<sup>88</sup> For example, some post *Casey* decisions sustaining abortion health regulations acknowledge that the regulations may be unnecessary and may even operate to undermine women’s health, but find that this evidence is not sufficient to render the regulations irrational or demonstrate illegitimate purpose. See *Tucson Woman’s Clinic v. Eden*, 379 F.3d 531, 540–41, 546–47 (9th Cir. 2004); *Women’s Med. Ctr. v. Bell*, 248 F.3d 411, 419–21, 423 (5th Cir. 2001).

<sup>89</sup> Moreover, the one exception, *Mazurek v. Armstrong*, is a *per curiam* decision that claimed to simply apply established case law upholding physician-only requirements for abortion. 520 U.S. 968, 974–75 (1997).

and the unfavorable precedent of *Geduldig*.<sup>90</sup> Today, gender equality claims increasingly are included as well, particularly in challenges to abortion health regulations, but the focus remains largely on due process.<sup>91</sup> Yet this factor fails to explain *Tucson Woman's Clinic*, where gender equal protection claims were pressed, to no avail.<sup>92</sup> It is also striking, given the Court's sympathy to gender equality concerns in regard to the spousal notification requirement of *Casey*, that courts invalidating abortion health regulations on undue burden grounds (or as irrational measures) have not similarly sought to buttress their conclusions by reference to these concerns.

Perhaps courts would be more sympathetic if gender equality challenges to abortion health regulations were asserted and developed more extensively, particularly if advocates clarified the extent to which such claims are consistent with the Supreme Court's decisions. I am skeptical, however, that even more sustained efforts to assert gender equal protection challenges would prove that successful. Instead, I believe an additional force is at work here, one that is rooted in administrative law and the broad regulatory powers of the modern administrative state. Framing abortion regulations as solely health regulations, unrelated to state's

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<sup>90</sup> A variety of factors likely played into the choice of substantive due process as the means for attacking abortion restrictions, including not just the greater development of this line of jurisprudence compared to gender equal protection at the time but also advocates' fears of undermining the chances of enacting an Equal Rights Amendment. See Law, *supra* note ?, at 985–987 & n. 115; MacKinnon, *supra* note ?, at 1288 n. 34; Reva Siegel, *Abortion as a Sex Equality Right: Its Basis in Feminist Theory*, in Martha Albertson Fineman & Isabel Karpin, eds., *Mothers in Law: Feminist Theory and the Legal Regulation of Motherhood* 61 (1995). Whether advocates erred in challenging abortion on substantive due process and privacy grounds rather than equal protection is a matter of some dispute among commentators. Compare Allen, *supra* note ? (arguing that both approaches have merit) and Jed Rubenfeld, *The Right to Privacy*, 102 *Harv. L. Rev.* 737, 788–91 (1989) (defending abortion under right to privacy, with privacy understood to mean protection against states' forcing women's lives into a standardized mold), with Sunstein, *supra* note ?, 31–32 (arguing against the substantive due process/privacy approach and in favor equal protection); Catherine MacKinnon, (same); compare also Jack M. Balkin, ed., *What Roe v. Wade Should Have Said* 233–34, 244–47, 252 (2005) (offering different scholars' views of whether *Roe* should and could have been decided on gender equal protection grounds).

<sup>91</sup> See *Tucson Woman's Clinic, Springfield Healthcare Center v. Nixon*, No. 05-4296-CV-C-NLL (W.D. Mo.), Complaint at ¶ 50, available at: [http://www.crlp.org/pdf/pdf\\_crt.MO.Complaint.pdf](http://www.crlp.org/pdf/pdf_crt.MO.Complaint.pdf); *Tummino v. Von Eschenbach*, Complaint, *supra* note ?, at ¶ 66. Gender equality claims have also been included in challenges to minor notification statutes, alleging that the imposition of parental notification requirements only on female minors violates equal protection. See, e.g., *Nova Health Sys. v. Fogarty*, Amended Complaint, 2001 WL 34782765 at ¶ 62a (June 22, 2001); *Wicklund v. Lambert*, 979 F. Supp. 1285, 1289 (D. Mont. 1997).

<sup>92</sup> In addition to *Tucson Woman's Clinic*, gender equal protection claims were expressly rejected by the district court in *Armstrong v. Mazurek*, 906 F. Supp. 561, 567–68 (D. Mont. 1995), although they were not discussed in the Ninth Circuit or Supreme Court *per curiam* decisions in that case. See also *Wicklund v. Lambert*, 979 F. Supp. 1285, 1289 (D. Mont. 1997). In addition, equal protection claims have been asserted under state constitutions. See *New Mexico Right to Choose/NARAL v. Johnson*, 975 P.2d 841, 850–57 (N.M. 1998); Linda J. Wharton, *State Equal Rights Amendments Revisited: Evaluating their Effectiveness in Advancing Protection Against Sex Discrimination*, 36 *Rutgers L. J.* 1201, 1248–54 (2005).



interest in preserving fetal life, leads courts to view these measures as simply one species of economic and social legislation. Viewed in those terms, the courts' stance becomes one of tremendous deference. In the words of the Supreme Court's famously lenient standard of *Williamson v. Lee Optical*:

Evils in the same field may be of different dimensions and proportions, requiring different remedies. Or so the legislature may think. Or the reform may take one step at a time, addressing itself to the phase of the problem which seems most acute to the legislative mind. The legislature may select one phase of one field and apply a remedy there, neglecting the others.<sup>93</sup>

It is no surprise that courts, in rejecting equal protection challenges to TRAP regulations, have invoked *Lee Optical* and the government's broad power to regulate in the name of health.<sup>94</sup> From *Lee Optical*'s one-step-at-a-time perspective, targeting abortion for special regulation appears perfectly legitimate, and the burden of persuasion is on those who claim it is suspect.

This creates a paradox. Framing these abortion measures as health regulations is necessary to highlight their gender discriminatory aspect and remove the fetal life rationale for treating abortion as unique. Doing so, however, creates a separate analytic obstacle to challenging measures that single out for abortion for regulation. Of course, the Court deviates from *Lee Optical*'s deferential stance when it perceives gender discrimination afoot,<sup>95</sup> but stressing the health aspect of abortion regulations tends to erase their gender discriminatory character. Under this framing, abortion's status as a medical procedure rises to the fore, rather than the reality that it is a medical procedure undergone only by women. Moreover, as a practical matter, health regulations frequently operate one step removed from women obtaining abortions, again serving to hide their gendered character. Other than informed consent requirements justified on grounds of women's psychological health, it is abortion providers who are directly affected by TRAP laws; the restrictive impact on women occurs indirectly as the result of pass-through costs. Similarly, while the net effect was to deny women easier access to emergency

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<sup>93</sup> 348 U.S. 483, 489 (1955).

<sup>94</sup> See *Tucson Woman's Clinic*, 379 F.3d at 546 n.2; *Greenville Women's Clinic*, 222 F.3d at 174; *Women's Med. Ctr.*, 248 F.3d at 419 & n.20; see also *Casey*, 505 U.S. at 884–85 (invoking *Lee Optical* in holding that physician-counseling requirement did not create an undue burden); *Friendship Med. Ctr.*, 505 F.2d at 1149–50 (early post-*Roe* decision stating that targeted abortion regulations might well satisfy *Lee Optical*, but measures targeting fundamental rights such as access to abortion trigger stricter scrutiny).

<sup>95</sup> The established mantra is that courts will review classifications in economic and social legislation deferentially *unless* a suspect category or fundamental constitutional right is involved. See *FCC v. Beach Communications*, 508 U.S. 307, 313 (1993); *City of New Orleans v. Duke*, 427 U.S. 297, 303 (1976).

contraception, the FDA’s action regarding Plan B took the form of denial of an OTC application submitted by Barr Labs.<sup>96</sup>

This framing of abortion regulations as ordinary health measures is evident in *Casey*. In laying out its analytic approach to abortion health regulations, the Court began by stating, “[a]s with any medical procedure, the State may enact regulations to further the health or safety of a woman seeking an abortion.”<sup>97</sup> On this account, constitutional protections for abortion operate merely as an outer limit, precluding only “unnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion.”<sup>98</sup> The decision that best illustrates the immunizing power of the health perspective, however, is *Mazurek v. Armstrong*.<sup>99</sup> *Mazurek* involved a challenge to Montana’s adoption of a physician-only requirement for performance of abortions. The Ninth Circuit had reversed the district court’s denial of a preliminary injunction, concluding that the plaintiffs had demonstrated sufficient possibility of success on their claim that the law was animated by the unconstitutional purpose of creating a substantial obstacle to abortion to merit that the district court reconsider the balance of hardships.<sup>100</sup> The Ninth Circuit was in turn reversed—summarily—by the Supreme Court. According to the Court, “even assuming . . . that a legislative *purpose* to interfere with the constitutionally protected right to abortion without the *effect* of interfering with that

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<sup>96</sup> See GAO Report, *supra* note ?, at Appendix II (non-approvable letter to Barr Research on Plan B OTC switch application, May 6, 2004).

<sup>97</sup> 505 U.S. at 878.

<sup>98</sup> *Id.* Whether unnecessary health regulations are constitutionally prohibited even if they do not create a substantial obstacle to abortion access was an issue left unresolved in *Casey*. Although the *Casey* joint opinion’s phrasing suggests that such unnecessary abortion regulations could be constitutional, it never says so expressly or overrules those parts of prior decisions that had invalidated health regulations found to be unnecessary as well as burdensome. See, e.g., *Akron v. Akron Center for Reproductive Health, Inc.*, 462 U.S. 416, 438 (1983); see also *Casey*, 505 U.S. at 920–21 (Stevens, J., concurring in the judgment and dissenting in part) (arguing that abortion restrictions that are irrational or unnecessary are also undue); compare *Tucson Woman’s Clinic*, 379 F.3d at 539 (inferring from *Mazurek* and *Casey* that regulations that are at least facially connected to women’s health are not unconstitutional because objectively unnecessary, but may be unconstitutional if they impose an undue burden), with *Greenville Women’s Clinic*, 222 F.3d 157, 197 (4th Cir. ) (Hamilton, J., dissenting) (“*Casey* and its predecessors teach us that health regulations which are unnecessary, i.e., not reasonably related to maternal health or which depart from accepted medical practice, cannot withstand constitutional scrutiny”). As the Ninth Circuit in *Tucson Woman’s Clinic* implicitly recognized, this is not really a debate over whether unnecessary health regulations are constitutional; if regulations are acknowledged to bear no relationship to women’s health, they would be irrational and unconstitutional on that ground, without reference to their relationship to abortion. Instead, the real question is whether courts defer to the government’s determination that a regulation serves a legitimate interest in preserving women’s health, or instead subject such claims to independent factual scrutiny.

<sup>99</sup> 520 U.S. 968 (1997) (per curiam).

<sup>100</sup> *Armstrong v. Mazurek*, 94 F.3d 566, 567–68 (9th Cir. 1996).

right . . . could render the Montana law invalid,” the physician-only requirement was clearly constitutional under *Casey* and other of its precedents.<sup>101</sup>

*Mazurek* is notable on many fronts; the Court’s reaching out to take the case at such an early stage being one, and its dicta attempting to do away with the purpose prong of the undue burden test being another.<sup>102</sup> For my purposes here, what is particularly striking about *Mazurek* is the Court’s emphasis on the states’ “‘broad latitude to decide that particular functions may be performed only by licensed professionals.’”<sup>103</sup> That latitude so immunized Montana’s physician-only requirement from claims of impermissible purpose that the lack of a health basis for the requirement, as well as evidence of illegitimate motives underlying its adoption, became irrelevant.<sup>104</sup> Against this strong presumption of legitimacy, claims that health regulations targeting abortion constitute gender discrimination—whether facially or based on invidious intent—seem destined to fail.

### B. *Gender Equal Protection and the Administrative Dimension*

So far, this discussion focuses on the health aspect of these abortion regulations, rather than their status as (at least in part) administrative agency promulgations. Indeed, it is striking how rarely decisions refer to the agency-promulgated character of abortion health regulations. This absence reflects the fact that the vast majority of decisions involve constitutional challenges brought in federal court, where the governing standards are the same regardless of the legislative or administrative nature of the measure at issue.<sup>105</sup> In addition, most

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<sup>101</sup> 520 U.S. at 972–75.

<sup>102</sup> *Id.* at 972. Courts have read *Mazurek* as at least putting high evidentiary burdens on illegitimate purpose claims. See *Karlin v. Foust*, 188 F.3d 446, 493 (7th Cir. 1999) (*Casey* and *Mazurek* suggest that a purpose challenge “will rarely be successful, absent some sort of explicit indication from the state that it was acting in furtherance of an improper purpose.”); see also *Tucson Woman’s Clinic*, 379 F.3d at 540–41, 546–47 (citing *Mazurek* and rejecting evidence supporting inference of improper motive where “scheme as a whole is a typical set of health and safety standards, unusual primarily because it singles out abortion clinics,” and death of a patient at an abortion clinic preceded adoption). The Court’s recent decision in *Ayotte v. Planned Parenthood* may revive inquiry into the purpose underlying enactment of abortion restrictions, albeit under the aegis of an examination of severability. See 126 S. Ct. 961, 968–69 (2006); Note, *After Ayotte: The Need to Defend Abortion Rights With Renewed “Purpose,”* 119 *Harv. L. Rev.* 2552, 2566–73 (2006).

<sup>103</sup> *Id.* at 973 (quoting *Casey*, 505 U.S. at 885).

<sup>104</sup> *Id.* at 973–74.

<sup>105</sup> See, e.g., *Women’s Medical Professional Corp. v. Baird*, 277 F.Supp.2d 862, 871 n.1 (S.D. Ohio 2003) (noting that written transfer agreement at tissue there was promulgated administratively rather than legislatively but noting this fact was “of little consequence” to its decision); see also *Founder’s Women’s Health Ctr. v. Ohio State Dept’t of Health*, Nos. 01AP-872, 01AP-873, 2002 WL 1933886 at \*5, \*7–\*10 (Ohio Ct. App. Aug. 15, 2002) (state court action invoking deferential standards for reviewing administrative agencies factual findings and interpretation of legislative scheme and upholding hearing examiner’s conclusion that abortion providers are subject to statutory

administrative abortion measures originate in legislation that itself targets abortion for regulation, a dynamic that operates to obscure—or at least downplay—the agency role.

As a result, discerning an administrative effect in health regulation challenges is based largely on conjecture. Nonetheless, it seems plausible to think that the administrative aspect of these regulations may operate to reinforce the *Lee Optical* paradigm. Adequate facility size and equipment, training and qualification requirements, likelihood of harmful health consequences or improper use of medication—these are the sort of questions typically seen as matters for administrative agency expertise. Regulations and decisions addressing these matters thus come with a presumption of deference rooted in administrative law, for which *Lee Optical* may operate as a proxy.<sup>106</sup> This reinforcing dynamic is hardly unique to the context of abortion health regulations. On the contrary, *Lee Optical* and doctrines of administrative deference stand in a symbiotic relationship with one another. Modern deference to administrative decisionmaking would be indefensible without acceptance of the government’s broad power over economic and social legislation; nor would this power amount to much if the government could not delegate much of the substance of regulation to administrative agencies without losing the benefit of deferential review.<sup>107</sup>

Similarly, the administrative backdrop of these abortion measures serves to further erase their sex-based nature. Administrative regulation can take the form of promulgation of rules targeted at abortion providers, in response to abortion-specific legislative measures. It also occurs on a case-by-case basis, however, as a result of application of a general statutory and regulatory scheme. The FDA’s encounters with RU-486 and Plan B are the prime instances here, but case-by-case regulation can also occur at the state and local level; for example, in the issuance or revocation of licenses and exemptions. Such a case-by-case posture can make identifying dissimilar treatment more difficult.<sup>108</sup>

At the same time, the case-by-case posture limits the ability to prove that administrative decisions restricting access to abortion will prove onerous or are

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licensure requirements).

<sup>106</sup> In the drug regulation context, for example, courts are extremely deferential to the FDA’s scientific judgments. See Noah, *supra* note ?, at 592–93; see also *Henley v. FDA*, 77 F.3d 616, 620–21 (2d Cir. 1996) (noting, in rejecting challenge to FDA labeling decision on oral contraceptives, that “[t]he FDA possesses the requisite know-how to conduct such analyses [of existing body of scientific research], by sifting through the scientific evidence to determine the most accurate and up-to-date information regarding a particular drug, and how those data affect human usage”).

<sup>107</sup> See, e.g., Robert L. Rabin, *Federal Regulation in Historical Perspective*, 38 *Stan. L. Rev.* 1189, 1269 (1986); see also *id.* at 1262–72 (describing historical emergence of deferential administrative review in the aftermath of the Court’s acceptance of broad regulatory power).

<sup>108</sup> Cf. Matthew Diller, *The Revolution in Welfare Administration: Rules, Discretion, and Entrepreneurial Government*, 72 *N.Y.U. L. Rev.* 1121, 1200–02 (2000) (arguing that pattern and practice lawsuits are harder to bring in contexts of discretionary individual decisionmaking and easier to bring where governing standards are specified in governing rules).

animated by invidious motives. This point is illustrated by the Sixth Circuit’s recent decision in *Women’s Medical Professional Corporation v. Baird*, upholding application the requirement that surgical facilities have written transfer agreements with hospitals to a clinic owned by a prominent abortion provider.<sup>109</sup> Bowing to public pressure as well as internal opposition by members of their boards of directors, local hospitals refused to enter such an agreement with the clinic. Thus, application of the written transfer requirement meant the clinic—the only clinic in a fifty mile radius, and the only clinic in all of southern Ohio that provides late second-term abortions—would have to close.<sup>110</sup> Nonetheless, the Sixth Circuit denied that application of the requirement created an undue burden on abortion access. In so holding, it emphasized that only one clinic was affected and that the director of the state’s health department had granted waivers of license requirements for other abortion clinics in Ohio, the latter fact serving in the Sixth Circuit’s analysis to defeat the claim that the director was motivated by an unconstitutional purpose of limiting access to abortion.<sup>111</sup>

Concerns about not intruding on administrative expertise also may make courts resistant to perceiving regulatory measures as illegitimate even if targeting of abortion is acknowledged. Administrative agencies regulate in targeted ways all the time, issuing rules designed for a particular activity or substance while leaving other activities or substances unregulated, or setting policy through adjudication that may govern only a narrow range of factually indistinguishable cases. As a general matter, administrative law grants agencies great deference in these regulatory choices, on the ground that the inherent policy and resource implications of such decisions are more appropriate for agency control.<sup>112</sup> Viewing administrative tailoring as potentially suspect, rather than as an appropriate exercise of substantive knowledge, is thus at odds with the basic presuppositions of administrative law. True, regulations that facially target suspect classifications are not shielded from enhanced scrutiny by their administrative character. But fears of intruding unduly on a broad range of agency decisionmaking seems likely to make courts resistant to the argument that targeting a procedure or drug used solely by one sex is for that reason a sex-based classification warranting greater justification. For example, on that logic enhanced

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<sup>109</sup> 438 F.3d 595 (6th Cir. 2006).

<sup>110</sup> See *Baird*, 438 F.3d at 599. On remand, the clinic is seeking a TRO to prevent the health department from disclosing the names of physicians who have agreed, if they can remain anonymous, to provide back-up care in support of the clinic’s application for a waiver. See *Pltfs’ Motion on Remand, Women’s Med. Prof. Corp. v. Baird*, 2006 WL 1111922 (Mar. 20, 2006).

<sup>111</sup> See *Baird*, 438 F.3d at 605–09; see also *Mazurek v. Armstrong*, 520 U.S. 968, 973–74 (1997) (per curiam) (similarly arguing that claim of unconstitutional purpose “is positively contradicted by the fact that only a dingle practitioner is affected”).

<sup>112</sup> See, e.g., *Heckler v. Chaney*, 470 U.S. 821, 831–33 (1985); *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 294 (1974) (emphasizing that choice of whether to proceed by general rules or case-by-case discretion “lies in the first instance within the [agency’s] discretion” and that where factual differences exist, an agency “has reason to proceed with caution, developing its standards in a case-by-case manner.”).

scrutiny is as warranted of FDA decisions affecting uterine or prostate cancer drugs, or of Health and Human Services' program to encourage maternal breastfeeding,<sup>113</sup> as of decisions affecting abortion.

### C. *Equal Protection and Abortion*

In my view, these doctrines of deference mean that gender equal protection is unlikely to prove a fruitful avenue for challenging administrative regulations of abortion. Indeed, the same is true of other types of equal protection challenges. In the past, courts frequently invalidated abortion health regulations under the fundamental rights strand of equal protection analysis,<sup>114</sup> under which measures singling out protected rights for regulation ordinarily trigger strict scrutiny.<sup>115</sup> But *Casey's* articulation of the undue burden standard undermines this approach. The claim that the abortion right receives greater constitutional protection under equal protection than under due process is implausible, all the more so given that the reason for according this right heightened equal protection scrutiny in the first place is its privileged status under due process. Hence, the Ninth Circuit's conclusion that, in the case of abortion, fundamental rights equal protection scrutiny collapses into undue burden analysis appears correct.<sup>116</sup>

Nor does invalidation of abortion health regulations under some form of heightened rationality review seem a probable scenario. To be sure, some support for such an approach exists, in abortion precedent invalidating second trimester hospitalization requirements found to "depart from accepted medical practice" or be "unnecessary."<sup>117</sup> By describing such regulations as unreasonable, the Court signaled that rationality review in the abortion context should take a more searching guise

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<sup>113</sup> See Roni Rabin, *Breast Feed Or Else*, N.Y. Times, June 13, 2006, at F1.

<sup>114</sup> See *supra* note ?.

<sup>115</sup> See cases cited *supra* in note ?; see also *San Antonio School District v. Rodriguez*, 411 U.S. 1, 16–17 (1973) (noting that legislation found to interfere with fundamental constitutional rights is subject to strict scrutiny).

<sup>116</sup> See *Tucson Woman's Clinic*, 379 F.3d at 544–45; see also *Washington v. Glucksberg*, 521 U.S. 702, 755 n.3 (1997) (Souter, J., dissenting) (noting, in rejecting substantive due process arguments for a right to assisted suicide, that "the Equal Protection Clause . . . does essentially nothing in a case like this that the Due Process Clause cannot do on its own"); Peter Westen, *The Empty Idea of Equality*, 95 Harv. L. Rev. 537, 551 (1982) (same).

<sup>117</sup> *Akron v. Akron Center for Reproductive Health*, 462 U.S. 416, 431, 438 (1983); see also *Roe v. Wade*, 410 U.S. 113, 163 (1973) (holding that the state's interest in "the preservation and protection of maternal health" becomes compelling, at the end of the first trimester and therefore states could "regulate the abortion procedure to the extent that the regulation *reasonably relates*" to this interest) (emphasis added); *Doe v. Bolton*, 410 U.S. 179, 192–96 (1973) (invalidating requirement that first trimester abortions be performed only in accredited hospitals as not reasonably related to health concern); *Word v. Poelker*, 495 F.2d 1349, 1351–52 (8th Cir. 1974) (invalidating St. Louis measure targeting abortion, concluding that it was not "legitimately related to the recognized objectives of state regulation" and penalized women seeking abortion and their physicians).

than it ordinarily assumes.<sup>118</sup> Again, however, this methodological precedent appears at least somewhat dubious post-*Casey*.<sup>119</sup> The signal conveyed by *Mazurek* is that states should be given leeway in regulating abortion unless their efforts significantly impede women's access to abortion.<sup>120</sup> Enhanced rationality review is also at odds with the doctrines of deference discussed above, and for the same reasons seems unlikely to emerge as abortion regulation becomes more administrative.

Equal protection thus is unlikely to offer advocates a way around the limitations of current protections against under due process. This does not mean that equality concerns, and particularly gender equality concerns, can play no role in the abortion context. But it suggests that if equality concerns gain judicial traction here, it will be through being integrated into the undue burden standard, as occurred in *Casey* itself, rather than through independent equal protection challenges. This conclusion seems only stronger outside of the health context, where biological realities of reproduction confound efforts to demonstrate the gender discriminatory aspect of abortion restrictions.

Put differently, I am doubtful that advocates can avoid engaging with the undue burden standard and abortion's constitutional uniqueness. The challenge lies in encouraging courts to expand their understanding of the ways abortion is unique,

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<sup>118</sup> Compare *Akron*, 462 U.S. at 438–39 (“It is true that a state abortion regulation is not unconstitutional simply because it does not correspond perfectly in all cases to the asserted state interest. But the lines drawn in a state regulation must be reasonable, and this cannot be said” of *Akron*'s second-trimester hospitalization requirement” because “evidence [demonstrated] that—at least during the early weeks of the second trimester—D & E abortions may be performed as safely in an outpatient clinic as in a full-service hospital”) and *Simopoulos*, 462 U.S. at 511, 516–17 (although state has “legitimate interest in regulating second-trimester abortions,” “its discretion does not permit it to adopt regulations that depart from accepted medical practice”) with *Williamson v. Lee Optical*, 348 U.S. 483, 487–88 (1955) (“The Oklahoma law may exact a needless, wasteful requirement in many cases. But it is for the legislature, not the courts, to balance the advantages and disadvantages of the new requirement. . . . It is enough that there is an evil at hand for correction, and that it might be thought that the particular legislative measure was a rational way to correct it.”).

<sup>119</sup> This is not to say that under *Casey* second-trimester hospitalization requirements are constitutional. On the contrary, such requirements may well constitute undue burdens on access to previability abortions, given the extreme and easily calculable increase in costs they impose. *Planned Parenthood v. Janklow*, 216 F. Supp.2d 983, 992–93 (D. S.D. 2002) (holding South Dakota second-trimester hospitalization requirement unconstitutional as creating an undue burden and concluding *Akron* still valid on such requirements' unconstitutionality), rev'd on other grounds, *Planned Parenthood v. Rounds*, 372 F.3d 969 (8th Cir. 2004); *Jackson Women's Health Org'n Inc. v. Amy*, 330 F. Supp.2d 820 (S.D. Miss. 2004) (preliminarily enjoining requirement that second-trimester abortions be performed only in licensed surgical facilities or hospitals); *Reproductive Servs. v. Keating*, 35 F.Supp.2d 1332 (N.D. Okla. 1998) (preliminarily enjoining second trimester requirement for abortions); contra *Davis v. Feiker*, 952 P.2d 505, 515–16 (Okla. 1998) (concluding *Akron* no longer retains its validity post-*Casey* and holding evidence failed to establish that second-trimester hospitalization requirement creates an undue burden).

<sup>120</sup> See supra note ?. On the other hand, while decision such as *Akron* and *Simopolous* predate *Casey*, they have not been overruled; moreover, their emphasis on medical practice has continued in other abortion contexts, most notably in rejection of partial-birth abortion bans and insistence on good faith health exceptions to abortion restrictions. See *Stenberg v. Carhart*, 530 U.S. 914, 930–38 (2000); see also *Ayotte v. Planned Parenthood*, 126 S. Ct. 961, 967 (2006).

in ways that better reflect the realities of women’s lives and abortion regulation. Abortion is unique not just in what it represents for potential life, but also in its relationship to women’s equality—and, of particular relevance to administrative abortion measures, in the danger that opposition to abortion rather than legitimate health concerns lead it to be singled out for regulation. In short, advocates need to convince courts that abortion’s uniqueness does not necessarily justify abortion-specific regulation, but on the contrary may necessitate subjecting some abortion-specific measures to greater scrutiny. *Mazurek* stands as a significant obstacle to such arguments, however, and the reality at present is that the undue burden standard offers limited protection against unnecessarily onerous abortion health regulations.<sup>121</sup>

### III. ABORTION AND ADMINISTRATIVE LAW

In sum, constitutional law seems unlikely—at least in the short run—to offer much protection against unwarranted health regulations and increasing administrative restrictions of abortion. A potential alternative exists, however, for trying to redress the lack of fit between many such regulations and the government’s health interest. That alternative is ordinary administrative law.

Significantly, the Court has rejected the claim that *Lee Optical* and deferential constitutional rationality review should govern in the federal administrative law context. While insisting that “a court is not to substitute its judgment for that of the agency,” the Court nonetheless has imposed potentially substantial requirements of relevancy and explanation on federal agencies:

[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made. . . . Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.<sup>122</sup>

As noted above, broad legislative regulatory authority entails—at least in practice—deference to administrative decisions.<sup>123</sup> Thus, administrative law’s imposition of such close scrutiny stands in some tension with constitutional law’s

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<sup>121</sup> See, e.g., *Baird*, 438 F.3d at 602–09; *Greenville Women’s Clinic*, 222 F.3d at 163–72. But see *Planned Parenthood v. Atchinson*, 126 F.3d 1042, 1048–49 (6th Cir. 1997) (finding illegitimate purpose where medical offices structured similarly to abortion clinic where not similarly required to obtain a certificate of need).

<sup>122</sup> *Motor Vehicle Mfrs. Ass’n v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29, 42–43 & n.9 (1983).

<sup>123</sup> See *supra* text accompanying note ?.



reliance on the *Lee Optical* model. At the same time, however, close scrutiny under the administrative law rubric also reflects constitutional law's deference to legislative regulatory choices, both as to the substance of economic and social legislation and as to the decision to delegate substantial decisionmaking to administrative agencies. In light of this deference, the courts have used subconstitutional doctrines of administrative law as a means to check arbitrary governmental action.<sup>124</sup>

Not surprisingly, given these conflicting demands of deference and scrutiny, in practice the intensity of judicial review of federal agency action has varied.<sup>125</sup> The net result is that federal courts generally defer, but sometimes undertake a more potent "hard look" review of agency decisionmaking. Such hard look scrutiny is most common in regard to notice and comment or informal rulemaking, but also occurs in adjudicatory contexts, even in regard to informal decisions over which agencies enjoy substantial discretion.<sup>126</sup> Often what triggers greater scrutiny is judicial perceptions of perceived agency arbitrariness, expansion of power, or improper influences.<sup>127</sup>

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<sup>124</sup> See Gillian E. Metzger, *The Story of Vermont Yankee: A Cautionary Tale of Judicial Review and Nuclear Waste in Administrative Law Stories* 143–49, 160–65 (Peter L. Strauss, ed. 2005) (discussing development of hard look review); see also Lisa Schultz Bressman, *Beyond Accountability: Arbitrariness and Accountability in the Administrative State*, 78 N.Y.U. L. Rev. 461, 467 (2003) (arguing that "efforts at preventing arbitrariness mainly have been taking place under the rubric of 'ordinary' administrative law rather than 'constitutional' administrative law"); *American Trucking Ass'ns v. EPA*, 175 F.3d 1027, 1061 (D.C. Cir. 1999) (distinguishing between assessing constitutionality of delegation and whether in exercising delegated powers agency acted arbitrarily or capriciously).

<sup>125</sup> Compare *State Farm*, 463 U.S. at 46–57 (subjecting National Highway Traffic Safety Administration's decision to rescind passive restraint requirement to searching scrutiny) with *Baltimore Gas & Elec. Co v. NRC*, 462 U.S. 87, 98–105 (1983) (deferring to NRC's determination that uncertainties concerning long-term storage of nuclear waste need not be considered in assessing environmental effects of proposed nuclear plants). While the discussion here focuses on judicial review of agency factfinding and reasoning, similar variation exists in judicial review of agency statutory interpretations. See Lisa Schultz Bressman, *How Mead has Muddled Judicial Review of Agency Action*, 58 Vand. L. Rev. 1443 (2005).

<sup>126</sup> See, e.g., *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 35, 366–79 (1998) (engaging in close scrutiny of factual record and reversing NLRB determination in formal adjudication that successor employer lacked a good faith reasonable doubt as to continued union support, criticizing the agency for not adhering to its stated standards and thereby foregoing reasoned decisionmaking); *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971) (undertaking "thorough, probing, in-depth review" of informal adjudicatory decision by Secretary of Transportation).

<sup>127</sup> For example, although only expressly raised in the partial concurrence, the more searching scrutiny employed in *State Farm* was at least in part a result of the political backdrop of the passive restraint rule's rescission, specifically a new Presidential administration with stated opposition to heavy regulation of U.S. car manufacturers. See 463 U.S. at 59 (Rehnquist, J., concurring in part and dissenting in part); Christopher F. Edley, Jr., *Administrative Law: Rethinking Judicial Control of Bureaucracy* 63–65 (1990). The Court more recently emphasized that while politics is a legitimate consideration, agencies must nonetheless explain their changes in approach. See *National Cable & Telecomm. Ass'n v. Brand X Internet Servs.*, 125 S. Ct. 2688, 2699–2700 (2005); see also *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159–61 (2000) (rejecting FDA's assertion of

The lack of fit between administrative abortion regulations and the government's health interests is the type of discrepancy that potentially may provoke greater judicial review. In administrative law terms, this lack of fit suggests a lack of reasoned decisionmaking. Inconsistent agency actions in addressing abortion or reproduction issues similarly may trigger greater judicial scrutiny.<sup>128</sup> Such inconsistency not only raises the impression of arbitrary administrative action, it also suggests that the agency's stated rationale is not what is actually motivating its actions.

Consider in this regard the example of South Carolina's TRAP regulations: The district court in *Greenville Women's Clinic* found that officials at the state's Department of Health and Environmental Control (DHEC), which promulgated the regulations, "took no meaningful steps to ensure that" the regulations would further the state's interest in the health of women obtaining first trimester abortions.<sup>129</sup> Instead, the driving force behind the regulations appears to have been administrative standardization, with officials essentially applying regulations applicable to second trimester abortions and other healthcare facilities to first trimester abortion providers. However, DHEC officials made no effort to determine if parts of the resulting regulations were medically appropriate for first trimester abortions and sought only limited input on the regulations as a whole from medical professionals.<sup>130</sup> Taking these findings as accurate, at the federal level such failure to seek evidence on the medical realities of first-trimester abortions and tailor regulations to fit the health risks actually presented would probably result in the regulations being vacated and remanded.

In the case of the FDA's refusal to approve Plan B for OTC status, the numerous ways in which the agency deviated from its standard practices are likely to provoke more searching examination than a refusal to grant OTC status might otherwise receive. Thus, while the agency's conclusion that usage studies for older teenagers and adults are not extrapolatable to younger teens is the type of scientific issue on which courts will ordinarily defer, the fact that the FDA has not questioned such extrapolations in the past puts on it here a greater onus of explanation and justification. Evidence that high level FDA officials solicited support for their

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jurisdiction to regulate tobacco under the FDCA and emphasizing broad expansion in FDA's regulatory authority that would result as grounds for not deferring to agency's construction of the statute).

<sup>128</sup> See, e.g., *Good Samaritan Hospital v. Shalala*, 508 U.S. 402, 417 (1993) ("[T]he consistency of an agency's position is a factor in assessing the weight that position is due."); *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29, 42 (1983) (stating agencies must provide "a reasoned analysis" for changing rules); see also Michael Asimow, *The Scope of Judicial Review of Decisions of California's Administrative Agencies*, 42 U.C.L.A. L. Rev. 1157, 1232 (1995) ("One important factor in establishing an abuse of discretion is an apparent inconsistency of the agency decision with its prior decisions.").

<sup>129</sup> *Greenville Women's Clinic v. Bryant*, 66 F.Supp.2d 691, 705 (D. S. Car. 1999), rev'd on appeal, 222 F.3d 157 (4th Cir. 2000).

<sup>130</sup> *Id.* at 706–10.

concerns about younger teenagers after having decided to deny the OTC switch application, rather than seeking to determine if these concerns were merited beforehand, may reinforce judicial concerns. Such after-the-fact justifications reinforce the suspicion that the FDA's decision was driven more by moral opposition to teenage sex and politics than by the public health concerns that constitute the agency's statutory mandate.<sup>131</sup> On that score, documents recounting that the FDA's Deputy Commissioner voiced fears that adolescents might "form sex-based cults centered around the use of Plan B" are hardly reassuring.<sup>132</sup>

The Plan B saga also demonstrates the importance of administrative constraints outside of judicial review. One remarkable feature of the FDA's handling of Plan B is the extent to which the professional staff of the Center for Drug Evaluation and Research (CDER), the arm of FDA that reviews OTC switch applications, opposed the decision to issue a nonapprovable letter. In official memoranda, emails, and meetings, the CDER staff made clear their disagreement with the FDA's decision and their concern that the decision was illegitimately based on opposition to teenage sex; these concerns even led one CDER director and an FDA advisory committee member to resign from the FDA.<sup>133</sup> Moreover, the FDA's standard procedures for delegating decisions on OTC switch applications to its professional staff provided numerous opportunities for that staff to address high level officials' concerns and seek to change their minds. Thus, in a certain light the FDA's handling of Plan B offers reaffirmation of administrative law's emphasis on agency expertise as a potent check on administrative arbitrariness. True, the constraining forces of professionalism and agency structure ultimately did not prevent the FDA from issuing a nonapproval letter. But even here these forces have fostered administrative accountability, playing a significant role in making public the FDA's unusual treatment of Plan B.

One important consequence of an administrative law approach is that challenges to state agency actions addressing abortion will be brought under state

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<sup>131</sup> See GAO Report, *supra* note ?, Appendix III at 44-46 (providing timeline of internal FDA actions on the Plan B OTC switch application); *id.*, Appendix V at 52 (memorandum from Office of New Drugs Director noting moral concerns regarding adolescent sexual activity and parental control raised by the Plan B OTC switch application); see also 21 C.F.R. § 310.200(b) (providing that the FDA Commissioner shall exempt any drug from prescription requirements upon finding that "such requirements are not necessary for protection of the public health" and is "safe and effective for use in self-medication"); *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 645-46 (1990)(emphasizing that the organic statute under which an agency acts determines the relevant factors it must and can consider and noting that an agency may be "ill-equipped" to take into account policy concerns outside its field of expertise).

<sup>132</sup> See *Tummino v. von Eschenbach*, CV 05-366, Decision and Order at 10, 32-33 (E.D.N.Y. Feb. 24, 2006) (Pohorelsky, M.J.) (recounting statement and other evidence suggesting that "the agency's senior decisionmakers were resting on improper concerns about the morality of adolescent sexual activity").

<sup>133</sup> See *id.*, at 6-14, 16-19, 23-24.

law and usually in state court.<sup>134</sup> Although the substance of state and federal administrative law is generally quite similar, the procedures by which state administrative action is challenged vary from state to state, as do some of the governing standards of judicial review.<sup>135</sup> Of particular relevance here, state courts are in some ways more deferential in their review of agency action; for example, hard look review of rulemaking and discretionary decisions is less common, although some states are moving towards more greater scrutiny.<sup>136</sup> On the other hand, some states' laws include features that are absent from federal law and that could prove useful to advocates, such as Florida's statutory requirement that agencies grant waivers from governing rules in certain contexts.<sup>137</sup> In addition, states increasingly are moving to central panel systems for Administrative Law Judges (ALJs), under which ALJs are not located within the agency whose decisions they review; in conjunction with this development, some states are also restricting agency review of ALJ decisions.<sup>138</sup> The net effect of these changes is to make state ALJs less subject to agency influence, a potentially significant insulation when ALJs are reviewing politically contentious licensing decisions affecting abortion providers.

It is important not to oversell the potential of administrative law as a constraint on abortion restrictions. While offering a basis for searching scrutiny, administrative law also puts strong emphasis on deferring to agency expertise and policy choices, an emphasis reflected (among other ways) in ostensibly deferential

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<sup>134</sup> Although state courts are the more common forum for state administrative review, federal courts can exercise supplemental jurisdiction over state law claims involving review of agency action. See *City of Chicago v. International College of Surgeons*, 522 U.S. 156, 167–73 (1997).

<sup>135</sup> For a comprehensive if somewhat dated overview of state administrative law, see William A. McGrath, *Project: State Judicial Review of Administrative Action*, 43 *Admin. L. Rev.* 571 (1991); see also Arthur E. Bonfield, *The Federal APA and State Administrative Law*, 72 *Va. L. Rev.* 297 (1986) (discussing the twinned evolution of state and federal administrative law and core concepts common to both).

<sup>136</sup> See Michael Asimow et al., *State and Federal Administrative Law* (2d ed. 1998) § 9.08, at 602, 608–09; see also McGrath, *Project*, supra note ?, at 777–87 (describing state court review of agency policy decisions).

<sup>137</sup> See Fla. Stat. Ann. 120.542 (1); Jim Rossi, *The Revised Florida Administrative Procedure Act: A Rulemaking Revolution or Counter-Revolution*, 49 *Admin. L. Rev.* 345,353–58 (1997) (discussing Florida's waiver provision).

<sup>138</sup> See James E. Flanagan, *Redefining the Role of the State Administrative Law Judge: Central Panels and their Impact on State ALJ Authority and Standards of Agency Review*, 54 *Admin. L. Rev.* 1355, 1356–61 (2002). No such central ALJ division exists at the federal level, but federal ALJs have similar independence protections. The bigger contrast concerns agency review of ALJ decisions: under the federal Administrative Procedure Act agencies can review ALJ determinations de novo, although the ALJ decision becomes part of the record. See 5 U.S.C. §§ 557(b)(c); see also *Universal Camera v. NLRB*, 340 U.S. 474 (1950) (emphasizing that ALJ decision is part of the record and that ALJ credibility determinations may be entitled to particular weight in assessing whether an agency decision is supported by substantial evidence).

standards of review.<sup>139</sup> Abortion is an issue of perhaps unrivaled political contestation, and courts therefore may well perceive abortion regulation as an area where agency policy choices should be given freer rein—abortion’s uniqueness again coming to the fore. After all, one of the Court’s strongest endorsements of agency change in position in response to politics came in a case involving abortion regulations.<sup>140</sup> The politics of abortion may prove even more important in state courts, where judges are often elected and decisions favoring abortion providers may rally anti-abortion groups to oppose a judge’s reelection.<sup>141</sup> Nor does focusing on administrative law come without costs; abortion rights advocates may find it easier to bring constitutional challenges in federal court than to pursue unfamiliar state law claims in state court venues.

Yet pursuing standard administrative law challenges has an appeal. It takes seriously the claim that abortion regulation is simply ordinary administrative regulation, and pursues this claim to its logical conclusion: abortion regulation then should be subject to the same constraints applicable to other less publicly contentious instances of administrative decisionmaking.<sup>142</sup> It also has the advantage of involving a set of standards and requirements that are not abortion-specific, and thus not subject to evisceration with waning judicial support for constitutional protection of abortion. Administrative law also offers advocates a variety of procedural

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<sup>139</sup> See *Dickinson v. Zurko*, 527 U.S. 150, 159–161 (1999) (discussing greater deference courts give to agency determinations than to lower court determinations, as evident in standards of review, and identifying agency expertise as one basis for the difference); *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837, 842–44, 864–66 (1984) (emphasizing importance of judicial deference to agency policy choices in articulating deferential standard for review of agency interpretations of statutes for which agency has implementation responsibility).

<sup>140</sup> See *Rust v. Sullivan*, 500 U.S. 173, 186–187 (1991) (upholding federal regulations prohibiting recipients of funds under Title X of the federal Public Health Service Act from engaging in abortion counseling, referral, and activities advocating abortion as a method of family planning).

<sup>141</sup> See Steven P. Croley, *The Majoritarian Difficulty: Elective Judiciaries and the Rule of Law*, 62 U. Chi. L. Rev. 689, 725–29, 738–39 & n. 147 (1995) (arguing that the elective status of state judges may lead to decisions compromising individual rights, and identifying instances when abortion decisions factored into judicial elections); Burt Neuborne, *The Myth of Parity*, 90 Harv. L. Rev. 1108, 1127–28 (1977) (arguing state judges’ elective status affects their decisions in controversial cases); see also Jim Rossi, *Overcoming Parochialism: State Administrative Procedure and Institutional Design*, 53 Admin. L. Rev. 551, 568 (2001) [hereinafter Rossi, *Overcoming Parochialism*] (emphasizing that the ALJ central panel system helps limit the importance of elected state judges in regulatory matters).

<sup>142</sup> In addition, some claims currently brought against state abortion regulations resonate particularly well with administrative law, especially attacks on regulations as improperly delegating standard-setting power to private (or, at least, non-publicly accountable) entities when they require abortion clinics to have a staff physician with hospital admitting privileges or a written transfer agreement with a hospital. Delegation and the problems it poses lie at the heart of administrative law. Moreover, many states have more potent constraints on delegations, and in particular on private delegations, than exist in federal law. See, e.g., *Texas Boll Weevil Eradication Found., Inc. v. Lewellen*, 952 S.W.2d 454, 456–59 (Tex. 1997); Rossi, *Overcoming Parochialism*, supra note ?, at 560–62; McGrath, *Project*, supra note ?, at 579–93, 600–02.

openings—internal agency proceedings such as notice and comment rulemaking or agency adjudications, in addition to judicial review—by which to pursue relief.<sup>143</sup> But in any event, whatever its advantages or disadvantages, expanding administrative regulation of abortion seems likely to make administrative law an unavoidable aspect of abortion litigation in the future.<sup>144</sup>

## CONCLUSION

Administrative regulation is spreading and becoming a more constant aspect of the abortion landscape. Intuitively, this development might appear to provide an opening for greater success with gender equal protection claims; such administrative measures are overwhelmingly health focused, and widespread agreement regarding the comparative safety of abortion as a medical procedure supports claiming that such singling out of abortion is unjustified. I have argued here that this appearance is deceptive. Leaving aside impediments of precedent, emphasizing the health focus of such regulation invokes the government's broad discretion in health regulation, and the administrative character of these measures reinforces the appropriateness of deferential scrutiny. Yet while constitutional law currently offers little protection

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<sup>143</sup> Administrative challenges may also offer remedial advantages. In particular, in finding that a rule is arbitrary and capricious or unsupported by the record in some regard, a court generally declares the rule void in toto; by contrast, in its latest abortion decision the Court instructed lower courts to engage in severability analysis when they find part of an abortion regulation unconstitutional. See *Ayotte v. Planned Parenthood*, 126 S. Ct. 961 (2006); Ronald M. Levin, "Vacation" at Sea: Judicial Remedies and Equitable Discretion in Administrative Law, 53 *Duke L. J.* 291, 294 (2003). On the other hand, concern about the regulatory gaps created by such judicial invalidations of agency rules has led to an increase in use of the remedy of remand without vacatur, under which that the regulation remains in effect (if not actively enforced) while the agency rectifies its errors. See Levin, *supra*, at 295–96; see also Kristina Daugirdas, Note, Evaluating Remand Without Vacatur: A New Judicial Remedy for Defective Agency Rulemakings, 80 *N.Y.U. L. Rev.* 278 (2005) (analyzing application of remand without vacatur within the D.C. Circuit).

<sup>144</sup> This is not only because more abortion regulations are being administratively promulgated, but also because the regulations themselves may lead to state administrative proceedings, such as license hearings or enforcement actions, with which federal courts may be unwilling to interfere. See *Younger v. Harris*, *Burford v. Sun Oil Co.*, 319 U.S. 315, 325–33 (1943). To date, arguments for abstention in abortion challenges have been largely unsuccessful, but these challenges usually involve claims that the statutes or regulations at issue are facially unconstitutional; where claims are brought to the application of regulatory requirements in specific cases, courts seem more disposed to consider abstention. See, e.g., *Kenneally v. Lungren*, 967 F.2d 329 (9th Cir.1992); *Women's Community Health Ctr v. Texas Health Facilities Comm'n*, 685 F.2d 974 (5th Cir. 1982); see also *Planned Parenthood v. Atchinson*, 126 F.3d 1042, 1046–48 & n.3 (6th Cir. 1997) (rejecting abstention in challenge to application of state certificate of need requirement to proposed abortion clinic, but noting that "argument in favor of abstention becomes much more persuasive" when state administrative proceedings had commenced). The courts' general willingness to sustain abortion health regulations against facial challenges suggests that providers unable to comply with regulatory requirements increasingly may need to seek administrative relief and pursue as applied challenges if their requests for relief are denied, raising the likelihood of abstention. Moreover, even if federal courts do not abstain, simply pursuing routes of administrative relief will entail greater involvement in agency proceedings.

against singling out of abortion and resultant burdens on particular providers, subconstitutional doctrines of administrative law may hold greater promise.