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UNITED STATES DISTRICT COURT DISTRICT OF ARIZONA

Tucson Woman's Clinic, et. al.,

Plaintiffs,

v.

Catherine Eden, in her capacity as Director of the Arizona Department of Health Services, et. al.,

Defendants.

No. CIV 00-141 TUC RCC

MEMORANDUM REGARDING SUMMARY JUDGMENT MOTIONS FILED BY THE DEFENDANTS APRIL 30, 2001

Today, the defendants have jointly filed six motions for partial summary judgment. The defendants have filed individual motions for each of the claims made by the plaintiffs in their Fourth Amended Complaint in an attempt to better delineate those claims and because different facts are generally applicable to each. The six motions collectively address all of the claims in the plaintiffs' case and demonstrate why judgment in this matter should be entered for the defendants as a matter of law.

I. STANDARD OF REVIEW.

To obtain summary judgment, the defendants are not required to "disprove" the plaintiffs' allegations—they need only point out plaintiffs' *lack of evidence* as to any *one* essential element of their claims. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Under Rule 56, Fed. R. Civ. P., the "burden then shifts to the [plaintiffs] to present evidence sufficient to support a verdict in [their] favor on every element" of every claim. *In re Apple Computer Secs. Litig.*, 886 F.2d 1109, 1113 (9th Cir. 1989).

Unless plaintiffs offer sufficient evidence for a jury to return a verdict in their favor, Rule 56(c) "'mandates the entry of summary judgment." *McGlinchy v. Shell Chem. Co.*, 845 F.2d 802, 808 (9th Cir. 1988) (quoting *Celotex*, 477 U.S. at 322). A "scintilla" of evidence is not enough, *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986), nor are speculative or inconclusive inferences drawn from circumstantial evidence, *In re Software Toolworks, Inc. Secs. Litig.*, 789 F. Supp. 1489, 1502 (N.D. Cal. 1992). Although inferences that are reasonable may be drawn in favor of the party opposing summary judgment, such inferences may not be used to refute affirmative evidence. *T.W. Elec. Serv. v. Pac. Elec. Contractors Ass'n*, 809 F.2d 626, 631 (9th Cir. 1987); *Kline v. Dir., OWCP, U.S. Dep't of Labor*, 877 F.2d 1175, 1179-80 (3td Cir. 1989). Moreover, where the evidence in support of summary judgment is clear, the court is not required to defer to the contrary opinion of an expert offered in opposition to summary judgment. *In re Apple Computer Secs. Litig*, 886 F.2d at 1116. In this case, plaintiffs have not—and cannot—bring forth competent evidence establishing the necessary elements of each of their claims necessary to

370053 (5th Cir. Apr. 13, 2001). Copies of both of those opinions are attached to this memorandum (as Exs. A and B, respectively), for ease of reference. In addition, a copy of the district court's opinion in the Women's Medical Center case (Women's Medical Center of Northwest Houston v. Archer, No. H-99-3639, slip op. (S.D.Tex., Dec. 29, 1999)) is attached as Exhibit C.

For the reasons set forth in the motions, memoranda and statements of fact, plaintiffs have failed in several respects to develop competent evidence that could support essential elements of their claims. Thus, all claims against the defendants should be dismissed with prejudice.

April 30, 2001.

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ExhibitA

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United States Court of Appeals, Fourth Circuit.

GREENVILLE WOMEN'S CLINIC; Charleston Women's Medical Clinic,

Incorporated; William Lynn, MD, on behalf of themselves and their patients seeking abortions, Plaintiffs-Appellees,

v.

Douglas E. BRYANT, in his official capacity as Commissioner of South Carolina Department of Health and Environmental Control;

Charles M. Condon, in his

official capacity as Attorney General of the State of South Carolina,

Defendants-Appellants,

Governor of South Carolina, Defendant.
Greenville Women's Clinic; Charleston Women's
Medical Clinic, Incorporated;

William Lynn, MD, on behalf of themselves and their patients seeking abortions, Plaintiffs-Appellees,

v.

Governor of South Carolina, Defendant-Appellant, and

Douglas E. Bryant, in his official capacity as
Commissioner of South Carolina
Department of Health and Environmental Control;
Charles M. Condon, in his
official capacity as Attorney General of the State of
South Carolina,
Defendants.

Greenville Women's Clinic; Charleston Women's Medical Clinic, Incorporated; William Lynn, MD, on behalf of themselves and their patients seeking abortions, Plaintiffs-Appellees,

v.

Douglas E. Bryant, in his official capacity as
Commissioner of South Carolina
Department of Health and Environmental Control;
Charles M. Condon, in his
official capacity as Attorney General of the State of
South Carolina,
Defendants-Appellants,
Governor of South Carolina, Defendant.

Nos. 99-1319, 99-1710 and 99-1725.

Argued Jan. 27, 2000. Decided Aug. 15, 2000.

Abortion clinics and abortion provider brought suit

challenging constitutionality of South Carolina regulation establishing licensure and operational requirements for physicians' offices and medical clinics performing five or more first trimester abortions per month. After temporary restraining order (TRO) was entered, the United States District Court for the District of South Carolina, at Greenville, William B. Traxler, Jr., J., 66 F.Supp.2d 691, concluded that regulation violated due process clause and equal protection clause. On appeal, the Court of Appeals, Niemeyer, Circuit Judge, held that: (1) regulation did not violate due process clause, and (2) regulation did not violate equal protection clause.

Reversed.

Hamilton, Senior Circuit Judge, dissented and filed opinion.

West Headnotes

[1] Administrative Law and Procedure 390.1 15Ak390.1

[1] Constitutional Law 38 92k38

Anticipated impact of statute or regulation which is subject of facial constitutional challenge is generally not an appropriate basis on which to strike down statute or regulation.

[2] Constitutional Law 274(5) 92k274(5)

State regulations that do not reach into heart of protected liberty do not violate the abortion-decision right grounded in due process clause. U.S.C.A. Const.Amend. 14.

[3] Constitutional Law 274(5) 92k274(5)

If abortion regulation serves a valid purpose, that is, one not designed to strike at the right itself, the fact that regulation also has incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate regulation as violative of due process clause. U.S.C.A. Const.Amend. 14.

[4] Abortion and Birth Control \$\iiin\$-0.5 4k0.5

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[4] Constitutional Law 274(5) 92k274(5)

One valid purpose served by abortion regulation which is subject of a due process challenge is a state's effort to further health or safety of a woman seeking an abortion. U.S.C.A. Const.Amend. 14.

[5] Constitutional Law @==274(5) 92k274(5)

If health regulation is unnecessary and has purpose or effect of presenting a substantial obstacle to a woman seeking an abortion, regulation will be found to impose an undue burden on the abortion-decision right grounded in due process clause. U.S.C.A. Const.Amend. 14.

[6] Abortion and Birth Control \$\infty\$=1.30 4k1.30

[6] Constitutional Law @--287.2(1) 92k287.2(1)

[6] Constitutional Law @-287.2(5) 92k287.2(5)

[6] Constitutional Law **296(1)** 92k296(1)

South Carolina regulation establishing licensure and operational requirements for physicians' offices and medical clinics performing five or more first trimester abortions per month did not violate due process clause; regulation, which was based on national healthcare standards for abortions, was rationally related to protecting health of women seeking abortions, and while the \$23-\$75 increased cost per abortion due to compliance could make it more difficult and would make it more expensive to procure abortion, there was no evidence that it would impose an undue burden on a woman's ability to make the decision to have an abortion. U.S.C.A. Const.Amend. 14; S.C.Code Reg. 61-12.

[7] Constitutional Law @==211(1) 92k211(1)

At its essence, equal protection clause requires that all persons similarly situated be treated alike. U.S.C.A. Const.Amend. 14.

[8] Constitutional Law © 211(1) 92k211(1)

Equal protection directive that all persons similarly situated be treated alike does not deny states the power to treat different classes of persons in different ways. U.S.C.A. Const.Amend. 14.

[9] Constitutional Law @==213.1(2) 92k213.1(2)

To withstand scrutiny under equal protection clause, a classification generally must be reasonable, not arbitrary, and must rest upon some ground of difference having a fair and substantial relation to object of legislation. U.S.C.A. Const.Amend. 14.

[10] Constitutional Law ©=213.1(1) 92k213.1(1)

If regulation impinges upon a fundamental right protected by Constitution, or operates to peculiar disadvantage of a suspect class, classification will be strictly scrutinized under equal protection clause. U.S.C.A. Const.Amend. 14.

[11] Constitutional Law 213.1(2) 92k213.1(2)

While classifications in legislation ordinarily will be upheld against an equal protection challenge if there is any reasonably conceivable state of facts that could provide a rational basis for classification, a regulation subject to strict scrutiny will be upheld only if it is justified by a compelling state interest. U.S.C.A. Const.Amend. 14.

[12] Constitutional Law 287.2(1) 92k287.2(1)

[12] Constitutional Law 287.2(5) 92k287.2(5)

[12] Constitutional Law @==296(1) 92k296(1)

Rational basis standard applied to abortion providers' equal protection challenge to South Carolina regulation establishing licensure and operational requirements for physicians' offices and medical clinics performing five or more first trimester abortions per month, where regulation did not impinge on a fundamental right and regulation was not directed at a suspect class. U.S.C.A. Const.Amend. 14; S.C.Code Reg. 61-12.

[13] Abortion and Birth Control \$\infty\$1.30

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4k1.30

[13] Constitutional Law @==230.3(1) 92k230.3(1)

[13] Constitutional Law 230.3(8.1) 92k230.3(8.1)

[13] Constitutional Law 240(1) 92k240(1)

[13] Constitutional Law 240(6.1) 92k240(6.1)

South Carolina regulation establishing licensure and operational requirements for physicians' offices and medical clinics performing five or more first trimester abortions per month did not violate equal protection clause; South Carolina had a rational basis for regulating abortion clinics while not regulating other healthcare facilities, and line drawn by regulation at five abortions per month was rationally related to its purpose of protecting health of abortions patients. U.S.C.A. Const.Amend. 14; S.C.Code Reg. 61-12.

*159 ARGUED: Floyd Matlock Elliott, Haynsworth, Marion, McKay & Guerard, L.L.P., Greenville, South Carolina, for Appellants. Bonnie Scott Jones, The Center for Reproductive Law & Policy, New York, New York, for Appellees. ON BRIEF: George Dewey Oxner, Jr., Boyd Benjamin Nicholson, Jr., Haynsworth, Marion, McKay & Guerard, L.L.P., Greenville, South Carolina; Nancy Staats Layman, Legal Division, Department of Health Environmental Control, Columbia, South Carolina; Charles Molony Condon, James Emory Smith, Jr., Office of the Attorney General, Columbia, South Carolina; Charles E. Carpenter, Jr., Donald V. Richardson, III, S. Elizabeth Brosnan, Richardson, Plowden, Carpenter & Robinson, P.A., Columbia, South Carolina, for Appellants. Randall Hiller. Greenville, South Carolina, for Appellees.

Before NIEMEYER, Circuit Judge, HAMILTON, Senior Circuit Judge, and SMALKIN, United States District Judge for the District of Maryland, sitting by designation.

Reversed by published opinion. Judge NIEMEYER wrote the opinion, in which Judge SMALKIN joined. Senior Judge HAMILTON wrote a dissenting opinion.

OPINION

NIEMEYER, Circuit Judge:

This case presents the important question of whether South Carolina's regulation establishing standards for licensing abortion clinics--Regulation 61-12 of the Carolina Department of Health Environmental Control, S.C.Code Ann. Regs. 61-12 (eff. June 28, 1996)--violates the Due Process Clause and the Equal Protection Clause of the Fourteenth Amendment by placing an undue burden on women's decisions to seek abortions and by distinguishing between clinics that perform a specified number of abortions and those that do not. Two abortion clinics and an abortion provider filed this action, on behalf of themselves and their patients, facially challenging the constitutionality of the Regulation. The district court concluded that the Regulation violated both of these clauses of the Fourteenth Amendment, declared the Regulation "invalid," and enjoined its enforcement.

As amplified herein, we reverse this decision and uphold the constitutionality of Regulation 61-12 because (1) the Regulation serves a valid state interest and is little more than a codification of national medical- and abortion- association recommendations designed to ensure the health and appropriate care of women seeking abortions; (2) the Regulation does not "strike at the [abortion] right itself," Planned Parenthood v. Casey, 505 U.S. 833, 874, 112 S.Ct. 2791, 120 L.Ed.2d 674 (1992) (joint opinion of O'Connor, Kennedy, and Souter, JJ.); (3) the increased costs of abortions caused by implementation of the Regulation, while speculative, are even yet modest and have not been shown to burden the ability of a woman to make the decision to have an abortion; and (4) abortion clinics may rationally be regulated as a class while other clinics or medical practices are not.

I

Prior to 1995, South Carolina regulated clinics at which second- trimester abortions *160 were performed. See S.C.Code Ann. §§ 44-41- 20(b), -70(b) (Law.Coop.1985); S.C.Code Ann. Regs. 61-12 (1982) (entitled "Minimum Standards for Licensing Clinics Performing Abortions"). The regulation under this earlier statute contained chapters covering abortion-clinic management, laboratory facilities and procedures, medical records and reports, clinic design and construction, and patient-care areas. See S.C.Code Ann. Regs. 61-12 (1982).

In 1995, the South Carolina legislature amended its statute to require any "facility in which any second trimester or five or more first trimester abortions are

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performed in a month" to be licensed as an abortion clinic by the Department of Health and Environmental Control ("DHEC"). S.C.Code Ann. §§ 44-41-10(C), -75(A) (West Supp.1999). In addition, it directed the DHEC to

promulgate regulations concerning sanitation, housekeeping, maintenance, staff qualifications, emergency equipment and procedures to provide emergency care, medical records and reports, laboratory, procedure and recovery rooms, physical plant, quality assurance, infection control, and information on and access to patient follow-up care necessary to carry out the purposes of this section.

Id. § 44-41-75(B). The DHEC responded by promulgating Regulation 61-12, effective June 28, 1996. See S.C.Code Ann. Regs. 61-12 (West Supp.1998) (hereinafter "Regulation 61-12" or "the Regulation").

In developing Regulation 61-12, the DHEC built on the preexisting version of its Regulation 61-12, as well as other DHEC regulations covering different types of healthcare facilities. The DHEC also consulted various medical standards and guidelines issued by medical care organizations, including groups dedicated to protecting abortion rights. These sources included: (1) Standards for Obstetric-Gynecologic Services (7th ed.1995), issued by the American College of Obstetricians and Gynecologists ("the ACOG"); (2) Manual of Medical Standards and Guidelines (1994), issued by Planned Parent-hood, which the manual describes as encouraging affiliates "to develop abortion services if such a need exists in the community and resources are available for conducting a safe and effective program"; and (3) Standards for Abortion Care (1988), a set of standards, the "purpose" of which is "to promote high quality care for all women seeking abortions" and "serve as a useful resource for local and state agencies charged with safeguarding the public's health," issued by the National Abortion Federation, which the standards describe as "an organization specifically committed to the provision and accessibility of high quality abortion services for all women." The DHEC also reviewed abortion regulations from other states and referenced the Guidelines for Construction and Equipment of Hospital and Medical Facilities (1992-93), a document issued by the American Institute of Architects, which purports to provide "model standards" "constructing and equipping new medical facility projects" and for "renovation or replacement work."

In addition to consulting established sources, the DHEC conducted public hearings, during which it

received suggestions from the abortion clinics that are parties to this case, incorporating some of them in new Regulation 61- 12. The new Regulation, entitled "Standards for Licensing Abortion Clinics," S.C.Code Ann. Regs. 61-12 (West Supp.1998), contains ten parts which address a range of medical, safety, and administrative requirements:

Part I, "Definitions and Requirements for Licensure," defines an abortion clinic as "[a]ny facility, other than a hospital ... in which any second trimester or five or more first-trimester abortions per month are performed." *Id.* § 101(B). It makes the operation of an abortion clinic without a license illegal. *See id.* § 102(A). It provides for periodic inspections, including at least one annually, and grants inspectors the authority to copy all documents required in the course of inspections. *See* *161 id. § 102(F). And it authorizes sanctions for non-compliance with the Regulation in the form of monetary penalties, as well as denial, suspension, or revocation of the license. *See id.* § 103.

Part II, "Administration and Management," requires every facility to formulate and review annually its policies and procedures. See id. § 201(B). It requires that each clinic maintain various administrative documents on file. See id. § 203. Every employee is required to complete in-service training and undergo a tuberculin skin test, see id. § 204(B), (F), and any employee diagnosed with a contagious disease is prohibited from performing certain work at the clinic, see id. § 204(D). It requires that every abortion be performed by a physician who is licensed by the State and requires that every clinic be affiliated with a physician who has admitting privileges at a local hospital. See id. § 205(C). A registered nurse must supervise all nursing care, and an ultrasound test may be conducted only by a person who has completed a course in ultrasonography. See id. § 205(D), (F). Each facility must display a copy of a statement specifying patients' rights, including the rights to dignity, privacy, and safety. See id. § 209.

Part III, "Patient Care," provides that each facility must have certain written patient-care policies and procedures to ensure professional and safe care and that no clinic may serve patients whose needs exceed the clinic's resources and capabilities. See id. § 301. Specified drugs and tools must be present, see id. § 303, and laboratory services must be available, either on site or through an arrangement with a laboratory, see id. § 304(A). A number of laboratory tests must be performed, including a urinalysis and testing for

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sexually transmitted diseases. See id. § 304(B), (C), (D). Staff at abortion clinics must have admitting privileges at a local hospital or have documented arrangements for emergency transfer to a hospital. See id. § 305(A). And facilities that perform abortions beyond the 14th week of pregnancy must meet additional requirements. See id. § 309.

Part IV, "Medical Records and Reports," requires that every abortion clinic maintain and retain for ten years specified categories of information and requires that the documents be treated as confidential. See id. §§ 401, 402. Abortion clinics must report to the DHEC all abortions performed, any fetal deaths meeting certain criteria, and any accidents or incidents. See id. § 403.

Part V, "Functional Safety and Maintenance," requires written safety policies and procedures and a disaster-preparedness plan and sets standards for maintenance, requiring that facilities be kept in good repair. See id. §§ 501-503.

Part VI, "Infection Control and Sanitation," requires certain daily sterilization procedures, see id. § 602, mandates proper laundering of linen and washable goods, see id. § 603, and requires the facility to be kept neat, clean, and free of insects, see id. § 604. Garbage and waste are required to be disposed of in a manner designed to prevent transmission of disease. See id. § 605. Outside areas must be maintained so as to minimize fire hazards, havens for insects and rodents, and unsafe conditions from accumulations of water, ice, and snow. See id. § 606.

Part VII, "Fire Protection and Prevention," requires clinics to have particular firefighting equipment and an evacuation plan and to conduct fire drills and inspections. See id. § 701.

Part VIII, "Design and Construction," requires that each abortion clinic have facilities for the care of each patient that meet applicable design and construction laws. See id. §§ 801, 802. New buildings or additions must satisfy building code requirements. See id. §§ 803, 804. Each facility must provide an adequate number of examination or procedure rooms, and each procedure room must have a suitable table and other equipment. See id. § 807(A), (B). Recovery areas must meet *162 particular requirements and there must be a room for temporary storage of waste, as well as an area to accommodate sterilization procedures. See id. § 807(E), (F).

Part IX, "Prerequisites for Initial Licensure," sets forth

the necessary documentation for obtaining a license from the DHEC and the certification that must be acquired for various physical items.

Finally, Part X states that conditions which arise and have not previously been addressed in the Regulation must be managed in accordance with the best practices as interpreted by the DHEC.

On June 27, 1996, one day before Regulation 61-12 was to take effect, the Greenville Women's Clinic, the Charleston Women's Medical Clinic, Inc., and Dr. William Lynn (collectively, the "abortion clinics") brought this action seeking a declaratory judgment that Regulation 61-12 is unconstitutional on its face because, among other things, it would violate their due process and equal protection rights, as well as those of their patients. They also sought an order enjoining enforcement of the Regulation and requesting attorneys fees and costs pursuant to 42 U.S.C. § 1988. The district court issued a temporary restraining order on June 19, 1996, which, by consent of the parties, was converted to a preliminary injunction. Finally, on February 5, 1999, the district court declared the Regulation invalid in its entirety.

The Greenville Women's Clinic, which has operated in Greenville, South Carolina, since 1978, has two licensed physicians who perform a combined average of more than 2,700 abortions per year. The physicians at the clinic testified that even prior to the promulgation of Regulation 61-12, their clinic operated in substantial compliance with requirements. They estimated that the additional cost of full compliance would be \$22.68 per abortion. The district court found that, prior to the Regulation's promulgation, the cost of an abortion was between \$325 and \$480 if the abortion was not complicated and was performed during the first trimester. The court found that the additional cost of full compliance for Greenville Women's Clinic would be in the range of \$23-\$32 per abortion.

The Charleston Women's Medical Clinic, Inc., which has operated in Charleston, South Carolina, for about 28 years, performs, on average, more than 2,400 abortions per year. That clinic is operated by a licensed physician and a licensed practical nurse. The district court found that compliance with Regulation 61-12 by the Charleston Women's Medical Clinic would cost between \$36 and \$75 per abortion.

Dr. William Lynn, who is a licensed physician, has conducted his practice since 1980 from two locations-

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in Beaufort, South Carolina (approximately 70 miles southwest of Charleston) and in Greenville, South Carolina. Dr. Lynn performs, on average, more than 900 abortions each year at the two sites. He testified that Regulation 61-12 would require him to undertake costly modifications to his Beaufort facility, and the district court found that his cost per abortion would increase by an amount between \$116 and \$368. The district court also concluded that the increased costs for Dr. Lynn's Beaufort facility would "likely force [Dr. Lynn] to cease performing abortions in his Beaufort office." *Greenville Women's Clinic v. Bryant*, 66 F.Supp.2d 691, 717 (D.S.C.1999).

There was no direct evidence about how many other abortion clinics in South Carolina would be affected by the Regulation or about the extent of any such impact. No woman who wanted an abortion or who claimed to be threatened by Regulation 61-12 was made a party to the action or testified before the district court, and no survey evidence of women in South Carolina was presented to demonstrate the likely effect that Regulation 61-12 would have on their decisions to obtain an abortion.

Following a bench trial, the district court concluded that the Regulation *163 "serve[s] no legitimate state interest ... [g]iven the lack of evidence that the regulation will operate to improve the health care currently being received in this state." Greenville Women's Clinic, 66 F.Supp.2d at 735. It continued that even if it did serve a valid purpose, the Regulation "places a substantial obstacle in the path of women seeking first trimester abortions and, thereby, imposes an undue burden on the woman's fundamental right to choose to undergo the procedure." Id. The undue burden, the court found, resulted from increased costs, delays in the ability to obtain abortions, decreased availability of abortion clinics, increased distances to travel to clinics, unlimited inspections of clinics, and compromises to patient confidentiality. See id. at 735-36. Accordingly, the court held that Regulation 61-12 violated women's Fourteenth Amendment due process rights. See id. at 736. The district court also ruled that the Regulation violated the abortion clinics' equal protection rights under either a strict scrutiny or a rational-basis standard of review because the Regulation "singles out physicians and clinics where abortions are performed regularly ... and imposes upon them requirements which are not imposed upon comparable procedures and not even upon all physicians who perform first trimester abortions." Id. at 742. Finally, the district court, acting under 42 U.S.C. § 1988, awarded the abortion clinics attorneys

fees and costs in the amount of \$324,040.

South Carolina appeals from the district court's judgment declaring Regulation 61-12 unconstitutional and enjoining its enforcement and from the award of attorneys fees.

II

South Carolina contends first that the district court's due process analysis is supported by neither the record nor the law. It maintains that Regulation 61-12, which is based on national healthcare standards for abortions, is rationally related to protecting the health of women seeking abortions, "even if such regulations might have the incidental [e]ffect of causing the price to obtain an abortion to increase." South Carolina notes that the abortion clinics and their experts agree as to the appropriateness of the national standards incorporated in the Regulation, and the Greenville Women's Clinic, the largest of the plaintiffs, admitted that it was already in substantial compliance with virtually all of the Regulation's requirements. The State argues that to the extent any clinic does not comply with Regulation 61-12, compliance will improve the quality of medical care for women seeking abortions. South Carolina also argues that the evidence does not support the conclusion that the increased cost of an abortion would impose a substantial obstacle for women in South Carolina seeking abortions.

The abortion clinics respond that the Regulation does not further a valid state interest because (1) it creates costly and unnecessary requirements which are more likely to harm than to protect the health of abortion patients and (2) the DHEC's drafting process indicates that the DHEC was not concerned with protecting the health of such women. The clinics acknowledge that the DHEC may have relied on standards and guidelines of national medical groups, but they argue that these are just that--standards and guidelines--and are neither designed to serve as mandatory directives nor appropriate for that purpose. Finally, the abortion clinics contend that, in any event, Regulation 61-12 imposes an undue burden on women seeking abortions in South Carolina because it would increase the price of abortions and force Dr. Lynn to cease performing abortions at his Beaufort facility.

The abortion clinics undertook a heavy burden in bringing a facial challenge to the constitutionality of Regulation 61-12. Because of the nature of facial challenges, they could not present the district court with a concrete factual circumstance--a particular case

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or controversy--to which to *164 apply the Regulation. The clinics therefore must argue about the Regulation's impact generally and prospectively, the type of action typically undertaken by legislatures, not courts. Because a trial on a facial challenge can focus only on arbitrarily selected hypotheticals to which the Regulation might apply, a court is required to speculate about the Regulation's overall effect.

[1] In this case, for example, the district court was not given--and could not be given--any data from South Carolina patients about the impact that particular costs had on their decision to seek an abortion. It was given only estimates by "experts." Accordingly, the impact of the Regulation in any given situation could only have been anticipated. Such anticipation, however, is generally not an appropriate basis on which to strike down statutes and regulations. See Bowen v. Kendrick, 487 U.S. 589, 612-13, 108 S.Ct. 2562, 101 L.Ed.2d 520 (1988) (noting that "[i]t has not been the Court's practice" to strike down a statute on a facial challenge "in anticipation" of particular circumstances, even if the circumstances would amount to a "likelihood").

Because of the conceptual difficulties that attend to ruling on the constitutionality of a statute in the abstract, the Supreme Court has held that "[a] facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid." United States v. Salerno, 481 U.S. 739, 745, 107 S.Ct. 2095, 95 L.Ed.2d 697 (1987); see also Rust v. Sullivan, 500 U.S. 173, 183, 111 S.Ct. 1759, 114 L.Ed.2d 233 (1991) (a facial challenge will fail if an act "can be construed in such a manner that [it] can be applied to a of individuals without infringing constitutionally protected rights").

In Planned Parenthood v. Casey, 505 U.S. 833, 112 S.Ct. 2791, 120 L.Ed.2d 674 (1992), the Supreme Court ruled that a statute regulating abortion was invalid because "in a large fraction of cases in which [it] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." Id. at 895, 112 S.Ct. 2791 (majority opinion) (emphasis added). Whether this holding displaced the Salerno standard for facial challenges in abortion cases has been the subject of considerable debate among the circuits. Compare, e.g., Planned Parenthood v. Lawall, 180 F.3d 1022, 1025-27 (9th Cir.1999) (applying Casey standard to facial challenge to abortion restriction); Women's Med. Prof'l Corp. v. Voinovich, 130 F.3d 187, 193-96 (6th Cir.1997)

(same); Jane L. v. Bangerter, 102 F.3d 1112, 1116 (10th Cir.1996) (same); Planned Parenthood v. Miller, 63 F.3d 1452, 1456-58 (8th Cir.1995) (same); Casey v. Planned Parenthood, 14 F.3d 848, 863 n. 21 (3d Cir.1994) (same), with Barnes v. Moore, 970 F.2d 12, 14 n. 2 (5th Cir.1992) (per curiam) ("we do not interpret Casey as having overruled, sub silentio, longstanding Supreme Court precedent governing challenges to the facial constitutionality of statutes"); see also Okpalobi v. Foster, 190 F.3d 337, 354 (5th Cir.1999) (noting that subsequent Fifth Circuit decisions were arguably inconsistent with application of the Salerno standard). This circuit, sitting en banc, acknowledged the uncertainty as to which standard applies but declined to resolve the issue. See Planned Parenthood v. Camblos, 155 F.3d 352, 358-59 & n. 1 (4th Cir.1998) (en banc) ("Because we conclude ... that the [challenged abortion regulation] is facially constitutional under either the Salerno or the Casey standard, we need not, and do not, decide which of these two standards applies in facial challenges to abortion statutes"). Previously, a panel of this court had stated its agreement with the Fifth Circuit position in Barnes v. Moore, observing that until the Supreme Court specifically overrules Salerno in the abortionregulation context, "this Court is bound to apply the Salerno standard as it has been repeatedly applied in the context *165 of other abortion regulations reviewed by the Supreme Court ... and in the context of challenges to legislative acts based on other constitutional grounds." Manning v. Hunt, 119 F.3d 254, 268 n. 4 (4th Cir.1997) (emphasis added).

While we believe that the observation in Manning was part of the court's holding because application of Salerno was necessary to the ruling in that case and not dictum, we add the observation that the logic of the Salerno test is necessary to show deference to legislatures, particularly in light of the limitation imposed by Article III of the Constitution that the judiciary act only in cases and controversies. See U.S. Const. art. III, § 2. As we explain below, when the abortion clinics are confronted with Salerno 's requirement that no set of circumstances exists under which Regulation 61-12 would be valid, they fail, if for no other reason, because the impact on the Greenville Women's Clinic is so modest. Even when we apply a less deferential standard than that articulated in Salerno, we nevertheless conclude in this case that the record provides no evidence from which to conclude that Regulation 61-12 would present a "substantial obstacle" to "a large fraction" of women in South Carolina who might seek an abortion at a clinic subject to Regulation 61-12. Casey, 505 U.S. at 895, 112

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S.Ct. 2791 (majority opinion).

The record contains evidence from several abortion providers, only one of which would be adversely affected in any significant way in providing abortion services, Dr. Lynn's Beaufort facility. Moreover, even for women in Beaufort, no evidence suggests that they could not go to the clinic in Charleston, some 70 miles away. Nor are we provided with evidence of the impact that Regulation 61-12 would have on other South Carolina abortion clinics. Thus, inherent in our discussion of the impact that Regulation 61- 12 would have on women's abortion rights is the inability to decide a concrete case; we must speculate about the impact on all relevant women to determine, under the Casey standard, whether a large fraction would encounter a substantial obstacle to their choice to seek an abortion, an analysis that the record simply does not permit. Thus, on the abortion clinics' failure to present evidence that would satisfy either of the possible standards, we fall back on the Regulation's presumptive constitutionality.

The principles of the abortion right itself are now well-established. Beginning in 1973, women were found to have a fundamental right grounded in the Fourteenth Amendment to end a pregnancy by aborting the life of the fetus. See Roe v. Wade, 410 U.S. 113, 153-56, 93 S.Ct. 705, 35 L.Ed.2d 147 (1973); see also Maher v. Roe, 432 U.S. 464, 474, 97 S.Ct. 2376, 53 L.Ed.2d 484 (1977). The Court in Roe stated that the "right of privacy ... is broad enough to encompass a woman's decision whether or not to terminate her pregnancy." Roe, 410 U.S. at 153, 93 S.Ct. 705.

Following Roe, which recognized that the abortiondecision right was not absolute but subject to some regulation by the states, the Supreme Court decided numerous cases that uncovered difficulties in applying Roe and created widespread confusion. Accordingly, in 1992, the Court in Casey reexamined Roe and restated the applicable principles. In Casey, the Court rejected the trimester framework of Roe and adopted a revised "undue burden" standard to apply to challenged abortion regulations. Casey, 505 U.S. at 872-74, 112 S.Ct. 2791 (joint opinion of O'Connor, Kennedy, and Souter, JJ.). But it reaffirmed the "essential holding" of Roe--that a woman has a constitutional right to "choose to have an abortion before viability and to obtain it without undue interference from the State." Id. at 846, 112 S.Ct. 2791 (majority opinion). The scope of this right, however, is framed by the State's "legitimate interests from the outset of the pregnancy in protecting the

health of the *166 woman and the life of the fetus that may become a child." *Id*.

Most recently, in *Stenberg v. Carhart*, 530 U.S. ----, 120 S.Ct. 2597, 147 L.Ed.2d 743 (2000), the Supreme Court reaffirmed the principles articulated in the joint opinion in *Casey* that: (1) a woman has a constitutional right "to choose to terminate her pregnancy" before viability of the fetus "undue burden" on the woman's right to choose to terminate her pregnancy before fetal viability is unconstitutional; and (3) a State may regulate post-viability abortions "except where [they are] necessary, in appropriate medical judgment, for the preservation of the life or health of the mother." 530 U.S. at ----, 120 S.Ct. at 2600 (internal quotation marks and citations omitted).

In preserving the right of a woman to choose to have an abortion, the Court in Casey emphasized that the right is grounded in the liberty protected by the Fourteenth Amendment--"[t]he controlling word in the cases before us is 'liberty.' " 505 U.S. at 846, 112 S.Ct. 2791 (majority opinion); see also id. at 871, 112 S.Ct. 2791 (joint opinion of O'Connor, Kennedy, and Souter, JJ.) ("The woman's right to terminate her pregnancy before viability is ... a component of liberty"). And the liberty so recognized is defined as the right of a woman herself--not her husband, her parent, her doctor, or others--to make the decision to have an abortion. Id. at 877, 112 S.Ct. 2791 (joint opinion of O'Connor, Kennedy, and Souter, JJ.); see also Stenberg, 530 U.S. at ----, 120 S.Ct. at 2649. Only when the State unduly burdens the ability of a woman to make the abortion decision "does the power of the State reach into the heart of the liberty protected by the Due Process Clause." Casey, 505 U.S. at 874, 112 S.Ct. 2791 (joint opinion of O'Connor, Kennedy, and Souter, JJ.).

Accordingly, to the extent that state regulations interfere with the woman's status as the ultimate decisionmaker or try to give the decision to someone other than the woman, the Court has invalidated them. See Casey, 505 U.S. at 887-98, 112 S.Ct. 2791 (majority opinion) (striking down provision which required a physician performing an abortion on a married woman to obtain a statement from her indicating that she had notified her husband); Thornburgh v. American College of Obstetricians and Gynecologists, 476 U.S. 747, 767, 106 S.Ct. 2169, 90 L.Ed.2d 779 (1986)(invalidating reporting requirements that "raise the specter of public exposure and harassment of women who choose to exercise their personal, intensely private, right, with their physician,

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to end their pregnancy"); Bellotti v. Baird, 443 U.S. 622, 643, 99 S.Ct. 3035, 61 L.Ed.2d 797 (1979) (plurality opinion) (ruling that "if the State decides to require a pregnant minor to obtain one or both parents' consent to an abortion, it must also provide an alternative procedure whereby authorization for the abortion can be obtained" (footnote omitted)); Planned Parenthood v. Danforth, 428 U.S. 52, 74, 96 S.Ct. 2831, 49 L.Ed.2d 788 (1976) (holding that "the State does not have the constitutional authority to give a third party an absolute, and possibly arbitrary, veto over the decision of the physician and his patient to terminate the patient's pregnancy").

[2][3][4][5] On the other hand, state regulations that do not "reach into the heart" of the protected liberty do not violate the abortion-decision right. Casey, 505 U.S. at 874, 112 S.Ct. 2791 (joint opinion of O'Connor, Kennedy, and Souter, JJ.). If a regulation serves a valid purpose--"one not designed to strike at the right itself"--the fact that it also has "the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it." Id. One such valid purpose is a State's effort to "further the health or safety of a woman seeking an abortion." Id. at 878, 112 S.Ct. 2791. Of course, if such health regulations are unnecessary and have the "purpose or effect of presenting a substantial obstacle to a woman seeking an abortion," they will be *167 found to "impose an undue burden on the right." Id.

maintaining the distinction between regulations that trammel the woman's right to choose to have an abortion--those that impose an undue burden-and those that merely have an incidental effect on the woman's decision, the Court has upheld, both before Casey and in Casey, various regulations, the costs and effects of which, while amounting to interference and intrusion, did not reach the core of the protected liberty. See, e.g., Casey, 505 U.S. at 886, 112 S.Ct. 2791 (majority opinion) (upholding 24-hour waiting period although it would require a woman to make two visits to a doctor and increase the woman's exposure to abortion protestors); id. at 900-01, 112 S.Ct. 2791 (upholding a recordkeeping and reporting provision that would increase the cost of some abortions); Webster v. Reproductive Health Services, 492 U.S. 490, 530, 109 S.Ct. 3040, 106 L.Ed.2d 410 (1989) (O'Connor, J., concurring) (regulation requiring medical tests is constitutional where "the cost of examinations and tests that could usefully and prudently be performed ... would only marginally, if at all, increase the cost of an abortion"); Parenthood v. Ashcroft, 462 U.S. 476, 490, 505, 103

S.Ct. 2517, 76 L.Ed.2d 733 (1983) (upholding requirement for a pathology report that would impose a "small cost"). Only when the increased cost of abortion is prohibitive, essentially depriving women of the choice to have an abortion, has the Court invalidated regulations because they impose financial burdens. See Akron v. Akron Ctr. for Reproductive Health, 462 U.S. 416, 434-39, 103 S.Ct. 2481, 76 L.Ed.2d 687 (1983) (holding unconstitutional a hospitalization requirement for certain abortions that more than doubled the cost of such abortions).

In the case before us, the South Carolina legislature directed the DHEC to promulgate regulations to address medical and safety aspects of providing abortions, as well as the recordkeeping and administrative practices of abortion clinics. directed, the DHEC drafted Regulation 61-12, building on the existing regulation, which applied to secondtrimester abortion clinics, and consulting abortion regulations from other states. The DHEC also obtained and incorporated guidelines for outpatient facilities published by the American Institute of Architects, as well as standards and guidelines issued by the ACOG, Planned Parenthood, and the National Abortion Federation. Indeed, Regulation 61-12 largely tracks these medical standards and guidelines.

For example, the National Abortion Federation requires that all medical staff at member facilities be proficient in CPR, and the ACOG recommends specific plans for training personnel in CPR; Regulation 61-12 requires that all professional staff members be certified to perform CPR. See S.C.Code Ann. Regs. 61-12, § 204(C). The National Abortion Federation recommends that nursing-care providers receive training and orientation; the Regulation requires that each facility have and execute a written orientation program. See id. § 203(E). The ACOG recommends that physicians who perform abortions in their offices provide for prompt emergency treatment or hospitalization; the Regulation requires that each facility have an agreement with a doctor who has hospital admitting privileges. See id. § 205(C)(2). The National Abortion Federation recommends that a registered nurse or physician be responsible for a variety of components of the abortion procedure and requires that a registered nurse monitor recovering patients if general anesthesia has been used; the Regulation requires that a licensed registered nurse supervise nursing care. See id. § 205(D)(1). The National Abortion Federation requires that emergency drugs be kept on hand to treat seven specific conditions; the Regulation requires the availability of

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drugs to treat the exact same conditions. See id. § 303(A)(1). The National Abortion Federation states that testing for gonorrhea *168 and chlamydia may be routinely provided; the Regulation requires testing for gonorrhea and chlamydia prior to each abortion procedure. See id. § 304(C). The ACOG and the National Abortion Federation recommend that counseling be offered; the Regulation requires that arrangements be made for consultation. See id. § 307. The ACOG recommends retaining accurate medical records for each patient for the time period required by law; the Regulation requires that such records be retained for ten years. See id. § 401. The ACOG recommends specific plans and procedures for health and safety; the Regulation requires written policies and procedures for safety. See id. § 501. The ACOG recommends that the examining room contain facilities for sterilization; the Regulation sets out specific sterilization procedures. See id. § 602. The ACOG recommends procedures for disposing of contaminated the Regulation requires specific waste supplies; treatment of refuse and waste disposal. See id. § 605. The ACOG recommends procedures for proper use of fire equipment, and the National Abortion Federation recommends regular emergency drills; the Regulation requires firefighting equipment, alarm systems, and fire drills. See id. § 701. Planned Parenthood requires procedure rooms large enough to accommodate a stretcher or gurney, post- procedure recovery rooms, and dressing rooms, and the National Abortion Federation requires that the operating table be located in a room of adequate dimensions, illumination, and ventilation; the Regulation requires particular physical facilities at abortion clinics, such as procedure rooms with doors wide enough to accommodate a stretcher or wheelchair, recovery rooms, storage rooms, and a dressing room. See id. § 807. Planned Parenthood requires a battery-operated light source for emergency backup; the Regulation requires emergency power and lighting. See id. § 809.

The national standards promulgated by such medical groups as the ACOG, the National Abortion Federation, and Planned Parenthood indisputably aim to protect the health of women seeking abortions and one states explicitly that it is intended to "serve as a useful resource for local and state agencies charged with safeguarding the public's health." National Abortion Federation, Standards for Abortion Care (1998). In relying upon such standards, the DHEC was appropriately focused on ensuring that abortion is "performed by medically competent personnel under conditions insuring maximum safety for the woman." Akron, 462 U.S. at 430 n. 12, 103 S.Ct. 2481 (quoting

Connecticut v. Menillo, 423 U.S. 9, 11, 96 S.Ct. 170. 46 L.Ed.2d 152 (1975) (per curiam)). A witness for the abortion clinics testified that guidelines from organizations such as the ACOG and the National Abortion Federation "provide our best current assessment as to what is appropriate care." witness explained that the ACOG has "only one interest," the healthcare of women, and if a doctor "deviate [s] from [the ACOG guidelines and standards] without a documented reason for [the] deviation, in a court of law it will be construed as malpractice." The witness recognized that the ACOG's guidelines "are commonly used and relied upon by obstetricians and gynecologists nationwide to determine the standard and the appropriate level of care for their patients," and that the National Abortion Federation standards are "a distillate of extensive experience by highly skilled and experienced [abortion] providers."

This testimony on behalf of the abortion clinics should itself be sufficient to establish that Regulation 61-12 was reasonably designed to promote South Carolina's valid interest in women's health. But the DHEC was also entitled to draw support for its use of the standards from the observations made by the Supreme Court in abortion cases that the ACOG and National Abortion Federation standards indicate the "general medical utility" of a particular procedure. Ashcroft, 462 U.S. at 487 n. 10, 103 S.Ct. 2517; see also Akron, 462 U.S. at *169 435-37, 103 S.Ct. 2481 (relying on changes in the ACOG standards, among others, to demonstrate lack of justification for hospitalization requirement); Simopoulos v. Virginia, 462 U.S. 506, 517, 103 S.Ct. 2532, 76 L.Ed.2d 755 (1983) (upholding abortion regulations after noting that "[o]n their face, the ... regulations appear to be generally compatible with accepted medical standards governing outpatient second-trimester abortions" publications from groups including the ACOG)); see also Stenberg, 530 U.S. at ----, 120 S.Ct. at 2612 (discussing the ACOG's "medical opinion" in analyzing the appropriateness of "[m]edical treatments and procedures"). Regulation 61-12 thus indisputably represents a reasonable attempt to further the health of abortion patients in South Carolina.

The abortion clinics argue that Regulation 61-12 exceeds and, in some cases, conflicts with the recommendations of these national groups. Further, they assert that the recommendations are just that-recommendations--and that requiring clinics to follow them will not necessarily safeguard or improve the health of abortion patients. The abortion clinics also note that some officials of these medical groups do not

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support mandatory compliance with the recommendations.

While Regulation 61-12 does in some instances exceed the standards of the ACOG, Planned Parenthood, and the National Abortion Federation, the bulk of the provisions comport with those guidelines, and any deviations are not substantial. Any contrary claim is belied by the abortion clinics' own testimony in this case. One of the doctors who owns the Greenville Women's Clinic, when asked whether Regulation 61-12 was "consistent with what you would consider to be the appropriate standards for abortion practice," responded that "[m]ost parts of the regulation we already comply with and do, but because it's good medical practice." Another abortion-clinic doctor testified that he complied with a number of the Regulation's provisions because "any doctor that's licensed by the State of South Carolina and any doctor that's completed an OB/GYN residency successfully would do that in the normal operation." The fact that not all healthcare professionals agree with the adoption of each specific aspect of the Regulation is immaterial in light of South Carolina's "considerable discretion" in adopting licensing requirements aimed at the health of women seeking abortions. Simopoulos, 462 U.S. at 516, 103 S.Ct. 2532 ("In view of its interest in protecting the health of its citizens, the State necessarily has considerable discretion in determining standards for the licensing of medical facilities").

Moreover, contrary to the district court's suggestion, see Greenville Women's Clinic, 66 F.Supp.2d at 732, there is no requirement that a state refrain from regulating abortion facilities until a public-health problem manifests itself. In Danforth, for example, the Court upheld health measures that "may be helpful" and "can be useful." 428 U.S. at 80, 81, 96 S.Ct. 2831. It cannot be gainsaid that a regulation incorporating the recommendations of the leading institutional authorities in the field of abortion provision aims to "further the health or safety of a woman seeking an abortion." Casey, 505 U.S. at 878, 112 S.Ct. 2791 (joint opinion of O'Connor, Kennedy, and Souter, JJ.). Because South Carolina's Regulation 61-12 "appear[s] to be generally compatible with accepted medical standards governing ... abortions," Simopoulos, 462 U.S. at 517, 103 S.Ct. 2532, we cannot reasonably conclude that the Regulation was not directed at promoting South Carolina's valid interest in a woman's health.

Even though Regulation 61-12 is directed at the valid objective of safeguarding the health of women seeking

abortions, it may still be invalid if, in serving this objective, it unduly burdens "a woman's ability to make th[e] decision" to terminate a pregnancy. Casey, 505 U.S. at 874, 112 S.Ct. 2791 (joint opinion of O'Connor, Kennedy, *170 and Souter, JJ.). Thus, having determined that Regulation 61-12 serves a valid purpose, we must still consider whether the cost imposed by the lawfully directed regulation presents "a substantial obstacle to a woman seeking an abortion." Id. at 878, 112 S.Ct. 2791. But a regulation is not rendered invalid simply because it makes it "more difficult or more expensive to procure an abortion," id. at 874, 112 S.Ct. 2791, as "[a]ll abortion regulations interfere to some degree with a woman's ability to decide whether to terminate her pregnancy," id. at 875, 112 S.Ct. 2791. In making this undue-burden assessment, the Supreme Court has repeatedly emphasized that the focus must be aimed more directly at the ability to make a decision to have an abortion as distinct from the financial cost of procuring an abortion.

The district court found that enforcement of Regulation 61-12 would increase the cost of obtaining an abortion in varying amounts, depending on the abortion clinic. The Greenville Women's Clinic, which purports to follow national medical standards for providing abortions, indicated that it substantially complies with the requirements of Regulation 61-12 and that full compliance would cost about \$23. At the Charleston Women's Medical Clinic, the cost increase would be between \$36 and \$75. On the other hand, Dr. Lynn, who operates abortion clinics in Beaufort and Greenville, testified that he would have to make so many changes to his Beaufort facility that compliance would require him to cease providing abortions at that facility.

The record does not contain information indicating the manner in which Regulation 61-12 would actually affect any South Carolina woman's decision to seek an abortion. This is not due to a failure of proof but a problem inherent in conducting a facial challenge to the Regulation. The most that the parties could do in a preenforcement case is to speculate about the Regulation's impact. While they can reasonably forecast some cost increases, they can only surmise how any cost increase would affect a particular woman's decision to seek an abortion.

Even accepting the speculative figures relied upon by the district court, we believe the court erred in concluding that at the two major clinics in this casethe Greenville Women's Clinic and the Charleston 222 F.3d 157 (Cite as: 222 F.3d 157, *170)

Women's Medical clinic-- the impact from the expense of implementing Regulation 61-12 was unduly burdensome. While the \$23-\$75 increased cost per abortion due to compliance might make it "more difficult" and would make it "more expensive to procure an abortion," there is no evidence that it would impose an undue burden on "a woman's ability to make th[e] decision to have an abortion." *Casey*, 505 U.S. at 874, 112 S.Ct. 2791 (joint opinion of O'Connor, Kennedy, and Souter, JJ.). As to Dr. Lynn's Beaufort clinic, no evidence suggests that women in Beaufort could not go to the clinic in Charleston, some 70 miles away.

Both Casey and pre-Casey decisions support the conclusion that predicted costs to raise medical standards do not amount to an undue burden on a woman's choice to obtain an abortion. In Casey, the Court considered a mandatory 24-hour waiting period, which the lower court had found would often cause "a delay of much more than a day because the waiting period requires that a woman seeking an abortion make at least two visits to the doctor" and would increase the exposure of women seeking abortions to the "harassment and hostility of anti-abortion protestors." 505 U.S. at 886, 112 S.Ct. 2791 (joint opinion of O'Connor, Kennedy, and Souter, JJ.). As a result, the lower court concluded that the State regulation would especially burden women with the fewest financial resources, who had to travel long distances, and who needed to explain their absences to their husbands or to others. See id. Yet the Supreme Court upheld the provision, stating that "on the record before us, and in the context of this facial challenge, we are not convinced that the 24-hour waiting *171 period constitutes an undue burden." Id. at 887, 112 S.Ct. 2791 (emphasis added). The Casey Court also upheld a recordkeeping and reporting provision, under which every facility that performed abortions had to file with the State a detailed report on every abortion, as well as quarterly statistical data. Because this information was a "vital element of medical research," it could not "be said that the requirements serve no purpose other than to make abortions more difficult," even though the provision "might increase the cost of some abortions by a slight amount." Id. at 901, 112 S.Ct. 2791 (majority opinion).

Similarly, in *Ashcroft*, the Court upheld a reporting requirement because, "[o]n its face and in effect," it was reasonably related to accepted medical standards and constituted common medical practice, 462 U.S. at 487, 505, 103 S.Ct. 2517, even though the provision raised the cost of an abortion, *see id.* at 490, 103 S.Ct.

2517. In contrast, the Court in *Akron* struck down a provision requiring that all second-trimester abortions be performed in a hospital because the evidence indicated that the cost of an abortion would double and second-trimester abortions were "rarely performed" in hospitals. 462 U.S. at 435, 103 S.Ct. 2481.

In the case before us, as in *Casey*, the district court found that the Regulation would "caus[e] delays in the woman's financial ability to obtain an abortion" and would "increas[e] the distance a woman has to travel to obtain an abortion," thereby increasing the cost of an abortion. 66 F.Supp.2d at 735. But again, in the context of a facial challenge and in the absence of any evidence in the record about how the cost would affect women's ability to make a decision, we conclude that the clinics have failed to demonstrate that the Regulation places any serious burden on a woman's ability to make an abortion decision.

Moreover, the increased costs claimed by the three abortion providers are particularly modest when one considers that their purpose is to protect the health of women seeking abortions. And there is no evidence that the ability of any woman to obtain an abortion or to decide to obtain an abortion would be frustrated by these particularized costs. To conclude that any of the figures in this case would place an obstacle in the path of a woman's right to choose to have an abortion would necessitate the formulation of an arbitrary cost threshold beyond which a price increase may not pass. This would irrationally hamstring the State's effort to raise the standard of care in certain abortion clinics, the procedures and facilities of which do not adequately safeguard the health of their patients, simply because the clinics' performance falls so far below appropriate norms that the expense of upgrading their practices and equipment exceeds the arbitrarily defined amount.

Nor does it unduly burden a woman's right to decide to obtain an abortion that DHEC officials may inspect abortion clinics and copy necessary documents. Such inspections ensure compliance with healthcare standards, an end which the copying provision also furthers. See Danforth, 428 U.S. at 79, 81, 96 S.Ct. 2831 (noting that a statute which allowed medical records to "be inspected and health data acquired by local, state, or national public health officers" did not have a "legally significant impact or consequence on the abortion decision or on the physician-patient relationship" (internal quotation marks omitted)). This is particularly so in view of the Regulation's requirement that "[a]ll records shall be treated as

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confidential," thereby respecting patients' privacy. See id. at 80, 96 S.Ct. 2831 (noting that proper respect for patient's confidentiality was a factor in upholding reporting requirement); cf. Whalen v. Roe, 429 U.S. 589, 602 & n. 29, 97 S.Ct. 869, 51 L.Ed.2d 64 (1977) ("disclosures of private medical information to ... public health agencies are often an essential part of modern medical practice even *172 when the disclosure may reflect unfavorably on the character of the patient").

[6] In short, South Carolina Regulation 61-12 serves a valid purpose, "one not designed to strike at the right itself," and it is not invalid simply because it has the incidental effect of making it modestly more difficult or more expensive to procure an abortion. *Casey*, 505 U.S. at 874, 112 S.Ct. 2791 (joint opinion of O'Connor, Kennedy, and Souter, JJ.).

Ш

South Carolina also contends that the district court erred in finding that Regulation 61-12 violates the Equal Protection Clause. The Regulation applies to facilities that perform one second-trimester abortion or five or more first-trimester abortions per month, but does not apply to facilities that perform fewer than five abortions per month or that perform no abortions at all. South Carolina argues that this classification is rationally related to its interests in regulating those facilities that perform abortions on a regular basis and notes that an abortion is recognized to be "a unique act fraught with consequences that go beyond mere medical complications."

The abortion clinics argue that because Regulation 61-12 "targets abortion providers and their patients, treats them differently than providers and patients of comparable medical procedures, and directly impacts the exercise of the right to abortion," we must review the Regulation under a standard of strict scrutiny. The abortion clinics contend that, under the strict-scrutiny standard, the Regulation cannot be upheld because it is not narrowly drawn to protect the health of women seeking abortions since their safety "is no more or less compelling than the safety of patients undergoing comparable procedures," which the State does not regulate.

[7][8][9][10][11] At its essence, the Equal Protection Clause requires that "all persons similarly situated'... be treated alike." *Cleburne v. Cleburne Living Ctr.*, *Inc.*, 473 U.S. 432, 439, 105 S.Ct. 3249, 87 L.Ed.2d 313 (1985); *Reed v. Reed*, 404 U.S. 71, 77, 92 S.Ct.

251, 30 L.Ed.2d 225 (1971). But this directive does not deny States "the power to treat different classes of persons in different ways." Reed, 404 U.S. at 75, 92 S.Ct. 251. Most regulations define groups to which they apply or to which benefits are conferred and when any such group is defined, of necessity, the regulation favors or disadvantages other groups. See Romer v. Evans, 517 U.S. 620, 631, 116 S.Ct. 1620, 134 L.Ed.2d 855 (1996). To withstand scrutiny under the Equal Protection Clause, therefore, a classification generally "must be reasonable, not arbitrary, and must rest upon some ground of difference having a fair and substantial relation to the object of the legislation." Reed, 404 U.S. at 76, 92 S.Ct. 251 (internal quotation marks and citation omitted). If, however, a regulation "impinges upon a fundamental right protected by the Constitution," Perry Educ. Ass'n v. Perry Local Educators' Ass'n, 460 U.S. 37, 54, 103 S.Ct. 948, 74 L.Ed.2d 794 (1983), or "operates to the peculiar disadvantage of a suspect class," Massachusetts Bd. of Retirement v. Murgia, 427 U.S. 307, 312, 96 S.Ct. 2562, 49 L.Ed.2d 520 (1976), then the classification will be strictly scrutinized. While classifications in legislation ordinarily will be upheld against an equal protection challenge if "there is any reasonably conceivable state of facts that could provide a rational basis for the classification," FCC v. Beach Communications, Inc., 508 U.S. 307, 313, 113 S.Ct. 2096, 124 L.Ed.2d 211 (1993), a regulation subject to strict scrutiny will be upheld only if it is justified by a compelling state interest, see Roe, 410 U.S. at 155, 93 S.Ct. 705.

In Roe, the abortion-decision right was found to be fundamental. 410 U.S. at 154-55, 162-63, 93 S.Ct. 705; see also Maher v. Roe, 432 U.S. 464, 474, 97 S.Ct. 2376, 53 L.Ed.2d 484 (1977). But following Casey, that conclusion may be in doubt. The Casey decision does not refer to the abortion-*173 decision right as fundamental and does not apply the traditional strict-scrutiny standard which protects fundamental rights. Rather, the Court adopted an "undue burden" standard. Casey, 505 U.S. at 874, 112 S.Ct. 2791 (joint opinion of O'Connor, Kennedy, and Souter, JJ.); see also Stenberg, 530 U.S. at ----, 120 S.Ct. at 2636. Indeed, any regulation that does not "strike at the [abortion] right itself" is assessed by asking not whether it serves a compelling state interest, but whether it "serves a valid purpose." Casey, 505 U.S. at 874, 112 S.Ct. 2791 (joint opinion of O'Connor, Kennedy, and Souter, JJ.) (emphasis added). The dissenting opinion by Chief Justice Rehnquist characterizes the joint opinion in Casey as follows:

Roe decided that a woman had a fundamental right to

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an abortion. The joint opinion rejects that view. Roe decided that abortion regulations were subject to "strict scrutiny" and could be justified only in the light of "compelling State interests." The joint opinion rejects that view.

Id. at 954, 112 S.Ct. 2791 (Rehnquist, C.J., dissenting).

[12] But because we have concluded in Part II that South Carolina's Regulation 61-12 does not place an undue burden on a woman's ability to make an abortion decision, there is no need to resolve whether it remains a fundamental right for an equal protection analysis and thus requires application of the strict-scrutiny standard. See Harris v. McRae, 448 U.S. 297, 312, 322, 100 S.Ct. 2671, 65 L.Ed.2d 784 (1980) (having concluded that a law restricting federal funding for abortion violated no constitutionally protected right. the Court held it was unnecessary to analyze whether the law infringed a fundamental right for equal protection purposes). And likewise the equal protection analysis of a regulation applicable to abortion clinics, and not other medical clinics, would not be conducted under the strict-scrutiny standard. No authority exists to support a conclusion that abortion clinics or abortion providers have a fundamental liberty interest in performing abortions free from governmental regulation. See, e.g., Birth Control Centers, Inc. v. Reizen, 743 F.2d 352, 358 (6th Cir. 1984). Moreover, physicians as a group are not a suspect class. See Attorney Gen. of New York v. Soto-Lopez, 476 U.S. 898, 906 n. 6, 106 S.Ct. 2317, 90 L.Ed.2d 899 (1986)(recognizing suspect classifications to include those based on race, alienage, or national origin). Accordingly, because we are not considering a regulation that impinges on a fundamental right or that is directed at a suspect class, we review South Carolina Regulation 61-12 under the Equal Protection Clause by applying a rational-basis standard to determine whether the Regulation's classification of physicians who perform one secondtrimester abortion or five or more first- trimester abortions per month is rationally related to a valid governmental purpose.

The rationality of distinguishing between abortion services and other medical services when regulating physicians or women's healthcare has long been acknowledged by Supreme Court precedent. Beginning with *Roe* itself, the Court recognized not only the special medical interest of the women seeking abortions but also the State's interest in protecting prenatal life. *See* 410 U.S. at 150, 93 S.Ct. 705. The long stream of cases that followed *Roe* has only

heightened an awareness that for purposes of regulation, abortion services are rationally distinct from other routine medical services, if for no other reason than the particular gravitas of the moral, psychological, and familial aspects of the abortion decision. As the Court in *Casey* observed:

[T]he abortion decision ... is more than a philosophic exercise. 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 in the procedure; for the spouse, family, and society which *174 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.

Casey, 505 U.S. at 852, 112 S.Ct. 2791 (majority opinion). Similarly in Harris, the Supreme Court noted that it was rational for Congress to authorize federal reimbursement for medical necessities, but not for medically necessary abortions: "Abortion is inherently different from other medical procedures, because no other procedure involves the purposeful termination of a potential life." 448 U.S. at 325, 100 S.Ct. 2671 (emphasis added). And again in Danforth, the Court rejected the argument that "the State should not be able to impose any recordkeeping requirements [on abortion providers] that significantly differ from those imposed with respect to other, and comparable, medical or surgical procedures." 428 U.S. at 80-81, 96 S.Ct. 2831. In the same case, the Court applied the identical analysis to uphold a provision requiring that a woman certify in writing that her consent to the abortion was freely given and not the result of coercion, "[d]espite the fact that apparently no other ... statute ... requires a patient's prior written consent to a surgical procedure." Id. at 66-67, 96 S.Ct. 2831.

[13] We thus conclude that South Carolina has a rational basis for regulating abortion clinics while not regulating other healthcare facilities. See Williamson v. Lee Optical, 348 U.S. 483, 489, 75 S.Ct. 461, 99 L.Ed. 563 (1955) ("The problem of legislative classification is a perennial one, admitting of no doctrinaire definition.... [T]he 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").

The only question remaining is whether the line drawn by Regulation 61-12 at five abortions per month is rationally related to its purpose of protecting the health

IV

of abortion patients. When it is recognized that the State interest is in regulating those facilities that are in the business of providing abortions, drawing the line at those performing five abortions per month is rational. While anyone could say that it is just as rational to draw the line at ten abortions per month or three abortions per month, this type of line- drawing is typically a legislative function and is presumed valid. See Murgia, 427 U.S. at 314, 96 S.Ct. 2562. Indeed, line-drawing of this type is not only typical of legislation, it is necessary. Thus, the Americans With Disabilities Act provides that the right to be free from discrimination because of one's disability is granted to an employee of a company with 15 employees, but not to an employee of a company with only 14 employees. See 42 U.S.C. § 12111(5)(A). Similarly, Title VII of the Civil Rights Act of 1964 prohibits discrimination on the basis of race, color, religion, sex, or national origin by employers with 15 or more employees, but not employers with 14 or fewer employees. See 42 U.S.C. § 2000e(b). The statute books are filled with similar examples. See, e.g., the Family and Medical Leave Act, 29 U.S.C. § 2611(2) (giving rights only to employees employed 12 months or longer); Comprehensive Crime Control Act of 1984, 18 U.S.C. 3559(c)(1) (mandating a sentence of life imprisonment for persons convicted of three serious violent felonies). In a similar vein, South Carolina permits persons 16 years or older to obtain a driver's license, denying a license to persons 15 years or younger. See S.C.Code § 56-1-40; see also S.C. Const. art. XVII, § 14 (persons 18 years or older have "full legal rights and responsibilities"). In each of these instances, persons falling on one side of the line are treated differently from those on the other. But this result is inherent in legislation. Under rational-basis review, we need to determine only whether the line is drawn in a manner that reasonably furthers the legislative concern.

*175 In this case, South Carolina elected to regulate the business of providing abortions and determined that five per month would distinguish the abortion clinic from the facility performing abortions incidental to another medical practice. The selection of this number is reasonably related to the State's legitimate interest in promoting and protecting the health of women visiting abortion clinics, and therefore the actual placement of the line is not a decision that the courts may second-guess. No more than the abortion regulations examined by the Supreme Court in Danforth and Harris does the South Carolina regulation before us contravene the limitations of the Equal Protection Clause.

It is regrettable that our good colleague in dissent would rule on the basis that abortion is like any other simple medical procedure that is directed at injury or disease. Thought of in this way, it is understandable that he, like the district court, might find many of South Carolina's regulations unnecessary. Why have inspections, keep records, and minimize the medical risks for only the abortion procedure, when such a protocol is not mandated for comparable medical practices addressing injury and disease? But the importance of the deeply divided societal debate over the morality of abortion and the weight of the interests implicated by the decision to have an abortion can hardly be overstated. As humankind is the most gifted of living creatures and the mystery of human procreation remains one of life's most awesome events, so it follows that the deliberate interference with the process of human birth provokes unanswerable questions, unpredictable emotions, and unintended social and, often, personal consequences beyond simply the medical ones.

In adopting an array of regulations that treat the often relatively simple medical procedures of abortion more seriously than other medical procedures, South Carolina recognizes the importance of the abortion practice while yet permitting it to continue, as protected by the Supreme Court's cases on the subject. A woman in South Carolina who has determined to abort the life of a fetus can do so without significant interference from South Carolina's regulations and be assured thereby of a dignified and safe procedure. That these regulations impose a modest cost increase for increased medical safety and a modest compromise privacy in the form of inspections recordkeeping serves the complex public interests on the subject-the interests expressed by both those who favor abortion and those who oppose it.

Society's last word on this subject has not been spoken. But South Carolina's regulations incidental to the exercise of the abortion right should, in the meantime, be respected.

V

Because we reverse the district court's judgment finding Regulation 61-12 unconstitutional, we also reverse the district court's award of attorneys fees made under 42 U.S.C. § 1988 to the abortion clinics. The clinics are no longer prevailing parties. See

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Alexander S. v. Boyd, 113 F.3d 1373, 1388 (4th Cir.1997); Clark v. Township of Falls, 890 F.2d 625, 626-27 (3d Cir.1989).

REVERSED

HAMILTON, Senior Circuit Judge, dissenting:

After a six-day bench trial, the district judge, who presently is a judge on this court, wrote a ninety-four page decision setting forth innumerable factual findings which lead inexorably to the legal conclusions that South Carolina Code Annotated Regulation 61-12 violates both the Due Process and Equal Protection Clauses of the United States Constitution and that the unconstitutional portions of Regulation 61-12 are not severable from the constitutional portions. Cavalierly, the majority *176 today sets aside this thorough and meticulous decision rendered by our esteemed colleague without identifying a single finding of fact made by him as being clearly erroneous. accomplish this tour de force, the majority is compelled to set up and defeat a lack of evidence straw man. Unlike the majority, I believe the exhaustive and detailed factual findings made by the district judge amply support, more accurately compel, the decision rendered by him. Because I am in complete agreement with the district judge's holdings that South Carolina Code Annotated Regulation 61-12 violates both the Due Process and Equal Protection Clauses of the United States Constitution and that the unconstitutional portions of Regulation 61-12 are not severable from the constitutional portions, I dissent.

Ι

The constitutional issues presented in this case were hotly contested by the parties at trial, with each side putting forth extensive evidence in support of their respective positions. Based on the evidence presented, the district court resolved many factual disputes by making detailed findings of fact. Because many of the district court's factual findings are completely ignored by the majority, I set forth below the procedural history and facts of this case.

A

Prior to 1995, the State of South Carolina only required licensing of physicians' offices or other facilities in which second trimester abortions were performed. See S.C.Code Ann. §§ 44-41-20(b), -70(b) (Law.Coop.1995). On January 3, 1995, the South Carolina legislature amended Chapter 41 of

Title 44 to require licensing by the South Carolina Department of Health and Environmental Control (DHEC) of any non-hospital medical facility in which five or more first trimester abortions are performed in a month. See id. § 44-41-75(A) (West Supp.1999). This legislation also required DHEC to promulgate regulations concerning "sanitation, housekeeping, maintenance. staff qualifications, emergency equipment and procedures to provide emergency care, medical records and reports, laboratory, procedure and recovery rooms, physical plant, quality assurance, infection control, and information on and access to patient follow-up care necessary to carry out the purposes of this section." Id. § 44-41-75(B). Pursuant to this enabling legislation, DHEC promulgated a regulation, entitled "Standards For Licensing Abortion Clinics," see S.C.Code Ann. Regs. 61-12 (Regulation 61-12), which sets forth detailed requirements that an abortion clinic [FN1] must comply with in order to obtain and maintain a license to perform abortions.

FN1. An abortion clinic is defined as "[a]ny facility, other than a hospital ... in which any second trimester or five or more first trimester abortions per month are performed." S.C.Code Ann. Regs. 61-12, § 101(B). Accordingly, the definition of abortion clinic includes any physician's office in which five or more first trimester abortions per month are performed.

On June 27, 1996, the day before Regulation 61-12 temporarily went into effect, Greenville Women's Clinic (GWC) and Charleston Women's Medical Clinic, Inc. (CWMC), two medical clinics which offer first trimester abortion services in South Carolina, and Dr. William Lynn (Dr. Lynn), a physician that owns and operates medical practices in Beaufort and Greenville, South Carolina, brought this action against Douglas Bryant (Bryant) as the Commissioner of DHEC, the Governor of the State of South Carolina, and the Attorney General of the State of South challenging the constitutionality Regulation 61-12. On the same day, the plaintiffs filed a motion for a temporary restraining order, or, in the alternative, for a preliminary injunction.

On July 19, 1996, the district court granted the plaintiffs' motion for a temporary *177 restraining order and enjoined the defendants from enforcing Regulation 61-12, pending a hearing on the issuance of a preliminary injunction. The district court never held a hearing on the issuance of a preliminary injunction because, prior to the hearing date, the parties agreed to continue the injunction pending a decision by the

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district court on the merits.

Following a six day bench trial, the district court, on February 5, 1999, held that Regulation 61-12 was constitutionally infirm on due process and equal protection grounds. See Greenville Women's Clinic v. Bryant, 66 F.Supp.2d 691, 724-43 (D.S.C.1999). The district court also held that, in light of both South Carolina law and the text of Regulation 61-12, Regulation 61-12 was not subject to the doctrine of severability. See id. at 743-44. On April 13, 1999, the district court awarded the plaintiffs \$324,040.61 in costs and attorneys' fees. Bryant and the Attorney General of South Carolina appeal both the district court's decision on the merits and the order awarding costs and attorneys' fees. The Governor of South Carolina appeals only the district court's order awarding costs and attorneys' fees. [FN2]

FN2. Although the Governor of South Carolina appeals only the district court's order awarding costs and attorneys' fees, for ease of reference, I will refer to Bryant, the Governor of South Carolina, and the Attorney General of South Carolina as the defendants.

В

Located in Greenville, South Carolina, GWC provides gynecological services, including abortions through fourteen weeks of pregnancy measured from the pregnant woman's last menstrual period (lmp). [FN3] Drs. Terry Buffkin and Thomas Campbell, two physicians licensed to practice in South Carolina and board certified in obstetrics and gynecology, own and operate GWC. On average, GWC performs approximately 2,746 first trimester abortions per year.

FN3. Pregnancy is measured either from the date of a woman's lmp or from conception, which is generally considered to occur two weeks after a woman's lmp. Accordingly, eight weeks after the lmp is equivalent to six weeks from the date of conception. Under Regulation 61-12, the first trimester of pregnancy ends at fourteen weeks after the lmp. See S.C.Code Ann. Regs. 61-12, § 103(S).

Located in Charleston, South Carolina, CWMC also provides gynecological services, including abortions through 12.5 weeks of pregnancy measured from the pregnant woman's lmp. On average, CWMC performs 2,408 first trimester abortions per year.

Dr. Lynn owns and operates two medical practices, one in Beaufort, South Carolina, the other in Greenville, South Carolina. Dr. Lynn is licensed to practice medicine in South Carolina and is board

certified in obstetrics and gynecology. As part of his practice, Dr. Lynn performs abortions through 13.9 weeks of pregnancy measured from the pregnant woman's lmp. On average, Dr. Lynn performs 407 first trimester abortions per year in his Beaufort office and 536 first trimester abortions per year in his Greenville office.

All of the abortions performed at GWC, CWMC, and Dr. Lynn's two practices are first trimester abortions. In fact, there are no abortion providers in South Carolina who perform elective abortions (those not associated with medical complications) in the second trimester of pregnancy. [FN4]

FN4. Because the plaintiffs in this case only provide abortions during the first trimester of pregnancy, the plaintiffs' challenge to Regulation 61-12 is limited to its application to providers of first trimester abortions in South Carolina. Accordingly, I express no opinion as to the constitutionality of Regulation 61-12 as applied to facilities that may seek to perform second trimester abortions in the future.

The most common first trimester abortion procedure performed by the plaintiffs is the suction curettage procedure. The suction curettage procedure is also utilized for spontaneous miscarriages. Although not wholly without risks, it is undisputed that a suction curettage abortion during *178 the first trimester of pregnancy is a safe and quick medical procedure performed between six and fourteen weeks after a woman's lmp. [FN5] It involves dilating the cervix, inserting a suction catheter into the uterus, and applying suction to remove the contents of the uterus. Although the patient is usually in the procedure room for a total of ten minutes, the procedure itself only takes approximately two to five minutes. It involves no incision and a minimum of bleeding. procedure is also performed under general anesthesia or by applying a numbing medicine around the cervix. After the procedure, patients usually walk to the recovery area, where their pulse and blood pressure are monitored, and they are checked for any abnormal bleeding. Possible complications from the suction curettage procedure are fainting from vasovagal response, uterine perforation, excessive bleeding, infection, and retained tissue in the uterus. However, while the total complication rate for the procedure is about one in one hundred, serious complications are The rate for complications requiring hospitalization is only about one in 2000. And the mortality rate is one in 100,000, which is about twentyfive times less risky than carrying a pregnancy to term. There is no evidence in this case that a first trimester

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suction curettage abortion has ever resulted in a woman's death in South Carolina.

FN5. By way of comparison, according to one of the plaintiffs' experts whose testimony was credited by the district court, having a first trimester suction curettage abortion is safer than having a shot of penicillin in a physician's office.

Physicians in South Carolina, including Dr. Buffkin and Dr. Campbell, also perform medical abortions to terminate pregnancies located outside the uterus (such as in the fallopian tube) during the first six to seven weeks of pregnancy. A medical abortion is an even safer procedure than the suction curettage procedure. It involves the performance of a routine blood test to measure the patient's hormone levels, followed by the injection of a drug (methotrexate) into the patient's arm. There is no recovery time after the injection, and only mild vaginal bleeding. Follow-up care consists of rechecking the patient's hormone levels several days after the injection, and rechecks thereafter at seven-day intervals. Although currently limited in use to the termination of ectopic pregnancies, methotrexate and a second drug, RU- 486, are currently being used in research protocols for use in terminating intrauterine pregnancies.

C

Currently, South Carolina does not require licensing of physicians' offices outside of the abortion context. Furthermore, physicians licensed to practice medicine in South Carolina are not subject to DHEC regulation, but rather are governed by the South Carolina State Board of Medical Examiners. See S.C.Code Ann. §§ 40-47-5 to 40-47-270 (West Supp.1999). The State Board of Medical Examiners handles the examination and licensure of physicians within South Carolina, complaints against physicians, the suspension and revocation of licenses when appropriate, and the imposition of civil penalties and other sanctions against physicians. With the exception of standard building codes imposed by their particular locales, physicians' offices are not subject to any mandated design and construction requirements. Notably, unlike abortion clinics, physicians' offices that do not perform five or more abortions per month are not subject to the requirements of Regulation 61-12.

Regulation 61-12 is divided into ten "Parts." Part I of Regulation 61-12 sets forth "Definitions" and general "Requirements for Licensure" of abortion clinics. Part I defines an abortion as "[t]he use of an instrument, medicine, drug, or other substance or device with

intent to terminate the pregnancy of a woman, known to be pregnant, for reasons other than to increase the probability of a live birth, to *179 preserve the life or health of the child after live birth, or to remove a dead fetus." S.C.Code Ann. Regs. 61-12, § 101(A). Part I defines an abortion clinic as "[a]ny facility, other than a hospital ... in which any second trimester or five or more first trimester abortions per month are performed." *Id.* § 101(B).

In order to operate an abortion clinic, the clinic must first obtain a license from DHEC. See id. § 102(A). Prior to the issuance of a license, the abortion clinic must undergo a pre-licensure inspection. See id. § 102(F). Once the initial license is obtained, the abortion clinic must be inspected annually in order to obtain renewal of the license. See id. §§ 102(F), (H). In addition, Regulation 61-12 provides that the abortion clinic is subject to unannounced inspections by DHEC, see id. § 102(F)(1), during which DHEC inspectors "have access to all properties and areas, objects, records and reports, and shall have the authority to make photocopies of those documents required in the course of inspections or investigations." Id. § 102(F)(2).

Upon a determination by DHEC that an abortion clinic is in violation of "any statutory provision, rule or regulation relating to the operation or maintenance of such facility," DHEC may deny, suspend, or revoke the license. *Id.* § 103. In addition, DHEC may assess a monetary penalty up to \$5,000 for each violation. *See id.* § 103(F). The amount of a penalty is based upon the specific provision at issue, which has been preassigned as either a Class I, II, or III violation, with a Class I violation being the most serious. *See id.*

П concerns "Administration the Management" of the abortion clinic. Section 201 requires an abortion clinic to develop and implement detailed written policies and procedures for the operation of the clinic, which must include, at a policies and procedures to assure compliance with all federal, state, and local laws which govern the clinic; the designation of a person to whom responsibility for operation and maintenance of the abortion clinic is delegated and the establishment of methods for holding the person responsible; personnel policies and procedures, including in-service training requirements; a facility-wide quality improvement program, including statistical summaries and a written plan of implementation; a policy and procedure for patient rights and grievance procedures; functional safety and maintenance policies and procedures; a

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policy and procedure for incident reporting; and policies and procedures for obtaining informed consent from the patient. See id. § 201(B). In addition, the abortion clinic's policies and procedures must include a provision for annual review and evaluation of the clinic's other policies and procedures, as well as for its management and operation. See id.

Section 203 requires an abortion clinic to maintain on file all current policies and procedures concerning the operation of the clinic, memoranda of agreements and credentialing documentation, a copy of Regulation 61-12, annual elevator safety inspections, and annual heating, ventilation, and air conditioning inspection reports. See id. §§ 203(A)-(E).

Section 204 sets forth detailed personnel requirements for each abortion clinic. The abortion clinic must obtain and verify professional and personal background information on every employee, see id. § 204(A), and must develop and implement a written orientation program for new staff members, to include orientation on the clinic's other policies and procedures, see id. § 204(E). A formal, in-service training program must also be planned and provided for all employees and volunteers, and records kept of attendance. See id. § 204(F). The in-service training of all employees and volunteers must include four specified areas-infection control, fire protection, confidentiality and patient rights, and licensing regulations. See id. Written job descriptions must be prepared and reviewed annually, see id. § 204(G), and a personnel *180 file must be maintained on each employee and contain the employee's current job description that reflects the employee's responsibilities and work assignments, documentation of the employee's orientation. in-service education. appropriate licensure (if applicable) and tuberculin skin testing, see id. § 204(H). Annually, each employee must have a tuberculin skin test or, if previously positive, a chest x-ray to determine whether tuberculosis is present. See id. § 204(B). tuberculosis is diagnosed, the abortion clinic must provide treatment and investigate employee contacts. See id. Employees and volunteers are also banned from working if they have any infected wounds, boils, sores, acute respiratory infections, or any other contagious disease or illness. See id. § 204(D). In addition, all professional and allied health care staff members must be certified by the American Red Cross or the American Heart Association as capable of performing CPR, although only one such certified person must be with patients when they undergo the abortion procedure and during the recovery period.

See id. § 204(C).

Section 205 sets forth requirements for the clinical staff of an abortion clinic, which encompasses all physicians, nurses, and allied health professionals. See id. § 205(A). Abortions may only be performed by physicians licensed to practice medicine in South Carolina and who are also "properly qualified by training and experience to perform pregnancy termination procedures." See id. § 205(C). abortion clinic must also obtain and maintain signed, written agreements with at least one physician board certified in obstetrics and gynecology who has admitting privileges at a local hospital which provides obstetrical and gynecological services. See id. All nursing care is required to be under the supervision of a registered nurse licensed in the State of South Carolina, regardless of the presence of a physician in the abortion clinic, and the registered nurse must be "on duty to provide or supervise all nursing care" during preparation, the procedure, recovery, and discharge. Id. § 205(D). Licensed practical nurses may be employed so long as they work under the supervision and direction of a registered nurse. See id. § 205(E). Ultrasounds may only be conducted by physicians or ultrasound technicians who have documented evidence of completion of a training course in ultrasonography. See id. § 205(F). Finally, the entire clinical staff must participate in quarterly meetings to review and analyze clinical experiences, and minutes must be kept and maintained of each meeting. See id. § 205(B).

Section 209 requires an abortion clinic to "have written policies and procedures to assure the individual patient the right to dignity, privacy, safety, and to register complaints with [DHEC]." *Id.* § 209(A). A copy of the patient's rights must be conspicuously displayed, and a copy must be signed by each patient and included in the patient's medical record. *See id.* § 209(B).

Part III of Regulation 61-12 sets forth requirements for "Patient Care." Additional "patient care policies and procedures designed to ensure professional and safe care for patients" must be developed, id. § 301, and must include, but are not limited to, policies and procedures for admission criteria; physician and nurse responsibilities; details regarding the pre- operative procedures (including history and physical examinations, special examinations, lab procedures and consultations which will be required, and ultrasonography procedures); details regarding the actual abortion procedure (including the use of IVs, 222 F.3d 157 (Cite as: 222 F.3d 157, *182)

patients if they are "involved in the care and services provided by the facility." *Id.* § 308(E). The abortion clinic administrator must review the findings of the program and ensure corrective actions are taken. *See id.* § 308(F). The program must also identify and establish indicators of quality care, specific to the abortion clinic, that must be monitored and evaluated. *See id.* § 308(G). Annual review of the results is also required. *See id.* § 308(H).

Part IV of Regulation 61-12 sets forth requirements for "Medical Records and Reports." Section 401 begins by setting forth detailed requirements for the preparation and maintenance of medical records, which must include, at a minimum, twenty categories of information. See id. § 401. Section 401 requires a face sheet with patient identification data, including but not limited to, the patient's name, address, telephone number, social security number, date of birth, the father and mother's name if the patient is a minor, the husband's name, and the name, address, and telephone number of a person to be notified in the event of an emergency. See id. § 401(A)(1). The records are required to be kept confidential by the abortion clinic (although no such requirement is imposed upon DHEC inspectors who obtain them) and must be stored for a minimum of ten years. See id. §

Section 403 requires the preparation of additional reports, including a record of every accident or incident occurring in the abortion clinic which involves patients, staff, or visitors. See id. § 403(B). If it results in serious injury, the accident or incident must be self-reported to DHEC. See id. Serious injuries "include, but are not limited to," accidents and incidents that lead to hospitalization or death (other than of a fetus) and adverse drug reactions. Id.

Part V of Regulation 61-12, entitled "Functional Safety and Maintenance," requires additional policies and procedures, including, but not limited to, safety rules and practices for personnel, equipment, gases, liquids, drugs, supplies, and services; provisions for investigating accidents on the premises; provisions for disseminating safety-related information to employees and users of the abortion clinic; provisions for syringe and needle handling and storage; and provisions for managing infectious waste in accordance with another DHEC regulation already governing such matters. See id. §\$ 501(A)- (B). In addition, the abortion clinic must prepare and post a disaster preparedness plan for evacuation in the event of a fire or other emergency. See id. § 502(A). All parts and portions of the

abortion clinic are generically required to be kept "in good repair and operating condition," and "free of hazards." *Id.* § 503(A). In addition, "[a]ll wooden surfaces shall be sealed with a non-lead based paint, lacquer, varnish, or shellac that will allow sanitization." *Id.* A written preventive maintenance program must be developed and implemented for patient monitoring equipment and tested in accordance with manufacturer's specifications, but not less than annually. *See id.* § 503(B). Records of maintenance and testing must be kept. *See id.*

Part VI of Regulation 61-12 is entitled "Infection Control and Sanitation." Part *183 VI requires policies and procedures be established in writing to assure safe and aseptic treatment and protection of all patients and personnel against cross-infection. See id. § 601(A). Part VI also sets forth specific requirements for sterilization, including daily testing of the autoclave and a log of results, as well as periodic calibration and preventative maintenance as necessary, but not less than annually. See id. §§ 602(B)-(C). This part of Regulation 61-12 also requires that the abortion clinic "be kept neat, clean, and free from odors," id. § 604(A), mandates specific requirements for cleaning methods to be used and prohibits others, and imposes requirements for refuse and waste disposal, see id. §§ 604(A)-(C), 605. Section 606 requires that "[a]ll outside areas, grounds and/or adjacent buildings shall be kept free of rubbish, grass, and weeds that may serve as a fire hazard or as a haven for insects, rodents and other pests," and that all "[o]utside stairs, walkways, ramps and porches shall be maintained free from accumulations of water, ice, snow, and other impediments." Id. § 606.

Part VII of Regulation 61-12, entitled "Fire Protection and Prevention," provides detailed requirements for firefighting equipment and systems, an evacuation plan, training of employees in the evacuation plan, mandatory fire drills at least once every three months, maintenance of fire equipment, and maintenance of records proving compliance with the provisions. See id. §§ 701-03.

Part VIII of Regulation 61-12 sets forth detailed requirements for the "Design and Construction" of abortion clinics. There is no grandfathering provision (unlike other DHEC regulations governing medical and patient care facilities)--rather, all abortion clinics must be in full compliance within two years. See id. § 804. The requirements are set forth in detail, rendering a summary of them unproductive. Of note, Part VIII governs the number and size of procedure and

recovery rooms, specifies the design and equipment required in toilet rooms, regulates the direction of the air flow within the sterilization rooms, mandates a minimum width for doors and corridors, sets forth specific requirements for heating and air conditioning (the unit must be capable of maintaining a temperature between seventy-two and seventy-six degrees), regulates the abortion clinic's air supply and exhaust, regulates design criteria for abortion clinic entrances, sets forth specific requirements for the janitor's closets, and specifies the corridor glazing materials, wall finishes, wall bases, and interior finish materials that must be present. See id. §§ 807(A)-(Y).

Part IX of Regulation 61-12 sets forth additional "Prerequisites for Initial Licensure" of the abortion clinic, including plan and construction approval by DHEC, and specifies the documentation required to be submitted with the abortion clinic's initial application for licensure. See id. Part IX(A)-(B). Part X of Regulation 61-12, entitled "General," states in its entirety that "[c]onditions arising that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department." Id. Part X.

D

As noted earlier, prior to 1995, the State of South Carolina only required licensing of physicians' offices or other facilities in which second trimester abortions were performed. See S.C. Ann. §§ 44-41-20(b), -70(b) (Law.Co-op.1995). Effective, January 3, 1995, Chapter 41 of Title 44 was amended as follows:

- (A) A facility in which any second trimester or five or more first trimester abortions are performed in a month must be licensed by [DHEC] to operate as an abortion clinic and must comply with the provisions of Article 3 [the Woman's Right to Know Act].
- (B) The department shall promulgate regulations concerning sanitation, *184 housekeeping, maintenance, staff qualifications, emergency equipment and procedures to provide emergency care, medical records and reports, laboratory, procedure and recovery rooms, physical plant, quality assurance, infection control, and information on and access to patient follow-up care necessary to carry out the purposes of this section.

Id. § 44-41-75 (West Supp.1999). Pursuant to this enabling legislation, DHEC promulgated Regulation 61-12.

After the legislation requiring licensure of abortion clinics was passed, Alan Samuels (Samuels) of DHEC

was charged with the responsibility for supervising the drafting and promulgation of Regulation 61-12. Although Samuels has some experience in health care administration, he has received no formal medical training or education. Upon completion of his college education, Samuels served in the United States Army for twenty-four years, where he served with the adjutant general corps and the medical services corps as a personnel officer and hospital inspector. After leaving military service, Samuels began employment with DHEC, where his duties consisted of inspecting various types of health care facilities for compliance with existing regulations. He was eventually promoted to the position of director of DHEC's Health Licensing Division, and now is retired.

Although Samuels provided some input and edits during the drafting process, he did not personally draft any portions of Regulation 61-12. delegated the primary drafting responsibility to George Moore (Moore), who was the Director of Outpatient and Home Care within DHEC's Division of Health Licensing. Samuels testified that, when Regulation 61-12 was promulgated, he knew very little about abortion procedures or the differences between first trimester and second trimester abortions. The record reflects that Samuels conducted no meaningful study or research into the differences between a first and second trimester abortion, and conducted no meaningful inquiry into what regulatory requirements were appropriate for facilities performing only first trimester abortions.

Like Samuels, Moore has some education and experience with hospital administration, but has received no formal medical training or education. After receiving an undergraduate degree, Moore joined the United States Army where he served twenty-five years. He spent the early part of his service in the adjutant general corps performing general administrative duties, after which time he transferred to the medical services corps where he performed administrative duties associated with health care facilities and hospitals. During his service, Moore received a master's degree in hospital administration. Upon his retirement from military service in 1988, Moore began employment with DHEC, inspecting hospitals and nursing homes for compliance with existing regulations. He was later promoted to Director of Outpatient and Home Care within the Division of Health Licensing, the position he held when Samuels asked him to assume primary responsibility for the drafting of Regulation 61-12.

In preparation for drafting Regulation 61-12, however,

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Moore took no meaningful steps to educate himself about first trimester abortions, how they differed from second trimester abortions, or what requirements would be appropriate for a facility which performed only first trimester abortions.

For assistance with Parts VII and VIII of Regulation 61-12, Moore turned to William Lafferty (Lafferty), who was the Director of Health Facilities Construction with DHEC. Like Samuels and Moore, Lafferty has received no formal medical training or education. In drafting these portions of the regulations, Lafferty made no effort to determine whether the requirements were medically appropriate for facilities performing only first trimester abortions. Lafferty also approached the *185 design and construction requirements from the standpoint of new construction requirements and anticipated that existing facilities would grandfathered. The decision to include a mandatory two- year compliance provision in that portion of Regulation 61-12 instead of a grandfather provision was not made by Lafferty.

According to Moore, the preexisting South Carolina regulation governing second trimester abortions was utilized as a starting point for the new regulation, and many of the additional provisions of Regulation 61-12 were simply adopted or derived from DHEC regulations governing other types of health care They included regulations governing ambulatory surgical centers, renal dialysis facilities, community residential care facilities, day care facilities for adults, outpatient facilities for chemically dependent persons, habitation centers for the mentally retarded, residential treatment facilities for children and adolescents, nursing homes, and facilities providing home health care and hospice services. According to the DHEC officials, DHEC sought to standardize its regulations governing medical facilities and medical care so that the licensing requirements would have consistent wording, and to codify existing departmental practices. According to the DHEC officials, this attempt to standardize its regulations and to codify existing practices included DHEC's desire to grant its inspectors the authority to copy medical records in all medical facilities. According to Moore, departmental practice currently allows the copying of medical records during a complaint investigation. Moreover, Moore testified that DHEC would maintain the confidentiality of the records even though there is no provision in Regulation 61-12 that mandates such confidentiality. [FN7]

FN7. Interestingly, DHEC's regulation governing

ambulatory surgical centers contains a specific provision protecting the confidentiality of medical records. See S.C.Code Ann. Regs. 61-91, § 1001(E) (providing that records may only be removed from the premises by subpoena or court order).

Although the DHEC officials testified that they primarily utilized existing South Carolina regulations as the basis for drafting Regulation 61-12, there is evidence in the record that the DHEC officials consulted other points of reference. First, Moore obtained copies of abortion regulations from North Carolina and Tennessee, though he did not speak with anyone in those states about the regulations or how they had affected maternal health. Second, Moore reviewed standards and guidelines issued by the Planned Parenthood Federation of America, Inc. (Planned Parenthood), the National Abortion Federation (NAF), and the American College of Obstetricians and Gynecologists (ACOG). standards and guidelines published by Planned Parenthood, NAF, and ACOG are not mandated standards of care which can or should be imposed on licensed physicians. Rather, they are guidelines which should be followed with due regard for the medical judgment of the treating physician and the special needs of the patients that they serve.

During the drafting process, the general counsel of ACOG wrote a letter to DHEC expressing concern that the requirements of Regulation 61-12 would not enhance patient well-being or safety and offering DHEC the assistance of ACOG in the drafting of an appropriate regulation. The DHEC drafters declined ACOG's assistance.

After an initial draft of Regulation 61-12 was completed, Moore requested limited input and comments from two medical personnel associated with DHEC. The first, Dr. Richard Goodrich (Dr. Goodrich), is a licensed physician, board certified in obstetrics and gynecology, who practiced in Zanesville, Ohio until he retired. After his retirement, he moved to South Carolina and became a consultant with DHEC in the area of maternal and child health. During his medical practice, however, Dr. Goodrich performed only *186 two abortions, both of which were due to medical complications. Furthermore, Dr. Goodrich was not asked to and did not draft any portion of Regulation 61-12. Rather, he was only asked to review discrete portions of the regulation dealing exclusively with medical events and medical testing, and he conducted no review of and provided no input on the majority of the regulatory

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First, based on the evidence in the record, the district court found that the first trimester suction curettage abortion is one of the safest surgical procedures that can be performed. The procedure lasts approximately two to five minutes and has a low overall complication rate. Suction curettage abortions can be, and are currently being, safely performed in physicians' offices and outpatient clinics, except where the patient has particular medical conditions that would require the procedure to be performed in an ambulatory surgical center or hospital. Medical abortions are also quick medical procedures that can be safely performed in a physician's office or outpatient clinic. See Greenville Women's Clinic, 66 F.Supp.2d at 718.

Second, the district court found that physicians' offices and clinics that provide less than five first trimester abortions per month perform identical procedures to those which provide five or more first trimester abortions per month, and the risk to the patient undergoing the abortion procedure is identical. See id.

Third, the district court found that first trimester suction curettage abortions are comparable in terms of risks, duration, and invasiveness to a variety of obstetrical and gynecological surgical procedures which are frequently performed in physicians' offices in South Carolina. These would include suction curettage procedures performed on women who have experienced an incomplete spontaneous abortion, dilation and curettage procedures, endometrial biopsies, hysteroscopies, and insertion of intrauterine devices for birth control. See id.

Fourth, the district court found that first trimester suction curettage abortions are also comparable in terms of risks, duration, and invasiveness to a variety of non-obstetrical/gynecological surgical procedures that are frequently performed in physicians' offices in South Carolina. These would include the removal of subcutaneous lipomas and cysts, minor breast biopsies, and the removal of implanted ports and catheters which have been inserted into large veins in the neck and collarbone region for use in administering chemotherapy and dialysis. See id.

Fifth, the district court found that South Carolina is not currently experiencing a public health problem related to the provision of first trimester abortions by licensed physicians, nor was the state experiencing such a problem when Regulation 61-12 *188 was promulgated. The district court found no evidence that the plaintiffs or any other abortion providers in South Carolina are providing inadequate care to women

seeking abortions or that the rate of complications from abortions performed in South Carolina is greater than the national average. On the contrary, the district court found that South Carolina has experienced a similar, if not lower, average complication rate. See id. at 718-19.

Sixth, the district court found that, although the principal draftsmen of Regulation 61-12 have some expertise in hospital and health care administration, they have no training or education in the provision of hands-on medical care and little knowledge of the medical needs of women seeking first trimester abortions in South Carolina. See id. at 719. The district court found that they engaged in virtually no research, investigation, or other efforts to determine what types of requirements would be necessary or advisable for the abortion procedure, or what types of requirements would further or hinder the state's interest in maternal health. Nor did DHEC officials possess or seek information concerning the present safety of first trimester abortions or the relative risks associated with the procedure. See id.

Seventh, the district court found that, despite their admitted lack of medical knowledge in general and of abortion procedures in particular, the drafters of Regulation 61-12 sought only minimal input and assistance from knowledgeable medical experts during the drafting process, choosing to rely solely upon the limited review and advice of Dr. Goodrich and Lawyer as to discrete portions of the regulation. Furthermore, DHEC either rejected or ignored an offer by ACOG to assist in the drafting process. Although DHEC was under no legal obligation to consult with ACOG or to accept their assistance during the drafting process, the district court found that ACOG is unanimously considered to be a well-respected medical organization dedicated to improving the standard of health care in the field of obstetrics and gynecology. According to the district court, DHEC's rejection of ACOG's assistance further demonstrated DHEC's lack of interest in ensuring that Regulation 61-12 actually met the proffered goal of promoting maternal health and is consistent with the testimony of the DHEC witnesses that such a goal was not their primary motivation during the drafting process. See id.

Eighth, the district court found that, although it is uncontroverted that first trimester abortions are significantly less risky to the health of women than second trimester abortions, an existing South Carolina regulation governing second trimester abortions was utilized as a starting point for Regulation 61-12. With

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the exception of Section 309 of Regulation 61- 12 which specifically pertains to second trimester abortions, [FN8] the DHEC drafters drew no distinction between first and second trimester abortions in the text of the regulation. In addition, the DHEC drafters admitted that virtually no such distinctions were considered during the drafting process. See id.

FN8. Section 309 mandates additional qualifications which the performing physician must possess, additional equipment which must be on hand, and additional medical tests which must be administered for second trimester abortions. *See* S.C.Code Ann. Regs. 61-12, §§ 309(A)-(D).

Ninth, the district court found that, instead of attempting to tailor Regulation 61-12 to the particularized medical needs of women seeking first trimester abortion services in South Carolina, DHEC's goal during the drafting process was to standardize its health care and facility regulations and to codify existing departmental practices. See id. at 719-20. According to the district court, to the extent this was done, it was done without any meaningful inquiry or assessment as to whether the requirements would further the state's interest in maternal health and without assessing *189 whether first trimester abortions were comparable to the procedures performed in the other facilities regulated by DHEC. See id. at 720. The district court further found that clinics that provide first trimester abortions provide services that are significantly less risky, invasive, and lengthy than the services offered in ambulatory surgical centers, yet many of the requirements of Regulation 61-12 are as stringent, or in some respects more stringent, than those imposed upon ambulatory surgical centers. [FN9] See id.

FN9. In fact, Regulation 61-12 recognizes that the risks and potential complications of surgical procedures typically performed in ambulatory surgical centers are significantly higher than those associated with first trimester abortions. Under Regulation 61-12, licensed abortion clinics are restricted to performing abortions through eighteen weeks of pregnancy measured from the pregnant woman's lmp. S.C.Code Ann. Regs. 61-12, § 302(A). Abortion clinics performing abortions beyond fourteen weeks of pregnancy measured from the pregnant woman's lmp must meet the additional patient requirements in Section 309 of Regulation 61-12, which requires physician additional qualifications, medical equipment, and mandatory laboratory tests. See id. § Abortions beyond eighteen weeks of pregnancy measured from the pregnant woman's lmp must be performed in a hospital, although a licensed

ambulatory surgical center that is also licensed as an abortion clinic may perform abortions on patients through twenty-six weeks of pregnancy measured from the pregnant woman's lmp. See id. § 302(A).

Tenth, the district court found that Planned Parenthood, NAF, and ACOG standards and guidelines relied upon in part by DHEC are recommendations by the respective organizations and are not fairly characterized as mandated standards of care which can or should be imposed upon licensed physicians as regulatory requirements. Rather, they are guidelines which should be followed with due regard for the medical judgment of the treating physicians and the special needs of the patients they serve. Even if some of the existing guidelines could, in isolation, be appropriate matters for regulation, the district court found that Regulation 61-12 imposes requirements which greatly exceed the guidelines. See id.

Eleventh, the district court found that, in imposing the detailed requirements of Regulation 61-12, the DHEC drafters also failed to take any meaningful steps to evaluate the costs of compliance or its impact upon the availability of abortion services in South Carolina. See id. Based upon the evidence presented, the district court found that Regulation 61-12 will significantly increase the cost of abortion services in South Carolina. See id. The district court found that this increase in the cost of abortion services will delay a significant number of women from obtaining the procedure and, in some cases, result in their inability to obtain the procedure. See id. The district court further found that, as a pregnancy advances, the medical risks associated with abortion increase, and a full term pregnancy and childbirth is much more risky to the physical health of a woman than a first trimester abortion. See id.

Twelfth, the district court found that Regulation 61-12 contained a myriad of detailed and costly provisions that were medically unnecessary and, thus, were neither designed to further the health of women seeking first trimester abortions nor likely to accomplish this goal. For example, with respect to Part I of Regulation 61-12, the district court observed that its definition of an "abortion" included medical abortions currently used to terminate ectopic pregnancies. See id. at 721. However, all of the evidence in the record, including the testimony of Dr. Goodrich, suggested that Regulation 61-12's stringent requirements were medically unnecessary for a physician or abortion clinic that performed only

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medical abortions.

With respect to Part II, the district court found that this portion of Regulation 61-12 is permeated with requirements governing unnecessary physician qualifications, staffing, and staff training. See id. The district court observed that Regulation *190 61-12 requires physicians and clinics to hire a registered nurse to supervise all nursing care in the abortion clinic regardless of the fact that a licensed physician is present in the clinic to supervise all medical care, including nursing care. See id. The district court found that it is within accepted medical practice, both within the abortion context and in physicians' offices performing comparable surgical procedures, for a physician to hire licensed practical nurses (who command a lower salary than registered nurses) so long as they act under the supervision of the attending physician. See id. The district court found that the defendants offered no persuasive reason why a physician could not supervise the nursing care of patients during the recovery process simply because the physician may be in another room for a brief period of time. See id. In making this finding, the district court recognized that even DHEC's own medical consultant, Dr. Goodrich, opined that a registered nurse need not be on the premises to supervise care-only that the nurse have overall supervisory duties. See id.

Also with respect to Part II, the district court found that Part II's requirement that all abortion clinic health care personnel receive tuberculin skin testing is medically unnecessary in view of the fact that DHEC has not required such testing of all health care personnel and did not offer any justification for arbitrarily requiring this testing of all abortion care workers, but not all other health care workers. See id. at 722.

The district court also found that Regulation 61-12's requirement that *all* allied health care personnel in abortion clinics receive CPR training, as opposed to having one qualified person at the clinic at all times, was medically unnecessary in view of the fact that this requirement is imposed solely upon abortion providers who perform, according to all of the witnesses, one of the safest surgical procedures that is performed in this country, and DHEC did not offer any justification for arbitrarily imposing this requirement. *See id*.

With respect to Part III, the district court found that the level of policies and procedures required by this part, as well as the extensive in-service training requirements and other policies required in Part II, are costly endeavors unsubstantiated by a medical need. See id. The district court observed that such requirements may be appropriate for large medical care facilities with large staffs that do not interact on a daily basis. See id. However, according to the district court, Regulation 61-12 arbitrarily imposes it upon every clinic and every physician's office which performs five or more first trimester abortions per month-regardless of the number of staff or hours of operation. See id.

The district court also found that it was medically unnecessary to have every woman undergo (and pay for) testing for certain sexually transmitted diseases (but not others), without regard to whether such tests are medically indicated and indeed even when the physician determines that they are not, simply because the woman has chosen to obtain a first trimester abortion from a physician who performs them on a regular basis. [FN10] See id. The district court further found that Section 307's requirement that abortion providers have "consulting" arrangements with various specialists before they can obtain a license to operate is medically unnecessary and unduly burdensome because no evidence was presented relating to why licensed physicians are not capable of exercising appropriate discretion in recognizing and acting upon the medical needs of their patients in this regard. See id. at 722-23.

FN10. Of note, the district court found that the defendants presented insufficient evidence to support a finding that sexually transmitted diseases are more prevalent in woman seeking abortions or that abortion clinics present a public health problem in this regard. See Greenville Women's Clinic, 66 F.Supp.2d at 733 n. 16.

*191 Also with respect to Part III, the district court found that Regulation 61-12 inexplicably imposes requirements concerning access to emergency drugs which are not imposed upon any other physicians. See id. at 723. The district court also found that the equipment and supplies required by Regulation 61-12 will also increase the costs of providing abortions in South Carolina, and require equipment unnecessary for the safe performance of the first trimester abortion procedure. See id.

With respect to Part IV, the district court found that this part of Regulation 61-12 was particularly troubling. For example, the district court found that the requirement that a woman seeking an abortion provide the name of her spouse in addition to an 222 F.3d 157 (Cite as: 222 F.3d 157, *192)

(3) When directly billing physicians, laboratories in South Carolina charge between \$7 and \$20 per sample to perform a test for syphilis and between \$10 and \$22 to perform a test from a pap smear.

See id. The district court found that the substantial alterations that Dr. Lynn would have to undertake to bring his Beaufort practice in compliance with Regulation 61-12 will likely force him to close his practice, thereby eliminating the availability of abortions in this area of South Carolina. [FN13] See id. The district court also found that the increased cost of providing abortions and/or the closure of the only abortion clinic in one area of a state resulting from Regulation 61-12 will prevent a significant number of women from obtaining an abortion or, at a minimum, delay them from obtaining the abortion, both of which carry increased risks to the health of women. [FN14] See id. at 718. The district *193 court found that, as a pregnancy advances, the medical risks associated with an abortion procedure increase, and a full term pregnancy is more risky to the physical health of a woman than a first trimester abortion. See id. at 720.

FN13. At trial, the plaintiffs presented evidence that, to comply with Regulation 61-12, CWMC would require renovations costing approximately \$27,235, that Dr. Lynn's Greenville practice would require renovations costing approximately \$2,700, that Dr. Lynn's Beaufort office would need renovations costing approximately \$12,256, and that GWC would need renovations costing approximately \$3,700.

FN14. The district court's finding in this regard was premised on the testimony of the plaintiffs' expert, Dr. Stanley Henshaw, who is currently deputy director of research at the Alan Guttmacher Institute in New York, where he conducts studies relating to family planning and abortion services. Dr. Henshaw testified that an increase in the price of abortion procedures prevents a number of women from obtaining abortions and causes other women to delay their abortions until further along into their pregnancies. Dr. Henshaw also testified that relatively small increases in the cost of an abortion will have this effect, and that an increase of just \$25 can be expected to prevent one or two out of every 100 low-income women seeking an abortion from being able to obtain one. Dr. Henshaw also testified that a decrease in the number of abortion providers in South Carolina will result in a decrease in the number of women who are able to obtain an abortion in the state, and a corresponding increase in the number of women who must travel to obtain the procedure, e.g., from Beaufort to Savannah, Georgia and/or Charleston, South Carolina. Such a need to

travel will, in turn, reduce the ability to obtain an abortion or result in a delay in obtaining the abortion. And the need to travel carries its own costs, which will increase the overall cost of obtaining the abortion and compound the financial problem.

F

Based on the findings of the district court summarized above, the district court concluded that Regulation 61-12 violated the Due Process and Equal Protection Clauses of the Fourteenth Amendment. See id. at 724-43. With respect to the Due Process Clause, the district court held that Regulation 61-12 failed to pass constitutional muster under either the facial invalidity standard set forth in United States v. Salerno, 481 U.S. 739, 107 S.Ct. 2095, 95 L.Ed.2d 697 (1987), or the undue burden test set forth in Planned Parenthood v. Casey, 505 U.S. 833, 112 S.Ct. 2791, 120 L.Ed.2d 674 (1992) (plurality joint opinion of O'Connor, Kennedy, and Souter, J.J.). See Greenville Women's Clinic, 66 F.Supp.2d at 727-37. With respect to the undue burden standard set forth in Casey, the district court held that Regulation 61-12 did not serve and was not designed to serve the state's interest in maternal health. See id. at 730-35. To the contrary, the district court concluded that Regulation 61-12 would likely harm the health of women in South Carolina. See id. Accordingly, the district court concluded that Regulation 61-12 was unconstitutional under Casey. See id. at 735. The district court also concluded that even if Regulation 61-12 furthered the state's interest in maternal health, the burdens imposed by Regulation 61-12 upon abortion patients and providers constituted an undue burden on a woman's right to have an abortion prior to viability. See id. at 735-43. With respect to the standard set forth in Salerno, the district court concluded that Regulation 61-12 unconstitutional in all of its applications and, therefore, could not stand under Salerno. See id. at 736-43.

With respect to the Equal Protection Clause, the district court held that Regulation 61-12 violated the Equal Protection Clause under both the strict scrutiny test and the more lenient rational basis test. See id. at 737-43. With respect to the rational basis test, the district court held that Regulation 61-12 failed that test because it singles out physicians and abortion clinics performing five or more first trimester abortions per month from other physicians and clinics performing four or less first trimester abortions per month and/or other virtually identical procedures and places additional and onerous burdens upon physicians

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and abortion clinics which are neither justified by actual differences nor rationally related to the state's legitimate interest in protecting the health and safety of women seeking first trimester abortions. See id. at 740-43.

Finally, the district court concluded, in light of both South Carolina law and the text of Regulation 61-12, that Regulation 61-12 was not subject to the doctrine of severability. [FN15] See id. at 743-44.

FN15. In light of its ruling that Regulation 61-12 violated the Due Process and Equal Protection Clauses of the Fourteenth Amendment, the district court declined to address the plaintiffs' remaining claims that Regulation 61-12:(1) was unconstitutionally vague; (2) violated the abortion patients' confidentiality rights; and (3) violated the Establishment Clause of the First Amendment.

II A

The Due Process Clause of the Fourteenth Amendment states that: "nor shall any State deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV, § 1. "Although a literal reading of the Clause might suggest that it governs only the procedures by which a State may deprive *194 persons of liberty, ... the Clause has been understood to contain a substantive component as well, one barring certain government actions regardless of the fairness of the procedures used to implement them." Casey, 505 U.S. at 846, 112 S.Ct. 2791 (plurality joint opinion of O'Connor, Kennedy, and Souter, J.J.) (citation and internal quotation marks omitted). A woman's right to have an abortion is recognized as a fundamental right protected by the substantive component of the Due Process Clause of the Fourteenth Amendment. See Roe v. Wade, 410 U.S. 113, 155-66, 93 S.Ct. 705, 35 L.Ed.2d 147 (1973); see also Manning v. Hunt, 119 F.3d 254, 259 (4th Cir.1997). [FN16]

FN16. Because Regulation 61-12 applies to first trimester abortion providers, the plaintiffs have standing to challenge the constitutionality of the regulation. See Virginia v. Am. Booksellers Ass'n, 484 U.S. 383, 392, 108 S.Ct. 636, 98 L.Ed.2d 782 (1988); Doe v. Bolton, 410 U.S. 179, 188, 93 S.Ct. 739, 35 L.Ed.2d 201 (1973).

In *Roe*, the Supreme Court overturned a Texas statute prohibiting abortions unless an abortion was necessary to save the life of the mother. *See* 410 U.S. at 117-18,

93 S.Ct. 705. The Roe Court held that the right of personal privacy includes the right to have an abortion, but that the right "is not unqualified and must be considered against important state interests in regulation." Id. at 154, 93 S.Ct. 705. The Court determined that because abortion is a fundamental right, state abortion regulations should be analyzed under the strict scrutiny standard of review, and are, therefore, valid only if the regulation can be justified by a compelling state interest and if the regulation was narrowly drawn to further only that legitimate state interest. See id. at 155, 93 S.Ct. 705. According to the Court, the state's interest in preserving and protecting the health of the mother and in protecting potential human life increase in substantiality as the woman approaches term, becoming compelling at some point in the pregnancy. See id. at 162-63, 93 S.Ct. 705.

The Roe Court found that during the first trimester of pregnancy the decision to abort must be left to the wishes of the mother and the judgment of the mother's physician; that during the time after the first trimester but before viability of the fetus, the state could regulate the abortion decision in ways reasonably related to maternal health; and that after viability, the state could regulate or proscribe abortion except when necessary to preserve the life or health of the mother. See id. at 164-65, 93 S.Ct. 705.

Since *Roe*, the Court has struggled to formulate a precise standard for reviewing facial challenges to abortion regulations. In *Salerno*, the Court explained that

[a] facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid. The fact that [an Act] might operate unconstitutionally under some conceivable set of circumstances is insufficient to render it wholly invalid, since we have not recognized an "overbreadth" doctrine outside the limited context of the First Amendment.

481 U.S. at 745, 107 S.Ct. 2095. Thus, under Salerno, a facial challenge to a statute will fail if the statute has any constitutional application. Following Salerno, the Supreme Court applied Salerno's "no set of circumstances" test in a few pre-Casey cases involving abortion statutes. See, e.g., Rust v. Sullivan, 500 U.S. 173, 183, 111 S.Ct. 1759, 114 L.Ed.2d 233 (1991).

In Casey, however, the Court held that an abortion law is unconstitutional on its face if, "in a large fraction of the cases in which [the statute] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." 505 U.S. at 895, 112 S.Ct. 2791. Although *Casey* did not expressly overrule *Salerno*, it is inconsistent with *Salerno*. Under *Salerno*, no factual showing of unconstitutional application can render a law unconstitutional *195 if it has any constitutional application. Under *Casey*, a factual showing of unconstitutional application in "a large fraction of the cases" where the law applies can render a law unconstitutional, even if it has some constitutional application.

In Casey 's wake, many circuit courts held that Casey displaced Salerno in the abortion context. See, e.g., Planned Parenthood v. Lawall, 180 F.3d 1022, 1027 (9th Cir.) ("In light of our previous suggestion, combined with the great weight of authority holding that Casey has overruled Salerno in the context of facial challenges to abortion statutes, we apply Casey's undue burden standard in determining the facial constitutionality of [the statute at issue]."), amended by 193 F.3d 1042 (9th Cir.1999); Women's Med. Profil Corp. v. Voinovich, 130 F.3d 187, 193- 96 (6th Cir.1997) (concluding that Salerno is inapplicable to facial challenges to abortion regulations and applying Casey 's undue burden standard), cert. denied, 523 U.S. 1036, 118 S.Ct. 1347, 140 L.Ed.2d 496 (1998): Jane L. v. Bangerter, 102 F.3d 1112, 1116 (10th Cir.1996) (noting the difference between Casey and Salerno and applying Casey 's undue burden standard to facial abortion challenge); Planned Parenthood v. Miller, 63 F.3d 1452, 1458 (8th Cir.1995) (choosing to follow "what the Supreme Court actually did--rather than what it failed to say--and apply the undue-burden test" to facial abortion challenge); Casey v. Planned Parenthood, 14 F.3d 848, 863 n. 21 (3d Cir.1994) (noting that Supreme Court in Casey "set a new standard for facial challenges to previability abortion laws"). The Fifth Circuit has applied the Salerno test to a facial abortion challenge after Casey, see Barnes v. Moore, 970 F.2d 12, 14 (5th Cir.1992), but its application of Salerno has not been consistent, see Sojourner T. v. Edwards, 974 F.2d 27, 29-31 (5th Cir.1992) (striking down statute banning abortions as clearly unconstitutional under Casey, even though it permitted abortions to save the life of the mother and, therefore, arguably passed constitutional muster under Salerno), and the Fifth Circuit has yet to resolve the inconsistency. See Okpalobi v. Foster, 190 F.3d 337. 354 (5th Cir. 1999) (noting inconsistency but declining to address it because challenged law failed under both Casey and Salerno).

However, our circuit never resolved the Salernol Casey question, despite what the majority might have one believe. See ante at 164-65. In Manning, we applied the Salerno standard of review to an abortion statute, but the plaintiffs did not challenge its applicability. See 119 F.3d at 268 n. 4. In dicta, however, the court suggested that we would nonetheless apply the Salerno standard until the Supreme Court explicitly overruled it, stating that

[i]t is not the province of the court of appeals to predict how the Supreme Court will ultimately rule on an issue. Casey does not specifically overrule Salerno. At the moment, the most that can be said is that three Justices have indicated a desire to do so. Until the Supreme Court specifically does so, though, this Court is bound to apply the Salerno standard as it has been repeatedly applied in the context of other abortion regulations reviewed by the Supreme Court. ld.; see also Planned Parenthood v. Camblos, 155 F.3d 352, 381 n. 14 (4th Cir.1998) (en banc) (noting the Manning dicta but not deciding the question), cert. denied, 525 U.S. 1140, 119 S.Ct. 1031, 143 L.Ed.2d 40 (1999); id. at 389 n. 2 (Michael, J., concurring in the judgment) (asserting that Casey 's undue burden test must be applied to facial challenges to abortion restrictions).

The SalernolCasey question was finally resolved by the Supreme Court in Stenberg v. Carhart, --- U.S. ----, 120 S.Ct. 2597, 147 L.Ed.2d 743 (2000). In that case, a Nebraska physician brought a facial challenge to Nebraska's "partial birth" abortion statute. interpreted by the Supreme Court, the Nebraska statute banned the performance of second trimester dilation and extraction (D&X) abortions, *196 commonly referred to as "partial birth abortions," and the performance of dilation and evacuation (D&E) abortions, the most commonly used method for performing previability second trimester abortions. The Supreme Court applied Casey and concluded that the Nebraska statute was unconstitutional for two independent reasons. First, the Court concluded that the Nebraska statute was unconstitutional because the statute lacked any exception for the preservation of the health of the mother and the record evidence disclosed that, in some circumstances, a D&X abortion would be the safest abortion. See Stenberg, --- U.S. at ----120 S.Ct. at 2609-13. Second, the Court concluded that, because the Nebraska law applied to the performance of D&E abortions, the most commonly used method for performing previability second trimester abortions, the resulting fear of prosecution, conviction, and imprisonment felt by physicians who perform D&E abortions amounted to an undue burden

on a woman's right to have an abortion. See id. --- U.S. at ----, 120 S.Ct. at 2613-17.

In this case, the district court did not resolve the SalernolCasey question. See Greenville Women's Clinic, 66 F.Supp.2d at 726-27. Instead, the district court analyzed Regulation 61-12 under both standards and held that Regulation 61-12 failed to pass constitutional muster under either the Salerno or Casey standard. See id. at 727-37. Here, being bound by Stenberg, I only need to evaluate Regulation 61-12 under the principles set forth in Casey, as contrary to the majority's intimation, see ante at 164-65, Salerno, in the abortion context, is not recognized as the law by the current Supreme Court.

In Casey, the Supreme Court established the undue burden test for determining whether a statute restricting abortions could pass constitutional muster. Under Casey, a statute is invalid on its face if it places an undue burden on a woman's right to have an abortion before the fetus attains viability. See 505 U.S. at 878, 112 S.Ct. 2791. An undue burden exists if the state regulation has the effect of placing a substantial obstacle in the path of a woman's choice to obtain an abortion before the fetus attains viability. Id. at 877-78, 112 S.Ct. 2791. A statute that creates a substantial obstacle for a large fraction of those women affected by the regulation creates an undue burden and is facially unconstitutional. See id. at 894-95, 112 S.Ct. 2791. Thus, in Casey, the Court rejected Roe's trimester framework, but left intact a woman's fundamental right "to choose to have an abortion before viability and to obtain it without undue interference from the state." Id. at 846, 112 S.Ct. In reaching this conclusion, the Court recognized that the state's interests prior to viability "are not strong enough to support a prohibition of abortion or the imposition of a substantial obstacle to the woman's effective right to elect the procedure." Id.

In Casey, the Supreme Court was presented with constitutional challenges to various provisions in a Pennsylvania statute governing informed consent, parental consent, record-keeping and reporting requirements, and a medical emergency exception. See id. at 844, 112 S.Ct. 2791. Thus, the plurality opinion primarily focused on the state's legitimate interests in the potentiality of human life--holding that to promote this "profound interest in potential life, throughout pregnancy the State may take measures to ensure that the woman's choice is informed, and measures designed to advance this interest will not be invalidated so long as their purpose is to persuade the

woman to choose childbirth over abortion" and they do not impose an "undue burden on the right." *Id.* at 878, 112 S.Ct. 2791.

Nevertheless, the *Casey* plurality also provided guidance by addressing the state's concomitant, and equally legitimate, interest in preserving and protecting the health of women seeking abortion services--of particular relevance to the challenge in this case. Specifically, the *Casey* plurality held that as

*197 with any medical procedure, the State may enact regulations to further the health or safety of a woman seeking an abortion. Unnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on the right. Id. at 878, 112 S.Ct. 2791 (emphasis added).

The types of burdens that may be imposed by state regulation are varied in nature, but clearly include financial burdens which restrict or prohibit the exercise of the right. As noted by the *Casey* plurality:

Numerous forms of state regulation might have the incidental effect of increasing the cost or decreasing the availability of medical care, whether for abortion or any other medical procedure. The fact that a law which serves a valid purpose, one not designed to strike at the right itself, has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it. Only where the state regulation imposes an undue burden on a woman's ability to make the decision does the power of the State reach into the heart of the liberty protected by the Due Process Clause. Id. at 874, 112 S.Ct. 2791; see also id. at 901, 112 S.Ct. 2791. Furthermore, "[n]ot all burdens on the right to decide whether to terminate a pregnancy will be undue." Id. at 876, 112 S.Ct. 2791. As the Casey plurality noted:

A finding of an undue burden is a shorthand for the conclusion that a state regulation has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus. A statute with this purpose is invalid because the means chosen by the State to further the interest in potential life must be calculated to inform the woman's free choice, not to hinder it. And a statute which, while furthering the interest in potential life or some other valid state interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends.

Id. at 877, 112 S.Ct. 2791. Accordingly, the court must first determine whether Regulation 61-12 furthers

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the state's interest in maternal health, which is the state interest the defendants contend Regulation 61-12 was designed to serve. See id.; id. at 900-01, 112 S.Ct. 2791 ("The collection of information with respect to actual patients [which, under the statute at issue, will remain confidential] is a vital element of medical research, and so it cannot be said that the requirements serve no purpose other than to make abortions more difficult."). If Regulation 61-12 furthers the state's interest in maternal health, the court must next determine whether Regulation 61-12 imposes an undue burden on a woman's right to seek an abortion. See id. at 877, 901, 112 S.Ct. 2791.

In this case, a careful review of the record discloses that Regulation 61-12 does not further the state's interest in maternal health. With respect to whether Regulation 61-12 furthers the state's interest in maternal health, I note that the Supreme Court has not provided much guidance in this area. However, several pre-Casey cases do provide some insight. For example, in Roe's companion case, Doe v. Bolton, the Court invalidated a Georgia law requiring that all first trimester abortions be performed in a licensed hospital where the state failed to show that only the hospital environment could ensure the quality of the operation and the protection of the patients. See 410 U.S. at 195, 93 S.Ct. 739.

In Akron v. Akron Center for Reproductive Health, Inc., 462 U.S. 416, 103 S.Ct. 2481, 76 L.Ed.2d 687 (1983), the Supreme Court was presented with a challenge to an Ohio ordinance which, among other things, required all second trimester abortions to be performed in a hospital. See id. at 422, 103 S.Ct. 2481. Reaffirming the *198 prohibition against over regulation of a relatively safe surgical procedure, the Court held that the [s]tate's discretion to regulate on [the basis of maternal health] does not ... permit it to adopt abortion regulations that depart from accepted medical practice.... If a State requires licensing or undertakes to regulate the performance of abortions during this period, the health standards adopted must be legitimately related to the objective the State seeks to accomplish.

Id. at 431, 103 S.Ct. 2481 (citation and internal quotation marks omitted). The Court then invalidated the ordinance, holding that it "imposed a heavy, and unnecessary, burden on a woman's access to a relatively inexpensive, otherwise accessible, and safe abortion procedure." Id. at 438, 103 S.Ct. 2481. [FN17]

FN17. The Supreme Court in Casey overruled only

those parts of Akron that were "inconsistent with Roe's statement that the state has a legitimate interest in promoting the life or potential health of the unborn." Casey, 505 U.S. at 870, 112 S.Ct. 2791. Thus, the Akron decision continues to inform us as to the propriety of regulations purportedly enacted to further the state's interest in maternal health.

From the above discussion, it is evident that the State of South Carolina has a legitimate interest from the outset of pregnancy in protecting the health of women seeking abortions, and that this interest is sufficiently important to allow the state to regulate abortion providers, including providers that limit their services to abortions during the first trimester. See Casey, 505 U.S. at 876, 112 S.Ct. 2791. Furthermore, this interest allows the state to regulate, within the boundaries of Casey and its predecessors, such matters as the qualifications of the person performing the procedure, the facilities in which the abortions are performed, and the availability of medical care after the procedure and in the event of an emergency. See Roe, 410 U.S. at 149- 50, 93 S.Ct. 705. However, 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 and must be invalidated. See Casey, 505 U.S. at 878, 112 S.Ct. 2791; Akron, 462 U.S. at 431, 103 S.Ct. 2481.

In my view, Regulation 61-12 is riddled with unnecessary requirements, i.e., requirements not reasonably related to maternal health or which depart from accepted medical practice. For example, Regulation 61-12's requirement that each abortion patient be tested for particular sexually transmitted diseases is not an accepted medical practice where there are no symptoms or other accepted medical reasons or risk factors to justify such a test. [FN18] Also, Regulation 61-12 requires an abortion clinic to perform urine pregnancy tests on all abortion patients, including those whose pregnancy have been confirmed by other means, e.g., ultrasound. In addition, Regulation 61-12 places medically unnecessary administrative requirements on abortion clinics which are clearly inappropriate to medical offices of such small sizes as the plaintiffs' offices. For example, DHEC has mandated -- without regard to the number of staff or size of the abortion clinic--the development of extensive policies and procedures, frequent staff meetings, formal in-service training and required staff certifications, and medical testing of employees which, while probably appropriate for a hospital or a large outpatient surgical center, are unnecessary in a small physician's office or clinic. Furthermore, there is no

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evidence in the record demonstrating how Regulation 61-12's construction and design requirements will further the health *199 of women seeking abortions in South Carolina, and no explanation is offered as to why all of these requirements are so much greater for these clinics than they are for other physicians' offices performing the same type of procedures.

FN18. In the district court, the defendants argued that selected diseases are more prevalent in women seeking abortions or that abortion clinics present a public health problem in this regard. However, the district court found insufficient credible evidence to support such a finding.

Another requirement which is not an accepted medical practice is Regulation 61-12's requirement that a registered nurse, as opposed to a licensed physician, supervise nursing care. There is no evidence in the record to suggest that a physician is not capable of supervising nursing care. In addition, Regulation 61-12 requires that an abortion clinic "be kept ... free from odors" and that all outside areas "be kept free of rubbish, grass, and weeds that may serve ... as a haven for insects, rodents and other pests." S.C.Code Ann. Regs. 61-12, §§ 604 and 606. However, there is no evidence in the record suggesting that these requirements would ensure the quality of a first trimester abortion procedure or the protection of patients.

The same can be said about Part X of Regulation 61-12 which grants DHEC the authority to impose penalties for any condition which, while not mandated or prohibited by Regulation 61-12, DHEC deems to be "against the best practices" as later defined by DHEC. *Id.* Part X. Obviously, Part X of Regulation 61-12 subjects physicians to unnecessary uncertainty in the operation of their practices and invites arbitrary enforcement. Finally, it is not an accepted medical practice to permit a state agency, such as DHEC, to enter an abortion clinic, copy records, and disseminate them publicly, but this is precisely what Regulation 61-12 allows. [FN19]

FN19. The majority implies that Regulation 61-12 requires DHEC to treat all abortion patient records as confidential. See ante at 171-72. However, Regulation 61-12 imposes no such requirement on DHEC. Rather, under Regulation 61-12, only the abortion clinic must treat patient records as confidential. See S.C.Code Ann. Regs. 61-12, § 402. Succinctly put, Regulation 61-12 allows DHEC to enter an abortion clinic, inspect its records, and make photocopies of these records, see id. § 102(F), and

Regulation 61-12 places no limitation on DHEC's use of the records once photocopies are made. Thus, Regulation 61-12 differs markedly from the provisions upheld by the Supreme Court in Whalen v. Roe. 429 U.S. 589, 97 S.Ct. 869, 51 L.Ed.2d 64 (1977), and Planned Parenthood v. Danforth, 428 U.S. 52, 96 S.Ct. 2831, 49 L.Ed.2d 788 (1976), two cases cited by the majority. See ante at 171-72. In each of these cases, the statute at issue required the state agency which had access to the patient records to treat the records as confidential and/or significantly limited the state agency's use of the patient records. See Whalen, 429 U.S. at 594, 97 S.Ct. 869 (New York statute had extensive measures to insure records remained confidential and provided that the public disclosure of the identity of patients was expressly prohibited); Danforth, 428 U.S. at 79-81, 96 S.Ct. 2831 (Missouri statute mandated that patient information required on patient forms was confidential and to be used only for statistical purposes). In my view, Regulation 61-12 is more akin to a provision of a Pennsylvania statute rejected by the Supreme Court in Thornburgh v. American College of Obstetricians and Gynecologists, 476 U.S. 747, 106 S.Ct. 2169, 90 L.Ed.2d 779 (1986); in that case, even though the Pennsylvania law under review stated that patient reports were not public records, Pennsylvania law permitted the reports, which contained both information about the women who obtained abortions and information about the doctors who performed them, to be made public and also did not limit the Commonwealth's use of patient information. See id. at 764-68, 106 S.Ct. 2169. One other point on the issue of confidentiality is worth noting. Both the guidelines of the NAF and ACOG prohibit the release of any medical record without the patient's consent.

In summary, Regulation 61-12 does not further the state interest of protecting maternal health. In fact, Regulation 61-12 has the opposite effect. As found by the district court, Regulation 61-12 will substantially increase the cost of abortions in South Carolina because Regulation 61-12 requires unnecessary tests be performed, unnecessary staff be hired, and, in some cases, extensive renovations to existing facilities be made. Because Regulation 61-12 will result in a substantial increase in the cost of obtaining an abortion in South Carolina, a significant number of women will be forced to either delay having an abortion, or forego having one altogether. *200 This, in turn, will result in increased health risks to women seeking abortions. Accordingly, Regulation 61-12 serves no other

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purpose than to make abortions more difficult to obtain, and, therefore, Regulation 61-12 violates the Due Process Clause of the Fourteenth Amendment. See Casey, 505 U.S. at 877, 112 S.Ct. 2791; id. at 900-01, 112 S.Ct. 2791.

The majority concludes that Regulation 61-12 was designed to further the State of South Carolina's interest in maternal health largely on the basis that Regulation 61-12 is generally compatible with accepted medical practice governing abortions, more specifically, the guidelines promulgated by ACOG and NAF. See ante at 167-69. The majority's analysis ignores the significant departures that Regulation 61-12 makes from those guidelines, the attendant costs associated with those departures, and the effect of those costs on the availability of abortions in the State of South Carolina. Regulation 61-12 goes far beyond the recommendations of ACOG and NAF, and, in some cases conflicts with them. Thus, while the ACOG and NAF guidelines address physical plant and equipment needs in abortion clinics, they do not suggest or support the extensive plant and equipment requirements (such as mandating numerous separate rooms or areas, utility sinks, and specific air exchanges, sheltered entryways, special janitor's closets) included in Regulation 61-12. Similarly, the ACOG and NAF guidelines do not contain any recommendations supporting the staffing requirements imposed by Regulation 61-12. For example, none of the guidelines require that a registered nurse supervise nursing care in an abortion facility if the attending physician is able to supervise that care. In addition, the ACOG and NAF guidelines do not support the testing requirements imposed by Regulation 61-12; specifically, they do not call for any routine testing of abortion patients other than for Rh factor and anemia, and they state that sexually transmitted disease testing should be performed on the basis of risk factors. Likewise, while the ACOG guidelines address the administration of abortion clinics, they do not require the extensive written policies, procedures, and formal meetings required by Regulation 61-12. Also, the ACOG and NAF guidelines forbid the release of any medical information from a patient's record without the prior consent of the patient, thus conflicting with Regulation 61-12's mandate that abortion providers permit DHEC to copy and remove patient records. In addition, while the ACOG and NAF guidelines recommend that counseling be offered, Regulation 61-12 requires something very different. It mandates the establishment of relationships with outside specialists in various areas to whom patients can be referred. Finally, it should be noted that the district

court found as a fact that the ACOG and NAF guidelines were just that, guidelines. They are not mandates.

The upshot of this discussion is that the departures from the ACOG and NAF guidelines listed above, coupled with many others not discussed, result in a substantial increase in the cost of obtaining an abortion in the State of South Carolina. As noted above, because Regulation 61-12 will result in a substantial increase in the cost of obtaining an abortion in South Carolina, a significant number of women will be forced to either delay having an abortion, or forego having one altogether. Also, the costs will likely force the closure of Dr. Lynn's Beaufort office, which will result in the elimination of abortion services in that part of South Carolina. Under such circumstances, one must conclude that Regulation 61-12 does not further the State of South Carolina's interest in maternal health.

Even if Regulation 61-12 furthers the state interest of protecting and preserving the health of women seeking abortions, Regulation 61-12 cannot stand if it imposes an undue burden on a woman's fundamental right to obtain an abortion, see id. at 877-78, 112 S.Ct. 2791, as a regulation *201 which has "the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends." Id. at 877, 112 S.Ct. 2791. A review of the record makes it clear that Regulation 61-12 will impose an undue burden on the right to obtain an abortion prior to viability. As noted earlier, a first trimester suction curettage abortion in South Carolina currently costs between \$325 and \$480, depending on the gestational age, the type of sedation or anesthesia needed, and the medical testing indicated. Based on the costs of complying with Regulation 61-12, the district court found that Regulation 61-12 would raise the cost of each abortion performed by the plaintiffs in the following ranges: (1) for CWMC, the cost will increase between \$36.48 and \$75.03; (2) for Dr. Lynn's Greenville practice, the cost will increase between \$93.09 and \$170.39; (3) for Dr. Lynn's Beaufort practice, the cost will increase between \$115.67 and \$367.50; and (4) for GWC, the cost will increase between \$22.68 and \$32.39. See Greenville Women's Clinic, 66 F.Supp.2d at 717. A significant increase in the cost of obtaining an abortion alone can constitute an undue burden on the right to have an abortion. See Casey, 505 U.S. at 901, 112 S.Ct. 2791 ("While at some point increased cost could become a substantial obstacle, there is no such showing on the record before us."). It follows that the decreased availability of abortions due to the closure

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of the only abortion clinic in one area of a state also constitutes an undue burden on the right to have an abortion, as it increases the distance a woman has to travel to obtain an abortion, thereby significantly increasing the time and the cost to obtain an abortion.

Regulation 61-12 will impose a significant increase in the cost of obtaining an abortion in South Carolina, which, in turn, will prevent woman from obtaining abortions. For example, for a woman in Beaufort, South Carolina, the cost of a first trimester abortion will increase, at a minimum, \$115.67, or, if Dr. Lynn's Beaufort practice closes because of Regulation 61-12, it may result in the elimination of abortion services in that part of the state altogether. Also the increased costs of providing abortions resulting from Regulation 61-12 at other facilities throughout South Carolina will prevent a significant number of women from obtaining an abortion or, at a minimum, delay them from obtaining an abortion, thus, resulting in increased health risks to women in South Carolina.

Regulation 61-12 also imposes additional burdens, unrelated to cost, on the right to obtain an abortion. For example, Regulation 61-12 grants DHEC inspectors the right to inspect abortion clinics at will and without limitation; such inspections can be initiated by anonymous complaints. During any such inspection, DHEC inspectors are granted the right to copy confidential patient records, and Regulation 61-12 does not ensure that DHEC will keep these records confidential. Obviously, this requirement would have a chilling effect on a woman's freedom to choose to have, and a physician's willingness to perform, an abortion. Another example is Regulation 61-12's requirement that a married abortion patient disclose her husband's name. Obviously, this requirement is not necessary for the provision of safe medical care, and there are a host of reasons why a married patient would prefer not to disclose her husband's name. Cf. Casey, 505 U.S. at 893-98, 112 S.Ct. 2791 (holding that Pennsylvania law requiring spousal notification prior to abortion imposes an undue burden on the right to have an abortion). Thus, this requirement also hinders a woman from obtaining an abortion. Finally, physicians performing five or more first trimester abortions per month must be licensed by the State of South Carolina and be "properly qualified by training and experience to perform" abortions. S.C.Code Ann. Regs. 61-12, § 205(C). However, Regulation 61-12 provides no guidance on the additional credentials required beyond that of a medical *202 license to meet this qualification standard. Thus, physicians who perform five or more

first trimester abortions per month operate under a constant fear that they will be declared "unqualified" by DHEC under some vague and amorphous standard. Obviously, this readily apparent fear would have a chilling effect on a physician's willingness to perform an abortion, thus, resulting in an adverse impact on a woman's ability to obtain an abortion. Cf. Stenberg, ---U.S. at ----, 120 S.Ct. at 2617 ("In sum, using this law some present prosecutors and future Attorneys General may choose to pursue physicians who use D&E procedures, the most commonly used method for performing previability second trimester abortions. All those who perform procedures using that method must fear prosecution, conviction, and imprisonment. The result is an undue burden upon a woman's right to make an abortion decision."). Under these circumstances, I am simply constrained to conclude that Regulation 61-12 imposes an undue burden on a woman's fundamental right to obtain an abortion. Cf. Ragsdale v. Turnock, 841 F.2d 1358, 1373-74 (7th Cir.1988) (invalidating portions of a similar licensure regulation which mandated, among other things, detailed physical plant requirements, policies and procedures, and staffing requirements); Birth Control Ctrs., Inc. v. Reizen, 743 F.2d 352, 364-65 (6th Cir.1984) (invalidating detailed, specific regulatory criteria governing the physical layout of abortion facilities, staffing requirements, and equipment requirements).

In its opinion, the majority concludes that Regulation 61-12 does not constitute an undue burden on a woman's right to obtain an abortion. See ante at 169-72. The pillar supporting the majority's holding is its observation that the plaintiffs failed to produce evidence demonstrating that the cost increases resulting from the promulgation of Regulation 61-12 would have an adverse effect on a women's ability to obtain an abortion in South Carolina. See ante at 170-71. This pillar is a transparent facade, at best.

In part, the district court's finding of an undue burden was premised on the testimony of the plaintiffs' expert, Dr. Stanley Henshaw. Dr. Henshaw testified that an increase of just \$25 can be expected to prevent one or two out of every 100 low-income women seeking an abortion from being able to obtain one. Under Supreme Court case law, this constitutes an undue burden on a woman's right to obtain an abortion. See Casey, 505 U.S. at 894-95, 112 S.Ct. 2791 (invalidating law that imposed substantial obstacle on a large fraction of the one percent of abortion patients who are married and do not voluntarily notify their spouses of the abortion).

compelling reason to justify the difference in treatment, the court invalidated the regulations. See id. at 1153. It had previously noted, however, that "on the record before th[e] court there is no basis for determining whether the regulations are even reasonably related to a valid state concern." Id. at 1150.

*204 The Sixth Circuit has also been called upon to address comprehensive health regulations on several occasions. First, in *Mahoning Women's Center v. Hunter*, 610 F.2d 456 (6th Cir.1979), vacated on other grounds, 447 U.S. 918, 100 S.Ct. 3006, 65 L.Ed.2d 1110 (1980), the court affirmed the district court's decision to invalidate, under the strict scrutiny test, a city ordinance imposing costly medical and building code requirements on first trimester abortion clinics, while leaving unregulated the performance of other medical and surgical procedures. *See id.* at 460-61.

Next, the Sixth Circuit addressed the constitutionality of a Michigan licensing scheme which required all free-standing surgical outpatient facilities (FSOFs) to with staffing, structural, equipment, counseling, consent, and record-keeping requirements in order to obtain a license to operate. See Birth Control Ctrs., Inc., 743 F.2d at 357. Because the licensing scheme applied to abortion clinics, albeit not exclusively, four abortion clinics challenged the scheme on equal protection grounds because it exempted private physicians offices where abortions were performed. See id. at 356-57. affirmed the district court's application of the rational basis test as the appropriate standard of review, because the "differentiation between FSOFs and physicians' private offices did not involve any suspect class nor implicate any fundamental right." Id. at 358. In particular, the court held that "no suspect classification was involved ... since the state ha[d] chosen to regulate all FSOFs, not just abortion clinics," and distinguished Mahoning on this basis. Control Ctrs., Inc., 743 F.2d at 358 & n. 4.

Finally, in Women's Health Center of West County, Inc. v. Webster, 871 F.2d 1377 (8th Cir.1989), the Eighth Circuit, applying the rational basis test, upheld an abortion regulation which required emergency backup care against an equal protection challenge. See id. at 1381. The court noted that, although the regulation applied only to abortion providers, the state already required such backup care for all patients undergoing any outpatient surgery. See id. Thus, the regulation was a reasonable means of insuring the health of women seeking abortions and did not impose

a special requirement upon abortion providers. See id.

It is unnecessary for me to decide whether the strict scrutiny test or the rational basis test should be applied this case because Regulation 61-12 constitutionally infirm under the more lenient rational basis test. Under the rational basis test, the court must determine the relation between the classification adopted and the objective to be attained. Romer, 517 U.S. at 632, 116 S.Ct. 1620. "The search for the link between classification and objective gives substance to the Equal Protection Clause; it provides guidance and discipline for the legislature, which is entitled to know what sorts of laws it can pass; and it marks the limits of our own authority." Id. "By requiring that the classification bear a rational relationship to an independent and legitimate legislative end, we ensure that classifications are not drawn for the purpose of disadvantaging the group burdened by the law." Id. at 633, 116 S.Ct. 1620. Furthermore, even if the disadvantaged group does not rise to the level of a suspect class entitled to the application of strict scrutiny, the court must closely scrutinize laws that disadvantage a politically unpopular group because such laws "raise[] the inevitable inference that the disadvantage imposed is born of animosity toward the class of persons affected." Id. at 634, 116 S.Ct. 1620. '[I]f the constitutional conception of "equal protection of the laws" means anything, it must at the very least mean that a bare ... desire to harm a politically unpopular group cannot constitute a legitimate governmental interest.' " Id. at 634-35, 116 S.Ct. 1620 (quoting Department of Agric. v. Moreno. 413 U.S. 528, 534, 93 S.Ct. 2821, 37 L.Ed.2d 782 (1973)).

*205 The defendants contend that Regulation 61-12 does not violate the Equal Protection Clause because its provisions are rationally related to the legitimate state interest of protecting the health and welfare of women seeking abortions in the state. I disagree.

Obviously, South Carolina has a legitimate interest in protecting the health and welfare of women seeking abortions in the state. South Carolina also has a legitimate interest in promulgating uniform, minimum standards for the performance of surgical procedures, including first trimester abortions. And South Carolina could constitutionally require that abortions only be lawfully performed by physicians licensed by the State Board of Medical Examiners to practice medicine pursuant to such uniform, minimum standards, thereby addressing any concern that unqualified, unlicenced physicians will come within its borders and establish

222 F.3d 157 (Cite as: 222 F.3d 157, *205)

unregulated abortion clinics performing unsafe abortion procedures.

However, as the district court noted,

[t]he regulation singles out physicians and clinics where abortions are performed regularly, as part of the normal course of business and in relatively large numbers, and imposes upon them requirements which are not imposed upon comparable procedures and not even upon all physicians who perform first trimester abortions. In addition, the regulation's requirements reach far beyond those justified by actual differences in the procedure, or by the medical nature and risks of the procedure....

Furthermore, defendants have offered no satisfactory explanation as to why the state standards applied to physicians' offices and clinics performing comparable procedures would not suffice to regulate first trimester abortion providers or ensure the health, safety and welfare of patients seeking abortionsmuch less an acceptable basis for excluding physicians and facilities which perform first trimester abortions on a more infrequent basis....

Regulation 61-12 singles out all physicians and clinics who perform more than the occasional first trimester abortion and requires of them a license to operate their office or clinic. To obtain the license, the physicians and clinics must comply with comprehensive mandates governing the physical layout of the clinic or office, the medical equipment which must be purchased and maintained, the cleaning, maintenance, and operation of the clinic and the requisite equipment, the management and training of the staff, and the type of medical care and tests which must be administered and offered to the patients. The onerous, and largely unnecessary, requirements of this regulation are neither "narrow enough in scope [nor] grounded in a sufficient factual context for [the court] to ascertain that there existed some relation between the classification and the purpose it is now alleged to serve."

Greenville Women's Clinic, 66 F.Supp.2d at 742-43 (quoting Romer, 517 U.S. at 632-33, 116 S.Ct. 1620).

In summary, Regulation 61-12 singles out and places additional and onerous burdens upon abortion providers which are neither justified by actual differences nor rationally related to the state's legitimate interest in protecting the health and safety of women seeking first trimester abortions. Rather, "its sheer breadth is so discontinuous with the reasons offered for it that [Regulation 61-12] seems inexplicable by anything but animus toward the class that it affects." *Romer*, 517 U.S. at 632, 116 S.Ct.

1620. The fact that Regulation 61-12 was directed towards a politically unpopular group in the absence of any existing public health problem only bolsters this conclusion. [FN21] See id. at 632-34, 116 S.Ct. 1620.

FN21. Although the South Carolina legislature directed DHEC to regulate abortion facilities which performed five or more first trimester abortions per month, while leaving other licensed physicians under the exclusive supervision of the Board of Medical Examiners, it is undisputed that DHEC retained the discretion to refrain from treating abortion clinics and abortions differently than comparable facilities and procedures. For example, DHEC could have treated abortion clinics like other physicians' offices and clinics by promulgating regulations consistent with what is already required in physicians' offices by other laws and accepted standards. As to the physical plant requirements of Regulation 61-12, DHEC could have adopted regulations requiring the abortion clinic to meet all applicable building codes. As to staff qualifications and medical records, DHEC could have required the supervising physician to hire staff maintain medical records that, in his or her professional discretion, would appropriately provide for the needs and rights of the patients. On the other hand, with regard to needs unique to the abortion procedure, DHEC could have treated abortion providers differently from other physicians' offices and clinics, but only based on actual differences between those facilities. Instead, DHEC placed onerous burdens upon abortion providers which are neither justified by actual differences nor rationally related to the state's legitimate interest in protecting the health and safety of women seeking first trimester abortions.

*206 III

The only remaining issue in the case is the question of severability. The defendants contend that the district court erred in refusing to sever the unconstitutional portions of Regulation 61-12 from the constitutional portions. This argument is without merit.

Whether Regulation 61-12 is subject to the doctrine of severability is a question of state, rather than federal, law. *See Department of Treasury v. Fabe*, 508 U.S. 491, 509-10, 113 S.Ct. 2202, 124 L.Ed.2d 449 (1993). Under South Carolina law,

[t]he test for severability is whether the constitutional portion of the statute remains complete in itself, wholly independent of that which is rejected, and is of such a character as it may fairly be presumed that the Legislature would have passed it independent of 222 F.3d 157 (Cite as: 222 F.3d 157, *206)

that which is in conflict with the Constitution.

Thayer v. South Carolina Tax Comm'n, 307 S.C. 6, 413 S.E.2d 810, 815 (1992) (citation and internal quotation marks omitted). Moreover, if the statutory or regulatory scheme does not contain a specific severability clause, the legislature or agency is presumed to have "intended the act to be effected as an entirety or not at all." South Carolina Tax Comm'n v. United Oil Marketers, Inc., 306 S.C. 384, 412 S.E.2d 402, 405 (1991).

Applying this standard, I conclude that Regulation 61-12 is not a proper candidate for severance. Regulation 61-12 does not contain a severability provision, despite the fact that other DHEC regulations have included such provisions. See, e.g., S.C.Code Ann. Regs. 61-4, Part VI, § 601 (controlled substances regulation); S.C.Code Ann. Regs. 61-21, § T (sexually transmitted diseases). The absence of a severability clause is consistent with the scheme of the enabling legislation and the nature of the regulation. It is apparent that the South Carolina legislature intended for DHEC to create a comprehensive licensing scheme for abortion providers, as Regulation 61-12 sets forth areas to be addressed by the regulation as a whole, and the text of the regulation is comprehensive and interdependent, reflecting a similar intent that it stand or fall as a whole. In other words, because the South Carolina legislature directed DHEC to promulgate a comprehensive set of regulations governing virtually every aspect of the abortion procedure, it is evident that the South Carolina legislature intended for all of Regulation 61-12 to be enforced or none of it. Finally, I note that severance is simply not possible, as I am simply unable to "untangle the constitutional from the unconstitutional provisions." Ragsdale, 841 F.2d at 1375.

IV

I have some final comments concerning Part IV of the majority opinion. The accusatory tone of this portion of the majority opinion, aimed at me and the district

judge who decided the case below, can only *207 evince a majority which refuses to recognize that current Supreme Court precedent mandates that a woman still has the fundamental right to obtain an abortion. In its eagerness to uphold any impediment to a woman's fundamental right to a previability abortion, majority, interjecting the emotional and psychological aspect of a woman's decision, would desensitize the real and basic issue to be addressed when evaluating such regulations--that is, whether the regulations are medically necessary and, if so, whether the regulations impose an undue burden on a woman's fundamental right to have an abortion at the previability stage of pregnancy. There is no doubt that the State of South Carolina can, within limits, treat abortions differently from other medical procedures. But to resolve the question of whether regulations governing abortions are medically necessary, some reference to comparable procedures is necessary, if not inevitable.

When considering the majority's analysis based on its chosen and carefully selected facts, ignoring the findings of fact by the district court, it can only be concluded that the majority's opinion is based on its view of the law as it would like to see it and, perhaps more significantly, on not what the current law would dictate, but only what the majority prophecies the law will be if and when this case reaches the Supreme Court. This is simply unacceptable; cases are to be decided on what the law is. It's just that simple.

To sum up, Regulation 61-12 is violative of the Due Process and Equal Protection Clauses of the Fourteenth Amendment, and, under South Carolina law, Regulation 61-12 is not subject to the doctrine of severability. Accordingly, I would affirm the judgment of the district court. [FN22]

FN22. With regard to the argument of the defendants attacking the district court's award of attorneys' fees, the argument is without merit.

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--- S.Ct. ---- (Mem) 69 USLW 3382

(Cite as: 2001 WL 178202 (U.S.))

Supreme Court of the United States

GREENVILLE WOMEN'S CLINIC V. BRYANT, SC CMM'R OF HEALTH.

No. 00-798.

Feb. 26, 2001.

The petition for writ of certiorari is denied.

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Exhibit B

(Cite as: 2001 WL 370053 (5th Cir.(Tex.)))

Only the Westlaw citation is currently available.

United States Court of Appeals, Fifth Circuit.

WOMEN'S MEDICAL CENTER OF NORTHWEST HOUSTON; Robert P. Kaminsky, M.D., on

behalf of themselves and the patients they serve;
Denton Health Services for
Women; Austin Women's Health Center, P.A.;
Lamar Robinson, M.D.; Fred W.
Hansen, M.D.; L. Tad Davis, M.D.; Mary E. Smith,
M.D., Plaintiffs-Appellees,

Dr. Charles E. BELL, Acting Texas Commissioner of Health; John Cornyn, Texas Attorney General, Defendants-Appellants.

No. 00-20037.

April 13, 2001.

Texas physicians brought §1983 action challenging constitutionality of 1999 amendments to Texas Abortion Facility Reporting and Licensing Act and three regulations under the Act. Physicians moved for preliminary injunction prohibiting enforcement of amendments and regulations. The United States District Court for the Southern District of Texas, John D. Rainey, J., granted injunction. Appeal was taken. The Court of Appeals, Wiener, Circuit Judge, held that: (1) amendments, which based licensing requirements on whether facility did more or less than 300 abortions per year, did not violate equal protection clause, and (2) physicians were likely to succeed on merits of claim that regulations, which required a licensed abortion provider to ensure that a patient's dignity and self-esteem were enhanced and defined "quality care" by expectations of patient, were impermissibly vague under the due process clause.

Affirmed in part, reversed in part and remanded.

[1] Federal Courts \$\infty\$815

170Bk815

A district court's grant of a preliminary injunction is reviewed for abuse of discretion. Fed.R.Civ.Proc. Rule 65, 28 U.S.C.A.

[2] Federal Courts \$\sim 776\$

170Bk776

[2] Federal Courts **362** 170Bk862

Each of the four elements required to support a preliminary injunction, including substantial likelihood of success on the merits, presents a mixed question of fact and law on appeal of a district court's grant of preliminary injunction: findings of fact are reviewed only for clear error, and legal conclusions are subject to de novo review. Fed.R.Civ.Proc. Rule 65, 28 U.S.C.A.

[3] Injunction \$\iiin\$ 138.1 212k138.1

The four elements of a preliminary injunction are: (1) substantial likelihood of success on the merits; (2) substantial threat that plaintiff will suffer irreparable injury; (3) injury outweighs any harm the injunction might cause the defendant; and (4) injunction is in the public interest. Fed.R.Civ.Proc. Rule 65, 28 U.S.C.A.

[4] Federal Courts \$\infty\$776 170Bk776

[4] Federal Courts **315** 170Bk815

Although the ultimate decision whether to grant or deny a preliminary injunction is reviewed only for abuse of discretion, a decision grounded in erroneous legal principles is reviewed de novo. Fed.R.Civ.Proc. Rule 65, 28 U.S.C.A.

[5] Constitutional Law 230.3(1) 92k230.3(1)

[5] Constitutional Law 230.3(8.1) 92k230.3(8.1)

Amendments to Texas Abortion Facility Reporting and Licensing Act, which changed standard for licensing from facilities where 51% of patients in calendar year received abortions to facilities where more than 300 abortions were performed in any twelve-month period, were subject to rational basis review on equal protection challenge by physicians who became subject to Act as result of amendments. U.S.C.A. Const. Amend. 14; Tex. Health & Safety Code §§245.001 -245.022.

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[6] Abortion and Birth Control ⋘1.30 4k1.30

Amendments to Texas Abortion Facility Reporting and Licensing Act, which changed standard for licensing from facilities where 51% of patients in calendar year received abortions to facilities where more than 300 abortions were performed in any twelve-month period, did not violate equal protection clause; classification based on number of abortions performed per year rationally served legislature's purpose of protecting health of Texas women. U.S.C.A. Const. Amend. 14; Tex. Health & Safety Code §§245.001- 245.022.

[6] Constitutional Law 230.3(1) 92k230.3(1)

[6] Constitutional Law 230.3(8.1) 92k230.3(8.1)

Amendments to Texas Abortion Facility Reporting and Licensing Act, which changed standard for licensing from facilities where 51% of patients in calendar year received abortions to facilities where more than 300 abortions were performed in any twelve-month period, did not violate equal protection clause; classification based on number of abortions performed per year rationally served legislature's purpose of protecting health of Texas women. U.S.C.A. Const. Amend. 14; Tex. Health & Safety Code §§245.001- 245.022.

[7] Constitutional Law @= 251.4 92k251.4

The Fourteenth Amendment's guarantee of Due Process proscribes laws so vague that persons of common intelligence must necessarily guess at their meaning and differ as to their application. U.S.C.A. Const. Amend. 14.

[8] Constitutional Law @= 251.4 92k251.4

A law is unconstitutionally vague under the due process clause if it: (1) fails to provide those targeted by the statute a reasonable opportunity to know what conduct is prohibited, or (2) is so indefinite that it allows arbitrary and discriminatory enforcement. U.S.C.A. Const. Amend. 14.

[9] Constitutional Law @= 251.4 92k251.4

[9] Constitutional Law 258(2)

92k258(2)

In order to satisfy the due process clause, a quasicriminal statute must define its terms with sufficient definiteness that ordinary people can understand what conduct is prohibited and in a manner that does not encourage arbitrary and discriminatory enforcement. U.S.C.A. Const. Amend. 14.

[10] Civil Rights **268** 78k268

Physicians challenging regulations under the amendments to Texas Abortion Facility Reporting and Licensing Act, which required licensed abortion provider to ensure that patient's dignity and self-esteem were enhanced and defined "quality care" by expectations of patient, as impermissibly vague under the due process clause were likely to succeed on merits of their claims, as required for preliminary injunctive relief; regulations carried penalties including fines and license revocation that could be characterized as quasicriminal. U.S.C.A. Const. Amend. 14; Tex. Health & Safety Code §§245.001- 245.022; 25 Tex. Admin. Code, §§139.51(1),(2), 139.2(43).

Janet Crepps (argued), Linda Ann Rosenthal, Center for Reproductive Law & Policy, New York City, Craig R. Smyser, Asim M. Bhansali, Smyser, Kaplan & Veselka, Houston, TX, for Plaintiffs-Appellees.

Gregory Scott Coleman, Stuart Kyle Duncan (argued), Austin, TX, for Defendants-Appellants.

Thomas Drought, Drought, Drought & Bobbitt, San Antonio, TX, for U.S. Catholic Conference and Texas Catholic Conference, Amicus Curiae.

Appeal from the United States District Court for the Southern District of Texas.

Before WIENER and STEWART, Circuit Judges, and SMITH, [FN*] District Judge.

WIENER, Circuit Judge:

*1 Plaintiffs-Appellees ("the plaintiffs") filed suit to challenge recent amendments to Texas law that for the first time require them to license their medical offices as abortion facilities. The district court entered a preliminary injunction against enforcement of the amendments, concluding that they violate the plaintiffs' equal protection rights. The court's injunction also prohibits enforcement of three companion regulations that were found to be unconstitutionally vague. We

2001 WL 370053 (Cite as: 2001 WL 370053, *1 (5th Cir.(Tex.)))

reverse the district court's injunction of enforcement of the amendments grounded in equal protection, but affirm the court's injunction prohibiting enforcement of the regulations grounded in unconstitutional vagueness.

I. FACTS AND PROCEEDINGS

The plaintiffs are Texas physicians who brought this action on behalf of themselves and their patients pursuant to 42 U.S.C. § 1983. They challenge the constitutionality of 1999 amendments that require them to comply with the Texas Abortion Facility Reporting and Licensing Act, which dates to 1985. [FN1] The amendments changed the threshold for facilities that must be licensed from those "used primarily for the purpose of performing abortions"-- that is, where at least 51 percent of patients treated in a calendar year receive abortions--to those in which more than 300 abortions are performed in any twelve-month period. Facilities in which fewer abortions are performed remain exempt from the licensing requirements.

The record in this case reveals that as of 1999, Texas had between 51 and 59 non-hospital abortion providers, comprising: (a) 31 licensed abortion facilities; (b) a single-digit "handful" of physicians providing fewer than ten abortions per year in their offices; (c) seven physicians performing more than ten but fewer than 300 abortions per year in their offices; and (d) twelve physicians, or some 20 percent of the total, who for the first time would be required to be licensed as a result of the amendments because each provides more than 300 abortions per year (the new threshold) in their offices, even though in each of these offices abortion patients constitute less than 51 percent of all patients treated (the old threshold). Four of these twelve physicians are the plaintiffs in this case. [FN2]

To summarize briefly several of the principal requirements of the amended Abortion Facility Reporting and Licensing Act and its regulations, a licensed abortion facility must:

- . Prominently post its license and provide each woman who initially consults the facility with a written statement about a toll-free telephone number maintained by the Texas Department of Health, which patients can call for information about a facility's license status, inspection violations, and penalties or other discipline imposed against it.
- *2. Maintain a written Quality Assurance program,

implemented by a Quality Assurance committee of at least four members, including a physician and a nurse, who must meet at least quarterly. [FN3]

- . Develop a written staff orientation and training program and written infection control policies and procedures. [FN4]
- . Be subject to annual and surprise on-site surveys by state inspectors.
- . Employ staff with specific qualifications, including a physician and a registered nurse or licensed vocational nurse.

In addition, a physician applying for a license must provide personal information, including his home address, Social Security number, date of birth, driver's license number, and Texas physician license number. The initial licensing fee is \$1,000, the first annual fee is \$1,500, and the annual renewal fee is \$2,500. Under the 1999 amendments, operation of an abortion facility without a license is a Class A misdemeanor, punishable by a jail sentence of up to one year and a fine of up to \$4,000, or both. Civil and administrative penalties of \$100 to \$2,500 per day also may be assessed for violations of the statute and regulations.

The practices of the plaintiff physicians vary, but as a group they administer their offices less formally than the regulations require. They insist that many of the administrative mandates in the 1999 amendments are unnecessary to their practices. Some plaintiffs testified that they will have to charge their abortion patients as much as \$100 more per procedure to cover the expenses associated with meeting the licensing requirements. The plaintiffs testified that they believe their private-office setting offers patients greater confidentiality, fewer confrontations with protesters, and a more personalized, supportive atmosphere than do abortion clinic settings. Some also objected to the rule that they must prominently display their abortion facility licenses at their offices, fearing that will offend some obstetrical and male patients and thereby damage their practices.

The only plaintiff who testified that he will stop performing abortions in his private office altogether rather than seek a license is Dr. Fred Hansen, an obstetrician/gynecologist with a private gynecology practice in Austin who performs approximately 950 to 1,050 abortions per year. Abortion is one of many gynecological procedures Dr. Hansen provides to his patients. Nearly all of his abortion patients are referred

to him by other physicians, many for medically indicated abortions resulting from profound fetal defects discovered in wanted pregnancies after the fifteenth week. Dr. Hansen testified that he is the only physician in Austin who provides abortions in a private office after the fifteenth week of pregnancy. His staff consists of one part-time and three full-time employees. Dr. Hansen expressed the belief that if he were to seek licensing and comply with the continuing requirements of licensing, patient care would suffer as a result of his and his staff's spending additional time on unnecessary administrative tasks.

Evidence heard by the district court regarding the Legislature's purpose in enacting the 1999 amendments reflects that state Sen. Chris Harris filed a Senate bill that would have required all physicians performing more than 10 abortions per year to become licensed. Sen. Harris stated that he was motivated by ongoing concerns about abortion safety, and by data that he interpreted as showing that some physicians were performing large numbers of abortions but escaping the licensing act through the 51 percent "loophole." [FN5] Sen. Harris stated that he did not want to limit abortion rights, but did want to protect the health and safety of women receiving abortions.

*3 Among those testifying in opposition to the bill was Peggy Romberg, executive director of the Texas Family Planning Association, who stated that she opposed the bill's 10-abortion trigger. In response to questioning by Sen. Harris, she stated that "my bottom ceiling would be about 300, of OB/GYN that provides abortion services that would be essentially about one a working day." Ms. Romberg told Sen. Harris that the number 300 would be "more acceptable" to the abortion rights community than setting the threshold at ten, and later said she suggested the number 300 as a "political compromise" with no medical, health, or safety basis.

Sen. Harris's bill did not pass, but similar language regulating physicians who perform 300 or more abortions per year was added by Rep. Leticia Van de Putte to a lengthy House bill dealing with general health department matters. That bill was adopted by both chambers and took effect September 1, 1999. Previously exempt physicians were not required to be licensed until Jan. 1, 2000. Rep. Van de Putte, who characterizes herself as "adamantly pro-choice," testified that she discussed the number 300 with pro-choice advocates and heard no objections. [FN6] She sought "a number that would not preclude access for women in this state to seek that procedure, but keeping

in mind that we wanted to have as our goal [the] health and safety of the women." Rep. Van de Putte also testified that she was influenced in supporting the bill by twenty years of experience as a practicing pharmacist, during which she counseled and dispensed medication to abortion patients. [FN7]

Following a two-day hearing, the district court granted the plaintiffs' motion for preliminary injunction barring the defendants from enforcing the 1999 amendments or the three challenged regulations pending a full review of the case on the merits. The court found that the plaintiffs had shown a substantial likelihood of success with respect to their claims that the amendments violate their equal protection rights and are unconstitutionally vague, but not on the claim that the amendments violate the due process rights of the plaintiffs' patients.

More specifically, the court found that, under Planned Parenthood of Southeastern Pennsylvania v. Casey, [FN8] the plaintiffs had not shown a substantial likelihood of success on the merits of their claim that the 1999 amendments impose an undue burden on a woman's right to abortion. The court concluded that the 1999 amendments were not passed for an improper purpose, and that there was no evidence of any legislative intent to place obstacles in the paths of women seeking abortions. The court also found that the benefits sought by the state in enacting the amendments justified the increased costs that might be borne by physicians or patients, or by Dr. Hansen's likely decision to stop performing abortions in his office rather than become licensed. The court concluded that the amendments do not have the purpose or effect of creating an undue burden on the right of Texas women to seek an abortion, and therefore do not unconstitutionally deny them due process. The court thus denied an injunction grounded in substantive due process because the plaintiffs had failed to show, on behalf of their patients, a substantial likelihood of success on their Fourteenth Amendment due process claim.

The court reached the opposite conclusion on the plaintiffs' equal protection claim. The court applied rational basis review to the physicians' assertion that they had been denied equal protection of the law. [FN9] These plaintiffs challenged two legislative classifications: (1) physicians who perform abortions in their offices and those who perform other, comparable surgical procedures in theirs, and (2) physicians who perform more than 300 abortions per year in their offices and those who perform 300 or

(Cite as: 2001 WL 370053, *5 (5th Cir.(Tex.)))

[1][2][3][4] A district court's grant of a preliminary injunction is reviewed for abuse of discretion. [FN14] Each of the four elements required to support a preliminary injunction, including substantial likelihood of success on the merits, presents a mixed question of fact and law. Findings of fact are reviewed only for clear error; legal conclusions are subject to *de novo* review. [FN15] Although the ultimate decision whether to grant or deny a preliminary injunction is reviewed only for abuse of discretion, a decision grounded in erroneous legal principles is reviewed *de novo*. [FN16] The standard of review is no different for our consideration of the district court's determination that three regulations are unconstitutionally vague. [FN17]

B. The 300-Abortion Threshold

*6 [5] The record contains no evidence of antiabortion animus, and no evidence that the 1999 amendments were passed in an attempt to limit abortion access or for any other improper purpose. [FN18] Therefore, the district court correctly chose to evaluate the 1999 amendments as health and safety regulations subject to rational basis review. [FN19] On de novo review, however, we disagree with the district court's conclusion that the plaintiffs are likely to succeed on the merits of their equal protection claim.

[6] All that is required to survive rational basis review is a showing that the classification under examination conceivably could be related to a legitimate governmental purpose. The court found--correctly, we believe--that the 1999 amendments have the legitimate state purpose of protecting the health of Texas women. The court's inquiry, therefore, is properly limited to whether a classification based on the number of abortions performed at a facility rationally serves that general purpose. Here, the answer clearly is "yes." Because without violating the Constitution, the State could have required all abortion providers to be licensed, it rationally could set an annual 300- abortion "floor" as an accommodation to private physicians who provide a number of abortions that the government considers to be too few to require licensing. Whether the court agrees with the accuracy of the line of demarcation drawn by the Legislature to distinguish the classification is of no great moment. [FN20]

Our holding today is consonant with the Fourth Circuit's recent decision in *Greenville Women's Clinic v. Bryant*, a case closely analogous to this one. [FN21] *Greenville* concerns South Carolina's 1995 amendment of its abortion clinic licensing statute. That statute, which previously applied only to clinics in which

second-trimester abortions are performed, was expanded by this amendment to cover every facility in which five or more first-trimester abortions are performed in one month. [FN22] The district court issued a preliminary injunction and, after a bench trial, held in part that the South Carolina amendment violated the equal protection rights of the plaintiff physicians. The Fourth Circuit reversed, writing:

When it is recognized that the State interest is in regulating those facilities that are in the business of providing abortions, drawing the line at those performing five abortions per month is rational. While anyone could say that it is just as rational to draw the line at ten abortions per month or three abortions per month, this type of line-drawing is typically a legislative function and is presumed valid. Indeed, line-drawing of this type is not only typical of legislation, it is necessary. [FN23]

The Greenville court gave examples of several types of legislation that draw similar lines, including the application of the Americans With Disabilities Act to companies with 15 or more employees but not to those with 14 or fewer employees; and a state's grant of drivers' licenses to persons age sixteen or older but not to those under sixteen. [FN24] The Fourth Circuit concluded:

In this case, South Carolina elected to regulate the business of providing abortions and determined that five per month would distinguish the abortion clinic from the facility performing abortions incidental to another medical practice. The selection of this number is reasonably related to the State's legitimate interest in promoting and protecting the health of women visiting abortion clinics, and therefore the actual placement of the line is not a decision that the courts may second-guess. [FN25]

*7 In the instant case, the district court mistakenly focused on whether the office of a physician who provides more than 300 abortions per year resembles the "high-volume" abortion clinics previously subject to licensure. [FN26] The appropriate question is not confined to whether the limit meets the legislative purpose of regulating high-volume, risky, or overburdened abortion facilities; rather, the 1999 amendments are constitutional if they serve any appropriate state goal. The amendments require Texas physicians who perform abortions in their offices to comply with licensing standards that cover issues such as staffing, infection control, and inspection by state officials. Such issues do bear a rational relationship to the legitimate state interest of protecting patient health and welfare. Through its Legislature, the State acted within its power in choosing to exempt physicians

III. CONCLUSION

*9 We acknowledge the concern expressed by the physicians who are the plaintiffs in this case, particularly Dr. Hansen, that their abortion patients have the opportunity to obtain personal care in a confidential setting, and without paying unnecessary administrative costs. Nevertheless, our role in evaluating the plaintiffs' substantial likelihood of success on their equal protection claim is limited to reviewing whether the annual 300-abortion threshold set by the state for subjecting abortion facilities to licensing bears some rational relationship to the state interest in protecting the health and welfare of Texas abortion patients. We conclude that it does. Any scrutiny beyond that is necessarily left to the Legislature, not the courts. Consequently, we must vacate the preliminary injunction prohibiting enforcement of the Texas abortion licensing statute, Tex. Health & Safety Code §§ 245.001-245.023 as amended in 1999.

We agree with the district court, however, that the plaintiffs have shown a substantial likelihood of success on their vagueness challenge to three contested provisions of the licensing regulations. We therefore affirm the preliminary injunction granted by the district court with regard to those regulations, ordering that Texas Commissioner of Health William R. Archer III and Texas Attorney General John Cornyn, in their official capacities, are enjoined from enforcing 25 Tex. Admin. Code §§ 139.2(43), 139.51(1), and 139.51(2) pending a full trial on the merits of this case.

AFFIRMED in part; REVERSED in part; and REMANDED to the district court for continued proceedings consistent with this opinion.

FN* District Judge of the Western District of Texas, sitting by designation.

FN1. Texas Abortion Facility Reporting and Licensing Act, Tex. Health & Safety Code §§ 245.001-245.022.

FN2. A fifth doctor, Mary E. Smith of Denton, also was a plaintiff, but ceased providing abortions at her private office while this appeal was pending and has been dismissed as a party to the case.

FN3. The regulations were revised in 1997, adding the provisions on quality assurance and patients' rights, among other changes. *See* 25 Tex. Admin. Code. §§ 139.1-139.60.

FN4. Facilities must maintain a total of nine administrative, nine clinical, and three additional written policies, covering at least thirty different subjects. 25 Tex. Admin. Code § 139.41.

Page 8

FN5. Any physician who executed an affidavit attesting that the number of patients for whom he performed abortions represented less than 51 percent of his patients during the previous calendar year was exempt from the licensing requirements.

FN6. There is no official legislative history on the House bill. The district court denied the plaintiffs' motion to strike the testimony of Sen. Harris and Rep. Van de Putte as inadmissible subsequent legislative history. The court noted that, in determining the legislative purpose in passing the statute, it would rely primarily on the official legislative history in the record and give lesser weight to the legislators' testimony. The official legislative history includes a transcript of a Senate Human Services Committee meeting in which the 1999 amendments to the Abortion Facility Reporting and Licensing Act were introduced as a Senate bill, and materials documenting the 1997-98 ad hoc committee process that promulgated the abortion licensing regulations found in 25 Tex. Admin. Code. §§ 139.1-139.60.

FN7. Rep. Van de Putte testified as follows about her view on setting the licensing threshold at 300 abortions per year:

I rationalized that if a physician did one a day for the number of working days, if you take 52 weeks out of the year, and you know, you get five working days, that would leave us with about 260 working days a year. Take off maybe about ten for holidays, that would leave you at 250. So averaging out even one a day would leave you with 250. And I felt that with an adequate buffer zone of an additional 50, would leave us with 300 so that a physician in their office, I felt, could comply with that number of procedures being done and giving adequate care to those women who seek that procedure.

FN8. 505 U.S. 833, 112 S.Ct. 2791, 120 L.Ed.2d 674 (1992).

FN9. The court concluded that the doctors did not plead an equal protection claim on behalf of their patients.

FN10. Citing Harris County, Tex. v. CarMax Auto Superstores Inc., 177 F.3d 306, 321 (5th Cir.1999).

FN11. Citing Romer v. Evans, 517 U.S. 620, 632, 116

S.Ct. 1620, 134 L.Ed.2d 855 (1996).

FN12. Q uoting Gregory v. Ashcroft, 501 U.S. 452, 473, 111 S.Ct. 2395, 115 L.Ed.2d 410 (1991).

FN13. 25 Tex. Admin. Code. §§ 139.1-139.60. The challenged provisions were added to the abortion licensing regulations during a 1997 revision that became effective Aug. 13, 1998. They were challenged by plaintiffs because they would first become applicable to them under the 1999 amendments to the licensing statute.

FN14. Hoover v. Morales, 164 F.3d 221, 224 (5th Cir.1998); Valley v. Rapides Parish Sch. Bd., 118 F.3d 1047, 1051 (5th Cir.1997); Sunbeam Prods., Inc. v. West Bend Co., 123 F.3d 246, 250 (5th Cir.1997).

FN15. Sugar Busters LLC v. Brennan, 177 F.3d 258, 265 (5th Cir.1999); Hoover v. Morales, 164 F.3d at 224. The four elements of a preliminary injunction are (1) substantial likelihood of success on the merits; (2) substantial threat that plaintiff will suffer irreparable injury; (3) injury outweighs any harm the injunction might cause the defendant; and (4) injunction is in the public interest. Hoover, 164 F.3d at 224.

FN16. Hoover, 164 F.3d at 224.

FN17. Campbell v. St. Tammany's Sch. Bd., 206 F.3d 482, 484 (5th Cir.2000), reh'g denied, 231 F.3d 937 (5th Cir.2000), petition for cert. filed, 69 U.S.L.W. 3514 (U.S. Jan. 24, 2001) (No. 00-1194); United States v. Monroe, 178 F.3d 304, 308 (5th Cir.1999), cert. denied, 528 U.S. 1010, 120 S.Ct. 511, 145 L.Ed.2d 395 (1999).

FN18. Plaintiffs-Appellees do not appeal the district court's finding that the 1999 amendments place no undue burden on Texas women seeking an abortion.

FN19. See, e.g., Romer, 517 U.S. at 632-33; City of Cleburne, Tex. v. Cleburne Living Ctr., Inc., 473 U.S. 432, 446, 105 S.Ct. 3249, 87 L.Ed.2d 313 (1985); Dep't of Agric. v. Moreno, 413 U.S. 528, 533, 93 S.Ct. 2821, 37 L.Ed.2d 782 (1973).

FN20. See Gregory v. Ashcroft, 501 U.S. 452, 473, 111 S.Ct. 2395, 115 L.Ed.2d 410 (1991) (noting that a law setting 70 as the retirement age for state judges "is founded on a generalization. It is far from true that all judges suffer significant deterioration in performance at age 70. It is probably not true that most do. It may not be true at all. But a State does not violate the Equal Protection clause merely because the classifications made by its laws are imperfect.") (internal quotation

omitted); see also City of New Orleans v. Dukes, 427 U.S. 297, 298, 96 S.Ct. 2513, 49 L.Ed.2d 511 (1976) (upholding ordinance banning all pushcart vendors from the Vieux Carre, but exempting those who had operated for eight or more years).

FN21. 222 F.3d 157 (4th Cir.2000), cert. denied, --- U.S. ----, 121 S.Ct. 1188, --- L.Ed.2d ----, 2001 WL 178202, 69 U.S.L.W. 3382 (U.S. Feb. 26, 2001) (No. 00-798).

FN22. Id. at 159-60.

FN23. *Id.* at 174 (citing *Mass. Bd. of Ret. v. Murgia*, 427 U.S. 307, 314, 96 S.Ct. 2562, 49 L.Ed.2d 520 (1976) (upholding mandatory police retirement age of 50)).

FN24. Id.

FN25. Id. at 175 (emphasis added).

FN26. The court wrote: "[I]t is not rational to assume that a physician providing 300 abortions per year will expose his patients to 'high volume' risks similar to those of a typical abortion clinic.... This 'one a day' rationale cannot be reconciled with the state's argument that some physicians may be providing so many abortions that they are unable to adequately take care of patients."

FN27. McDonald v. Bd. of Election Comm'rs of Chi., 394 U.S. 802, 809, 89 S.Ct. 1404, 22 L.Ed.2d 739 (1969).

FN28. Romer, 517 U.S. at 632.

FN29. Smith v. Goguen, 415 U.S. 566, 572 n. 8, 94 S.Ct. 1242, 39 L.Ed.2d 605 (1974) (quoting Connally v. Gen. Constr. Co., 269 U.S. 385, 391, 46 S.Ct. 126, 70 L.Ed. 322 (1926)).

FN30. Grayned v. City of Rockford, 408 U.S. 104, 108-09, 92 S.Ct. 2294, 33 L.Ed.2d 222 (1972).

FN31. Margaret S. v. Edwards, 794 F.2d 994, 999 (5th Cir.1986) (quoting Ferguson v. Estelle, 718 F.2d 730, 735 (5th Cir.1983)).

FN32. See 25 T.A.C. § 139.33(c); Tex. Health & Safety Code § 245.014.

FN33. United States v. Clinical Leasing Serv., Inc., 925 F.2d 120, 122 (5th Cir.1991) (quoting Kolender v. Lawson, 461 U.S. 352, 357, 103 S.Ct. 1855, 75 L.Ed.2d 903 (1983)).

FN34. Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc., 455 U.S. 489, 503, 102 S.Ct. 1186, 71 L.Ed.2d 362 (1982).

FN35. See Colautti v. Franklin, 439 U.S. 379, 391, 99 S.Ct. 675, 58 L.Ed.2d 596 (1979).

FN36. See Hill v. Colorado, 530 U.S. 703, 120 S.Ct. 2480, 2498, 147 L.Ed.2d 597 (2000) (noting that "speculation about possible vagueness in hypothetical situations not before the Court will not support a facial

attack on a statute when it is surely valid 'in the vast majority of its intended applications' ") (quoting *United States v. Raines*, 362 U.S. 17, 23, 80 S.Ct. 519, 4 L.Ed.2d 524 (1960)).

FN37. We further note that the defendants do not challenge the severability of the three enjoined provisions. *See, e.g., Leavitt v. Jane L.*, 518 U.S. 137, 139, 116 S.Ct. 2068, 135 L.Ed.2d 443 (1996).

END OF DOCUMENT

ExhibitC

IN THE UNITED STATES DISTRICT COURTS
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

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WOMEN'S MEDICAL CENTER OF N.W. HOUSTON; DENTON HEALTH SERVICES FOR WOMEN; AUSTIN WOMEN'S HEALTH CENTER, P.A.; ROBERT P. KAMINSKY, M.D., AND M.D., P.A.; LAMAR ROBINSON, M.D., AND M.D., P.A.; FRED W. HANSEN M.D., AND M.D., P.A.; L.L. TAD DAVIS, M.D. and MARY E. SMITH, M.D., AND M.D., P.A. on behalf of themselves and the patients they serve,

SOUTHERN DISTRICT OF TEXAS

ENTERED

DEC 29 1999

MICHAEL N. MILEY

Plaintiffs.

٧.

CIVIL

WILLIAM R. ARCHER III, Texas
Commissioner of Health; JOHN CORNYN.
Texas Attorney General; JOHN B.
HOLMES, JR., Harris County District
Attorney, BRUCE ISAACKS, Denton
Criminal District Attorney; KEN ODEN.
Travis County Attorney; and BILL HILL,
Dallas Criminal District Attorney,
in their official capacities.

Defendants.

CIVIL ACTION NO. H-99-3639

ORDER AND MEMORANDUM

Pending before the Court is the motion for preliminary injunction (Dkt. # 4) filed by the plaintiffs. Women's Medical Center of N.W. Houston; Denton Health Services for Women; Austin Women's Health Center. P.A.: Robert P. Kaminsky, M.D. and M.D., P.A.: Lamar Robinson, M.D. and M.D., P.A.: Fred W. Hansen M.D. and M.D., P.A.; L.L. Tad Davis, M.D.; and Mary E. Smith, M.D. and M.D., P.A. The plaintiff physicians brought this action "on behalf of themselves

¹ Also named as plaintiffs are the professional associations under which the physicians practice.

and the patients they serve. The defendants are Texas Commissioner of Health William R. Archer.

III, and Texas Attorney General John Cornyn.²

After reviewing the parties' submitted evidence and briefing, considering the testimony and exhibits received at a preliminary injunction hearing on December 13 and 14, 1999, reviewing the entire record, and analyzing the applicable law, the Court finds that the plaintiffs have met their burden of showing that they are entitled to a preliminary injunction with regard to their equal protection claims and their vagueness claims. Therefore, for the reasons set out in this order, the plaintiffs' motion for preliminary injunction (Dkt. # 4) is GRANTED with regard to the claims that the 1999 amendments violate the plaintiffs' equal protection rights; is GRANTED with regard to the claims that the 1999 amendments violate the plaintiffs' patients' due process rights.

I. Introduction

The plaintiffs filed this lawsuit under 42 U.S.C. § 1983 to challenge the constitutionality of the 1999 amendments to Texas' abortion licensing statute and regulations.³ The regulatory scheme requires that all facilities at which any abortions are performed become licensed and comply with detailed administrative, operating and personnel provisions. Prior to the 1999 amendments that are being challenged in this lawsuit, physicians' offices were exempt from the licensing requirement unless the physician's office was "used primarily for the purpose of performing abortions." See Tex. Health

The plaintiffs also sued Harris County District Attorney John B. Holmes, Jr.: Denton County Criminal District Attorney Bruce Isaacks: Travis County Attorney Ken Oden; and Dallas County Criminal District Attorney Bill Hill. However, Holmes, Isaacks, Oden and Hill were dismissed from the case on December 9, 1999 due to an agreement of the parties.

³ See Texas Abortion Facility Reporting and Licensing Act, Tex. Health & Safety Code §§ 245.001 through 245.022; see also 25 TAC §§ 139 1 through 139 60.

& SAFETY CODE § 245.004(2). (Vernon 1992). "Primarily," for purposes of the statute, has been interpreted by the regulations to mean "51 % or more of the patients actually treated within the previous calendar year. 25 TAC § 139.2(21)(B) (1998). The 1999 amendments will significantly narrow the exemption for physicians' offices, by requiring physicians' offices in which 300 or more abortions are performed in any twelve-month period to comply with the licensing scheme. See House Bill 2085, Sixty-Seventh Legislature, 1999 Regular Session, 1999 Tex. Sess. Law Serv. Ch. 1411 (H.B. 2085) (Vernon's). The plaintiff physicians currently provide a wide range of gynecological services, including abortions, in their private offices. It is undisputed that all of the plaintiffs were exempt from licensing and regulation under the pre-1999 law because abortion constitutes less than 51 percent of their practices. It is also undisputed that all of the plaintiffs currently perform more than 300 abortions per year, and therefore must become licensed abortion facilities if they wish to continue providing their current levels of abortion services. Previously unlicensed physicians' offices, such as those of the plaintiffs, must become licensed by January 1, 2000. The plaintiffs seek a preliminary injunction against enforcement of the 1999 amendments pending final resolution of their constitutional claims.

II. The Plaintiffs' Claims

The plaintiffs claim that the 1999 amendments will subject them to onerous administrative requirements that will do nothing to advance the health and safety of their patients. For example, they point out that the regulations require an abortion provider's non-medical office staff, including bookkeepers, receptionists, and insurance verification clerks, to be trained in infection control procedures and numerous other subjects that may be of questionable relevance to their jobs. The plaintiffs contend that the detailed administrative operating and personnel provisions depart from generally accepted medical practice and require a level of formal administration far beyond accepted

practice for private physicians' offices. Plaintiffs further contend that requiring written policies to be developed and maintained regarding more than 30 different subject matters, mandating that a "quality control committee" meet quarterly, or requiring that organizational charts be drawn up to show lines of authority, might be appropriate for a large clinic setting where many contract physicians work for a clinic owner who may not be a physician. But some of the requirements border on the absurd, plaintiffs assert, when applied to a private physician's office with four staff members. Some of the plaintiff physicians claim that the costs associated with compliance will require them to increase their fees for abortions. Other plaintiffs testified that they will cease performing abortions altogether, either due to being financially unable to absorb the anticipated costs of compliance, or due to their fear of incurring civil or criminal liability through arbitrary enforcement or varying interpretations of the statute and regulations. The plaintiffs allege that enforcement of the 1999 amendments will reduce abortion availability and increase costs, which may make these services inaccessible for some Texas women due to prohibitive expense or increased travel. In addition, the plaintiffs feel that the diversion of the physician and staff's time away from patient care, and toward policy-drafting and regulatory compliance, will cause the quality of care to deteriorate. The plaintiffs claim that the 1999 amendments will place an undue burden on Texas women's right to choose abortion and will violate their patients' constitutional guarantees of privacy in reproductive decision making.

The plaintiffs also allege that the 1999 amendments are irrational because they single out physicians who perform abortions in their offices for stringent and burdensome regulations, while physicians performing similar or more risky non-abortion outpatient procedures in their offices are not subject to similar requirements. In addition, the plaintiffs claim that it is irrational to regulate physicians who perform 300 abortions per year in a given location, while leaving unregulated physicians who perform fewer than 300 abortions. Therefore, the plaintiffs claim, the 1999

amendments violate their right to equal protection. Finally, the plaintiffs contend that certain regulatory provisions (which will be applied to them by the 1999 amendments) are unconstitutionally vague.

III. The Regulations

The following is a summary of some of the regulatory provisions to which the plaintiffs will be subjected on January 1, 2000, barring a preliminary injunction enjoining enforcement:

Licensed abortion facilities are required to provide written notice of the Department of Health's toll-free number to every woman "at the time the woman initially consults the facility." 25 TAC § 139.6. Women calling the number can access information regarding licensed abortion clinics, including status of license, date of last inspection, and any fines or penalties rendered against the facility. 25 TAC § 139.6. Additionally, at the time of "initial onsite consultation," each woman must be provided with a written statement informing her that any complaints about the facility shall be sent to the Health Department. 25 TAC § 139.50.

A written plan of quality assurance implementation must be created and maintained in a licensed abortion facility, and must be reviewed and updated or revised "at least annually." 25 TAC § 139.8 A quality assurance committee comprised of a physician "medical consultant." a registered nurse ("RN") or licensed vocational nurse ("LVN") and "at least two other members of the facility's staff" must be formed and must hold meetings "at least quarterly" and must, at a minimum, evaluate all services related to patient care, ensure review of complications, address issues of unprofessional conduct by any staff member, monitor infection control, address medication, address the integrity of surgical instruments,

⁶ Currently, the plaintiffs, and other exempt physicians offices, are not listed on any central registry of abortion providers. Once a physician is licensed as an abortion facility, however, any member of the public can verify with a phone call that a particular physician performs abortions. The plaintiffs fear that this will subject them and their patients to being targeted and harassed by anti-abortion activists.

medical equipment, and patient supplies, and address "the appropriateness of diagnosis and treatment. The QA committee must document all remedial action. 25 TAC § 139.8. "Quality" is defined subjectively in the regulations as "the degree to which care meets or exceeds the expectations set by the patient." 25 TAC § 139.2 (43).

"An abortion facility shall prominently and conspicuously post the license issued under the Act for display in a public area of the facility that is readily accessible to patients, employees, and visitors." 25 TAC § 139.21(7). Facilities must pay an initial licensing fee of \$1,000, a first annual renewal fee of \$1,500, then a \$2,500 annual fee to maintain the license. 25 TAC § 139.22.

Physicians applying for licenses must provide personal information such as their home address, Social Security number, date of birth, driver's license number, and Texas physician license number. 25 TAC § 139.23.6 Applicants must also provide information on previous felony arrests or convictions, criminal misdemeanor arrests or convictions, tax liens, and judgments.

A state inspector or "surveyor" may enter the premises of a licensed facility, announced or unannounced, "at reasonable times during business hours and at other times as it considers necessary to ensure compliance," not only with the abortion facility regulations, but with any order of the health commissioner, a court order granting injunctive relief, or "other enforcement actions." 25 TAC § 139 31. Inspection surveys are also performed annually in connection with license renewal. The surveyor is entitled to access all records, and "shall perform an on-site investigation . . . to investigate a complaint received by the department." If a surveyor finds a deficiency of any type, the facility owner must submit a written plan for correction of the deficiency within 10 days after being notified of the deficiency, and

The plaintiffs fear that having to post an abortion license in the waiting room will offend their male patients, or their female patients who are there for medical care other than abortion.

⁶ The plaintiffs fear that putting this personal information in the public record will subject them to harassment and threats.

"the department shall determine if the written plan or correction is acceptable." If the correction plan is not deemed acceptable, the facility owner must submit a revised plan within 10 days.

A license or license renewal may be refused if the facility fails to comply with any provision of the Act, or for numerous other reasons. 25 TAC § 139.32. Administrative penalties up to \$1,000 a day may be assessed for any violation. 25 TAC § 139.33. In determining the amount of an administrative penalty, the Health Department may consider all matters "that justice may require." *Id.* Operation of the facility without an appropriate license subjects the physician to criminal liability. *See* TEX. HEALTH & SAFETY CODE § 245.014: 25 TAC § 139.33. The criminal offense was previously a Class C misdemeanor, but the 1999 amendments will increase the offense to a Class A misdemeanor. *See* House Bill 2085, Sixty-Seventh Legislature. 1999 Regular Session, 1999 Tex. Sess. Law Serv. Ch. 1411 (H.B. 2085). While the maximum penalty for a Class C misdemeanor is \$400, a Class A misdemeanor is punishable by a jail sentence of up to one year and a fine of up to \$4,000, or both. *See* TEX. PENAL CODE §§ 12.21: 12.23.

A licensed abortion facility is required to create and maintain written policies and procedures dealing with at least 30 different subject matters. See 25 TAC § 139.41. et seq. The policies must cover the following areas:

- 1. administrative policies covering, "at a minimum,"
 - A. personnel
 - B. employee training, orientation, and evaluation,
 - C. employee and patient record system,
 - D. auditing system for monitoring state or federal funds.
 - E. advertisements.
 - F. accuracy of public education materials and activities in relation to abortion, birth control, and sexually transmitted diseases,
 - G. patient education/information services and referral services;
 - H. reporting requirements:

- I. procedures for the resolution of complaints regarding quality of care. (All complaints must be documented and investigated within 30 days).
- 2. Clinical policies covering, "at a minimum,"
 - A. the provision of medical and clinical services;
 - B. the provision of laboratory services;
 - C. examination of fetal tissue,
 - D. disposition of medical waste,
 - E. emergency services,
 - F. condition on discharge procedures,
 - G. clinical recordings,
 - H. reporting and filing requirements
 - I. monitoring post-procedure infections
- 3. A policy to ensure compliance with the Health and Safety Code,
- 4. A policy to ensure compliance with fire safety codes;
- 5. Policies on decontamination, disinfection, and sterilization, and storage of sterile supplies.

All of these written policies must be reviewed and revised as necessary, "periodically, but no less than once every two years," and must bear the date of the last review. 25 TAC § 139 41.

Section 139.42 requires a "written organizational structure" identifying the physician, administrator and clinical staff and providing "a description of the structure of an abortion facility and defines the lines of authority." Section 139.43 requires personnel policies, including job descriptions, orientation, training, annual evaluations, continuing education, and basic life support certification. All employees must sign a statement acknowledging patient rights. Section 139.44 requires a "written orientation and training program" that requires all employees, including office staff, to understand and demonstrate competency in about 10 different areas, including patient care, sterilization and infection control, abortion techniques and possible complications of the procedure. All training needs to be documented in each employee's file. Section 139.45 contains specific requirements for the contents of each employee's personnel file, including test results for mycobacterium tuberculosis and hepatitis B.

Section 139.46 sets out specific required job qualifications for the office administrator, education and information staff, and laboratory staff, including type of degree, and certain level and type of experience, and requires that the staff include an RN or LVN. Section 139.47 sets out the specific job duties of the office administrator. The administrator must "develop and make available to all staff and the department, a policy and procedure manual including protocols and description of the roles and responsibilities of all personnel." 25 TAC § 139.47(a)(4). Staffing schedules, time-worked schedules, and on-call schedules must be retained for two years, and retained schedules must be stored so they can be retrieved within two hours. 25 TAC § 139.47(c).

Section 139.48 sets out physical and environmental requirements, including a separate recovery room, "a written protocol for emergency evacuation for fire and other disasters tailored to the facility's geographic location," two functioning sinks and a functioning toilet, and the capacity to provide patients with liquids. In general, a facility must "have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times." 25 TAC § 139.48(1)(A).

The facility must develop and maintain written infection control standards which "shall include, but not be limited to" HIV. hepatitis B and C, tuberculosis and streptococcus. 25 TAC § 139 49. There also must be written policies on "educational course requirements" and "decontamination, disinfection, sterilization and storage of sterile supplies." These written policies must include provisions regarding "the receiving, cleaning, decontaminating, disinfecting, preparing and sterilization of critical items" and "assembly, wrapping, storage, distribution, and quality control of sterile items and equipment." Section 139.49 also requires written policies and procedures on cleaning procedure rooms, and a written policy on the "handling, processing, storing and transporting of clean and dirty laundry" Several pages of specific detailed sterilization instructions set out in the regulations are required to be included in the

reaches majority. Retained patient records must be retrievable within 2 hours. The facility must create and maintain "a readily accessible written protocol for managing medical emergencies." 25 TAC § 139.56. Physicians must have admitting privileges at a local hospital, or have "a working arrangement" with a physician who has admitting privileges. The facility "must have the necessary equipment and personnel for cardiopulmonary resuscitation." 25 TAC § 139.56(b).

Section 139.57 requires "written discharge instructions" including a list of specific information that must be included. Written policies are required regarding examination and referral of all patients who report complications. (Complaints and responses must be documented in the patient's record under "a written system of documentation"). A written policy must be developed regarding the review of the record-keeping system for complications.

Section 139.59 contains definitions of different levels of anesthesia, and sets out required procedures, equipment and standards for procedure rooms relating to anesthesia services.

Section 139.60 requires that the facility must be in compliance with other laws and regulations, including all state and federal laws on handling drugs, the Clinical Laboratory Improvement Amendments, the Certification of Laboratories Act, the Texas Medical Practice Act, the Physician Assistant Licensing Act, the Nursing Practice Act, the Board of Vocational Nurse Examiners rules, the Texas Pharmacy Act, the Health and Safety Code provisions on misbranded drugs, the Texas Deceptive Trade Practices-Consumer Protection Act, federal OSHA requirements, and federal regulations regarding fire prevention, emergency plans, personal protective equipment, eye protection and hand protection, fire extinguishers, food-borne pathogens, and hazardous use of chemicals.

IV. Findings of Fact⁷

In 1997, more than 84,000 abortions were performed in Texas. Under current law, Texas has 31 licensed abortion facilities. The abortion statistics that all physicians are required to report annually show there are 7 physicians who currently perform more than 10 abortions per year, but fewer than 300 abortions, so they are currently exempt from abortion facility licensing and will remain exempt under the 1999 amendments. A handful of physicians, "a single-digit number," perform fewer than 10 abortions a year. The challenged 1999 amendments will bring within the regulation only physicians who perform more than 300 abortions a year in their private offices, but whose abortion patients constitute less than 51 percent of their total private practice patients. The evidence before the Court indicates that there are 12 physicians in Texas (approximately 20 percent of the state's abortion providers) who meet this definition and who therefore will become subject to the abortion facility licensing and regulatory requirements as of January 1, 2000. Five of the 12 physicians affected by the challenged provisions are plaintiffs in this case.

Plaintiff Dr. Fred Hansen is a board certified physician with more than 30 years of OB/GYN practice. He owns a private gynecology practice in Austin under the professional association name Fred W. Hansen, M.D., P.A. Hansen provides comprehensive gynecological care to his patients, including annual exams and pap smears, treatment of female reproductive system problems, family planning, and infertility counseling. He also performs approximately 950 to 1,050 abortions a year. His office staff consists of a medical assistant, a receptionist, an office manager, and a part-time transcriptionist. Hansen said abortion is simply one procedure among many that he provides to his

⁷ To the extent that any conclusion of law is more properly characterized as a finding of fact, and vice versa, the Court adopts it as such.

⁸ Some abortions occur in hospitals, which are also exempt from abortion facility licensing.

patients. He does not advertise that he provides abortion; almost all of his abortion patients are referred to him by other physicians. He also receives referrals of active military personnel and dependents from many areas who cannot get an abortion for any reason at a military hospital, and many of his patients come regionally from the areas surrounding Austin.

In addition to his private practice, Hansen has served for 16 years as a medical director to Reproductive Health Services, an Austin abortion facility that has been licensed under Texas law since licensing of abortion clinics was first required in 1985.

Many of the abortions Hansen provides in his private practice are for what he calls "obstetrical tragedies" that occur in wanted pregnancies, such as the discovery of a profound fetal abnormality in the skull, heart, or other vital organs, or the diagnosis of a chromosomal defect. These "medically indicated" abortions typically occur past the 15th week of pregnancy, when perinatal tests reveal the problems with the pregnancy. Hansen testified that he is currently the only private physician in Austin who provides abortions beyond the 15th week of pregnancy, so if Hansen were to close his private abortion practice, couples in the Austin area who are facing the tragic choice of whether to abort a pregnancy when defects are discovered would have to go to an abortion clinic rather than a private office. This, Hansen says, would greatly reduce the emotional support and counseling such patients would receive. The private setting also offers an element of privacy lacking at a clinic, where virtually all of the patients there have come for an abortion. Currently, a woman in Hansen's waiting room could be there for birth control pills, an annual exam, or another gynecological procedure, not just an abortion. Hansen's office is not listed on any public registry of abortion providers, and he has been picketed rarely, only three times in the last 12 years. In contrast, he said, a clinic might see up to 35 patients a day, and clinic patients are subjected daily to confrontational anti-abortion picketers. Women seeking abortions at a clinic often must wait five to nine hours at the facility, and Hansen believes that their already fragile emotional state will deteriorate in this setting. In addition, staff turnover at clinics tends to be higher, so personnel are likely to be less experienced and sensitive to patients' needs.

Hansen testified that he, and other gynecologists, perform gynecological procedures in their offices other than abortion,

Abortion does not require a different, or more stringent, type of sterilization of instruments than other gynecological procedures Hansen performs in his office, such as endometrial biopsies, cervical biopsies, dilation and curettage ("D&C"), and the removal of a fetus that has died in utero. These procedures carry risks similar to those of abortion, and it would not be unusual for a gynecologist to perform a combined 300 or more of these procedures in a year. Hansen also testified that other outpatient surgical procedures are also routinely performed in physicians' offices, such as liposuction, which can involve more risks than abortion. Yet only abortion subjects a physician to regulation. Hansen knows of no other outpatient procedure that is regulated based on the number of procedures performed in a year. He testified that there is no medical or logical reason to distinguish between a physician who performs 300 abortions a year from one who performs 299 abortions a year, or from one who performs 300 similar gynecological procedures.

In his practice, Hansen testified, he has trained all of his employees in sterilization procedures, with the assistance of the manual for the sterilizer. He does not have written infection control and sterilization policies, because he and his seasoned staff already know the procedure. He is always there when the office is open, so he is there to see that sterilization is done properly, although due to the long tenure of his staff, it is "extremely rare" that he sees a sterilization problem

In fact, Harris testified that the removal of a fetus following demise — which is specifically excluded from the definition of abortion under 25 TAC § 139.2(1) and so would not subject a physician to regulation — is actually more dangerous to the patient than the abortion of a living fetus.

that needs correcting. "My infection rate is almost nonexistent," he testified. He admitted, however, that he had not calculated or come up with any hard estimate on how long it would take him to draft infection control or sterilization policies. He does not believe he could copy them from the licensed facility where he works because they are proprietary materials. He admitted that he has not looked to see whether some of the regulations duplicate requirements in statutes to which he is already subject, such as the Clinical Laboratory Improvement Amendments, OSHA, or the Texas Medical Practices Act.

If Hansen were to become licensed, he would have to immediately hire an RN or LVN, because the regulations require that an RN or LVN be on staff. ¹⁰ He testified that because he and his staff are all fully occupied by their current workload, (and because he does not believe that any of his current staff members have the required expertise to track compliance of these detailed regulations), he estimates that he would have to add an additional person to ensure compliance. Another option would be to replace his office manager and transcriptionist, who have worked for him for 14 and 22 years, respectively, and replace them with the RN and a staff person who would serve as the administrator in charge of regulation compliance. However, he does not believe an RN or LVN is necessary to provide good medical care to his patients. He does not currently have formal written personnel policies for his four employees, and he has no written organizational chart showing delegation of authority.

Hansen also expressed concern with the requirement that he post or provide each patient with notice of the toll-free number to the abortion licensing division where "all complaints" must be directed. "I run an integrated medical practice, and I just don't know how my 71-year-old patients are

¹⁰ See 25 TAC §§139.46(3)(B): 139.8; 139.53.

going to react [to a document telling them] that if they're dissatisfied that they're to call the abortion licensing division of the Texas Department of Health. It's a demeaning requirement to ordinary patients." Having to provide personal identifying information with the license application bothers him, because of recent incidents around the country where abortion practitioners were killed. He fears being more vulnerable to violent activists who might target him for harassment or violence.

Hansen estimates that if he were to become licensed and comply with the regulations, he would incur about \$60,000 in additional costs annually for the two new staff members. Since he does about 1,000 abortions a year, the extra staff expense alone would equal a cost of \$60 per procedure, although he testified that he would not necessarily raise the price to his patients.

In general, Hansen agreed that the requirement that freestanding abortion clinics be licensed and regulated by the state has done some good in deterring "individuals who would establish corner clinics, multistate clinics, and be interested only in it for a remunerative basis." When non-physicians own abortion clinics, Hansen said, he sees the possibility that quality medical care may be sacrificed to the "bottom line." He acknowledged that if a private physician is doing 2,000 abortions, a year, then "a more formal process might be perhaps advantageous." But he does not believe that becoming licensed at his own private office would improve patient care.

Hansen testified that he will stop providing abortions in his private office rather than seek to be licensed, because he believes patient care would suffer while he and his staff spend time on burdensome administrative tasks, and because he does not want to be subjected to possible fines and criminal penalties. He will continue to serve as medical director to Reproductive Health Services and will continue to perform abortions at that facility.

Plaintiff Dr. Mary Smith operates a private gynecology practice in Denton, Texas, under the professional corporation name Mary E. Smith, M.D., P.A., She does business as "Denton

Health Services for Women." ("DHS"), which she opened 22 years ago. At DHS she provides her patients with gynecological examinations, early pregnancy tests. sonograms, emergency contraception, family planning services, and testing and treatment for sexually transmitted diseases. She provides abortion services two mornings a week at DHS. Smith testified that she does much of the practice management herself. She has one full-time employee, a counselor who also answers the phone, and she employs a part-time receptionist, and an RN and an LVN who alternate coming in on days when she does surgery. She currently provides about 350 to 400 abortions a year at DHS. She testified that she feels comfortable with keeping the number of abortions she provides at around 400, because at that level she can remember each patient's name and personally supervise their care. "That's enough for me to keep in my head and know at home when they call me," she testified.

Smith also performs abortions two and a half days a week at the Fairmont Center, a licensed abortion clinic in Dallas. The Fairmont clinic is about 45 minutes to 90 minutes away from DHS by car, and she is not aware of any public transportation available between Dallas and Denton. She performs about 2,000 abortions a year at the Fairmont clinic. Occasionally she treats patients from Denton at the Dallas clinic. She testified that her experience with health department surveyors at the Fairmont clinic has been negative. However, she admitted that the regulations have the potential to improve health care in some physicians' offices, whether they perform abortion or other surgical procedures.

Smith testified that she is the only Texas abortion provider north of Dallas. Many of her patients are from Denton, a university town, but some come from throughout Denton County and north of Denton all the way to Oklahoma. Some patients drive in from other cities to come to her because they prefer a female doctor. "To my knowledge, I am the only female physician providing abortions in Texas," Smith testified. Many of her Denton patients have difficulty paying for an abortion and often have to delay

the procedure in order to come up with the money. A lot of the patients arrive by taxi or trolley and have no transportation back home, so Smith or her staff have to drive "quite a few" of their patients home after the procedure.

Smith and her nurses are responsible for sterilization of instruments, and Smith supervises the sterilization to be sure it is done properly. The counselor and receptionist do not have any training in sterilization. She testified that if she were to become licensed, she would have to purchase a new autoclave to meet the requirements of 25 TAC § 139.49, which requires sterilizers to be "monitored during operation" and requires recording and keeping records on the pressure, temperature, and time maintained at desired temperature and pressure. Because her "ancient" autoclave does not electronically record this data, she would either have to buy a new one or have someone sit in the room with the autoclave during the time when it is running to record all the required information. She would have to purchase an oral suction machine apparatus, which is required under 25 TAC § 139.59(f)(4) in facilities which use light sedation. She currently does not have any of the required written policies required by the regulations, and she sees no need to, for example, draft a written "advertising" policy regarding her one listing in the phone book, or to draft a written policy regarding the accuracy of public health information that she herself provides to her patients. She has no written complaint policy, but she personally deals with any complaints that come in. She has no written policy regarding the monitoring of post-procedure infections, but her patients can and do call her directly with any concerns about infection. "It's worked for me for 22 years," she testified. "I'm having a hard time understanding why I need to change." She believes that none of the regulations would improve patient care in her practice, because she would be distracted by having to meet all the requirements, which would take time and attention away from patient care. The required quality control committee composed of at least four staff members could not be assembled without requiring one or more of her part-time employees to take off from their other job to come in, because her four staff members are very rarely in the office at the same time. It would be very difficult to schedule such meetings during regular working time, because she and her staff already are fully occupied on the days the office is open and providing abortions.

Smith does not plan to become licensed. She testified that her practice in Denton is already struggling financially, and has only been continued due to her feelings of loyalty and commitment to the community of Denton. However, the increase in expenses due to the licensing fees, purchase of required equipment, and compliance with the regulations would make it financially impossible to continue. She would have to either hire someone to draft all the required policies, or find the time to draft them herself, because no one else on her staff would be capable of doing it. She has talked to the person who drafted the policies for the Fairmont Center in Dallas, and found out that drafting those policies took three months. She doesn't believe that the Fairmont policies could be used as a model for policies for DHS, because the procedures at a clinic of 20 employees are necessarily different from a private practice with four employees. Section 139.53 requires the recovery room to be supervised by a physician, physician extender or RN, and Smith testified that she needs her nurse to assist her with surgery, so she probably would have to hire another nurse to supervise the recovery room. She admitted, however, that she has not put pencil to paper to calculate exactly what all the costs of compliance would be.

Because 80 percent of her income is from providing abortions both at DHS and at the Fairmont Center in Dallas, ceasing to provide abortions in Denton would mean that she would have to shut down her entire private practice in Denton. As a result, her patients in Denton would lose the personalized care she has been able to give them, and some may be prohibited from obtaining abortions due to lack of money and transportation. "Some of them will make it to Dallas," she testified. "The ones who can't will go on and have babies."

Plaintiff Dr. Tad Davis is a board certified OB/GYN who conducts a private gynecology practice in Austin, Texas under the professional name. Austin Women's Health Center, P.A. ("AWHC"). Davis has approximately 15 part-time and full-time employees, including three frontdesk employees who do insurance verification, receptionist work and other clerical tasks, two certified counselors, four medical assistants, three LVN's, a bookkeeper, a personnel director and another physician. AWHC provides comprehensive gynecological care, including routine examinations, family planning, and diagnosis and treatment of diseases affecting the reproductive system. He also provides abortions up to 15 and a half weeks of pregnancy. His patients come regionally from the area surrounding Austin, including areas southwest to San Antonio, northeast to Waco, south to Interstate 10, and northwest to Killeen and Copperas Cove and up into the Texas panhandle, including Lubbock, Midland, and Odessa. He estimates that about 25 percent of his patients fall below the federal poverty level. Davis testified that his patients benefit greatly by the private atmosphere of a practice that provides a wide range of other medical care besides abortion, and by having the accountability of one physician who is responsible for the entire practice. "Unfortunately in clinics sometimes there is the cattle herd mentality where a number of patients are brought in, sent through procedures, and tender love and care is not given to them as much as in the private office," Davis testified:

Davis testified that having to comply with the regulations will jeopardize confidentiality, increase costs, and cause a great deal of dissatisfaction among his staff. He estimated that the additional costs of compliance will require him to raise his abortion fees by \$25 to \$50 per procedure. That estimate does not include the one-time cost of a consultant he intends to hire to come in and draft his policies and help him come into compliance. "The regs

are very difficult in the fact that they're open to interpretation," Davis testified. "They're very difficult in the fact that it requires pounds and pounds and pages and pages of paperwork, and things that physicians' offices are just not attuned to, so one has to have a consultant in order to proceed, if they're going to get licensing." He testified that his consultant estimates that it will take three weeks, at \$1,000 a day, to get all of the required policies written. In addition, the consultant estimated that he would have to close the office down for one week to train all of his employees. The cost of paying the consultant for three weeks, and the cost of closing down the office for a week to train his employees, would mean \$50,000 to \$60,000 in start-up costs, he testified. He admitted on cross-examination, however, that he has not attempted to locate a less expensive consultant, and he admitted that he did not provide his consultant with a copy of all the regulations to review before coming up with her cost estimate; he merely read some of the regulations to her over the phone. He also did not tell the consultant that the pre-licensing procedure includes a visit from a health department surveyor for the purpose of explaining and interpreting the regulations and helping the office become compliant. He testified, however, that he does not believe the health department will be of much help to him in interpreting the regulations, based on a phone call he made to the health department seeking to understand certain parts of the regulations. He states that the person he spoke to did not answer his specific questions, but merely read the regulation to him. He admitted, however, that he does not know who he spoke to and whether that person was an experienced surveyor. Davis admitted that he has not compared the various written manuals he currently has in his office with the regulations to see whether he already has on hand some of the required written policies. He testified that he would not have to add any more employees to comply with the regulations.

Davis does not believe that any medical benefit would be gained by having to train his front office employees -- whose sole duties are to verify insurance, perform receptionist duties, and schedule appointments -- in areas such as infection control and sterilization. He believes his practices are already effective to prevent infections. "Our complication rate has been one of the lowest in the world," he testified. In addition, he estimates that training the front desk employees and the bookkeeper, who do not have any medical education, will take longer than training a medical assistant or other person who has health care background or credentials. In addition some of his employees are part-time, so it may be difficult to schedule a time for them all to come in to be trained.

Currently, AWHC charges \$350 to \$550 for an abortion. Davis testified that all of the costs of compliance will be passed on to his abortion patients, many of whom "barely can come up with the funds now, and this will put them over the edge where they will not be able to have abortions." This increase of \$25 to \$50 (or more, depending on the period over which the start-up costs are recovered) per procedure will be on top of other expenses many of the abortion patients are already having to pay, such as medications, and the cost of travel and overnight accommodations for those patients who travel for long distances to come to his office. He testified that these estimates contemplate passing the increased costs along only to his abortion patients, not to his practice as a whole, and he admitted that he has not determined how long of a period he would use to defray the start-up costs.

Davis also performs other gynecological procedures in his office that carry risks similar or identical to abortion, such as D&Cs, endometrial biopsies, hysteroscopies, and conization. He testified that a D&C is virtually the same procedure as an abortion, and a

conization, in which a portion of the cervix is surgically excised for the diagnosis and treatment of pre-cancerous tissue, is more complicated and involves more risks than abortion. Yet only abortions will subject him to regulation. In addition, he testified that almost all physicians do some sort of invasive procedures in their offices, some of which carry a higher risk to the patient than abortion. He testified that tummy-tucks, facelifts, liposuction, endoscopy, and laparoscopy are commonly performed in physicians offices, but do not subject physicians to regulation. Laparoscopy, for example -- which has been approved by a reputable medical organization as being appropriately performed in a physician's office -- carries a risk 10 times higher than that of abortion. Davis sees no medical reason to regulate these other office surgical procedures differently from abortion. He also sees no reason to regulate a physician who performs 300 abortions a year in his office, but leave unregulated a physician who performs 299 abortions. On the contrary, in his experience a physician who does a greater number of procedures tends to be more competent than an occasional practitioner. He testified that the amount of time a doctor has to spend with each patient is not necessarily related simply to the number of abortions the doctor performs; rather, it depends on a number of factors, including the length of office hours, the availability of other medical support staif, and the number of total patients seen or non-abortion procedures performed.

Davis has for about 10 years participated in the review and discipline process of the Texas Board of Medical Examiners, and he testified that the TBME has done an excellent job for at least the last 10 or 12 years in monitoring physicians and disciplining physicians who provide substandard medical care. In addition, he testified that under the "captain of the ship" doctrine, the TBME holds the physician personally responsible for any substandard care provided

by his staff. He testified that the possibility of a complaint to the TBME or a malpractice lawsuit causes him to be vigilant in maintaining the proper standard of care for his patients. He admitted, however, that the TBME does not promulgate regulations or regularly inspect physicians' offices, but reacts only to complaints about a physician from patients, hospitals or other practitioners.

Davis testified that an abortion is one of the most traumatic events in a woman's life, and although his office tries to provide comfort, counseling, and "TLC" to maintain the patient's self esteem and self-worth, he's not sure that it is possible for an abortion to "enhance" a patient's self worth, as required by 25 TAC § 139.49. In fact, Davis believes that the time that will be required to reach and maintain compliance with the regulations will actually decrease the time he and his staff have available to provide personalized care, which could make the experience worse for many of his patients. Davis plans to seek to become licensed, but he has doubts about how long he will continue providing abortions, or whether in the future he will try to limit his abortions to fewer than 300 a year.

Plaintiff Dr. Robert Kaminsky is a Houston gynecologist who owns a private practice under the professional corporation Robert P. Kaminsky, M.D., P.A., doing business as Women's Medical Center of Northwest Houston. Kaminsky has one other physician who works with him at the Women's Medical Center, and he also employs a nurse practitioner, a part-time licensed vocational nurse ("LVN"), three full-time medical assistants, two receptionists, two office employees who deal with insurance verification, an accountant-bookkeeper, and an administrator. The office provides comprehensive gynecological care, including diagnosis and treatment of menstrual disorders and sexual dysfunction, contraceptive planning, infertility evaluation,

gynecological surgery and abortions. Kaminsky estimates that he personally performed 700 to 750 abortions during the last year, which is half of the abortions done in his office. He testified that he spends about half of his time doing abortions, and about two-thirds of his income in 1998 came from abortions.

In his medical opinion, abortion is no more complicated and entails no greater risk than many gynecological surgeries that he routinely performs in his office. Kaminsky also performs pap smears. IUD insertions, D&C's, and cervical and endometrial biopsies. Endometrial biopsy, a procedure to sample and remove a tissue specimen from the inside of the uterus, is virtually identical to a first-trimester abortion in technique and technical difficulty, as well as in the instruments and medication used.

He testified that he has developed infection and sterilization procedures that have proven extremely effective for all the surgical procedures he performs, although they may not meet all the particulars of the regulatory scheme. He uses the same sterilization procedures for abortions as for other procedures, and he testified that there is nothing about the abortion procedure itself that would require a different protocol. "There is no basis for the state to single out abortion procedures and dictate the sterilization and infection procedures," Kaminsky states. "Nor can I understand, from a medical perspective, why a distinction is made between physicians performing less than 300 abortions and those performing more than 300 in a twelve-month period." He testified that a medical assistant who has worked for him for 10 years instructs other medical assistants on how to sterilize instruments. He has no written sterilization policy other than manuals for the equipment. He has no written infection control policy, and states that his office has not had a problem with infection.

He does have a personnel policy, a checklist of items to cover in the orientation of new medical assistants, and some other instructional documents.

Kaminsky does not have a formal quality assurance program, but he monitors the provision of medical services on an ongoing basis, dealing with problems as they arise and during staff meetings if necessary. "This system, while informal, has proven efficient and effective," he states. "The quality assurance provisions in the regulatory scheme may be appropriate for an ambulatory surgery center setting because different physicians use the facility and patients will most often receive follow-up care in the private office of their referring physician. In my private office practice, where I am ultimately responsible for all of the medical care, I do not believe that this type of quality assurance program is necessary to ensure patient health and safety. Compliance, would, however, require additional staff time."

Kaminsky estimates that he spent approximately 45 minutes reviewing the challenged regulations, but that he has not asked his staff to review them, and he has not considered whether the regulations would require any physical changes to his facility. He admitted that he has not done a general cost estimate on how much it would cost him to comply with the regulations. He believes most of the additional costs will come from the additional staff time needed to develop the required written policies and to document compliance. He believes that having to comply with the regulations will likely result in an increase in abortion fees, which will force women to pay more for the procedure or go elsewhere.

Plaintiff Dr. Lamar Robinson provides a wide range of obstetrics and gynecology services, as well as other general practice medical care, in his private office in Dallas. He performs abortions at his private office, and he also performs abortions at a licensed abortion facility, the

Aaron's Women's Health Center in Dallas, for four half-days a week. Robinson testified that 2,211 abortions were performed at his private office during 1998, and he estimates that the 1999 total would be similar. He estimates that 40 or 50 percent of his income comes from abortions. He has 14 employees at his private office, and he has two other physicians who help him on a part-time basis. His employees include an office administrator, an office manager, a lab manager, a business manager, nurse practitioners, nurse staff, a registered nurse, several medical assistants, a designated cashier, and one designated receptionist.

Robinson has submitted a preliminary application and has paid an initial licensing fee to become licensed under the Abortion Facility Reporting and Licensing Act, and has participated in an initial telephone survey with the health department. He and his staff have compiled a list of anticipated costs associated with becoming licensed. He estimates that he will have additional payroll expenses for additional staff hours spent writing policies, generating new forms, and revising old forms. Robinson testified that he currently has written infection control procedures, written personnel policies and training materials. He anticipates having to make changes in his sterilization area, and expects to incur ongoing additional costs of about \$5 a patient to meet the requirement that new suction tubing be used for every procedure. Robinson currently charges \$250 for a first-trimester abortion in his private office. Overall, Robinson expects to incur costs associated with becoming licensed that will total as high as \$100 per patient.

Robinson objected to the requirement that the abortion facility license be "prominently displayed for everybody who comes in the door." See 25 TAC § 139.21(7) ("An abortion facility shall prominently and conspicuously post the license issued under the Act for display in a public area of the facility that is readily accessible to patients, employees and visitors.").

Robinson expects his practice to suffer due to the posting requirement, because the posted abortion license is likely to offend his obstetrical patients and male patients, some of whom oppose abortion.

Robinson sees no medical reason to single out abortion for this type of regulation. He states that he also performs diagnostic hysteroscopy and D&C procedures in his office, and that these procedures involve virtually the same instrumentation, sedation, techniques, duration, and risks as a first-trimester abortion. Yet only the abortions will subject him to regulation. The burdens of the regulatory scheme, according to Robinson, come from requiring an office which has operated informally, as most private offices do, to follow requirements more appropriate for a facility like an ambulatory surgery center. "I do not think these written policies are necessary to improve or ensure patient safety," Robinson testified. "Compliance with the provisions of the regulations would be driven by the threat of civil and administrative penalties and a loss of license rather than a perception that they will enhance the well-being of my patients."

The defendants introduced the deposition testimony of Dr. Janet Lawson, a board certified OB/GYN who is currently employed by the Texas Department of Health as the medical consultant for women's health. Lawson was formerly in private practice, and she has performed abortions in the past. Lawson testified that she participated in a committee in 1997 to revise the abortion facility regulations. The revisions that she helped draft became effective on August 13, 1998, and were applicable at that time to abortion clinics and physicians' offices used primarily for the purpose of performing abortions. Lawson was not involved in drafting the 1999 amendments that are being challenged in the instant case, so she did not participate in choosing the number 300 as a cut-off for the physicians' office exemption.

increase the number of abortions, or procedures that are done of any type," the physician tends to have less time to attend to issues like sterilization, counseling, and triage, and more of those duties are left to the physician's staff. Therefore, Lawson reasoned, it makes sense to require that the staff receive specific training to be able to handle problems or complications when the physician is not immediately available. "As the distance between the physician and the patient gets wider, it's harder for the physician to take care of [the patients'] needs, unless there's some specific policies, guidelines, processes, that are in place."

The defendants also presented the testimony of Dr. Kate Hendricks, a physician specializing in infectious diseases and epidemiology who currently is employed by the health department. Epidemiology is the study of how disease is distributed in a population, how disease spreads, and how that spreading can be prevented. Hendricks was involved in the 1997 committee that drafted the 1998 revisions to the abortion regulations. However, she testified that she was not involved at all in the passage of the 1999 amendments, and was not consulted regarding the narrowing of the physicians' office exemption to include all offices where 300 or more abortions are performed in a year.

During the 1997 revisions to the regulations, Hendricks was specifically involved in the subcommittee on sterilization regulations. She helped to select other resources the regulation drafters used, such as documents from the "hospital infection control" section of the Centers for Disease Control and Prevention.

She remembers that the applicability of the regulations to physicians' offices was discussed "some," but not extensively. Because the regulations at that time only applied to physicians' offices used primarily for abortions, the drafters had in mind only those "51 percent or

more" physicians' offices, she said. Hendricks testified that regardless of where a woman goes to have a procedure done, whether in an operating room, at a clinic, or in a physician's office, she should have the same protection from infections.

Hendricks testified that infection control standards and sterilization are important in the abortion context because the procedure invades the uterus, which is normally a sterile body cavity. She said that staff training is important in these areas, because some of the dangers of contamination are not obvious; for example, a staff member might accidentally cross-contaminate sterilized instruments if he or she has not been taught how to handle them properly. She also testified, however, the sterilization and infection control requirements that she helped to draft are equally applicable to all invasive surgical procedures performed in a physician's office. She states that the American College of Obstetrics and Gynecologists ("ACOG") would agree that such requirements are equally appropriate for abortion and all gynecological surgery.

During the 1997 committee discussions, the members did not discuss how much time it would take for physicians' offices to draft all of the required policies, but Lawson pointed out that there exist resources of medical information that can be used in drafting policies, so that physicians don't have to "do it from scratch."

Hendricks was asked to be a witness in a lawsuit where a woman died from a severe infection following an abortion, and she was notified by a hospital about another death following an abortion. She testified that those incidents occurred before 1997, in an abortion facility that was already licensed by the state. She has never been notified about, or attempted to track, any infections or deaths following other gynecological surgery in Texas. She has worked at the health department for 10 years, and often gets calls about incidents or outbreaks of disease in various health care areas.

but she has never been notified of any particular problems with infection following gynecology surgery or other outpatient surgeries performed in physicians' offices.

Hendricks testified that a first trimester abortion procedure is "quite similar" to a D&C procedure, in terms of both required instruments and level of invasiveness. She testified that there are no medical, health or safety reasons to distinguish a private physician's office where 300 abortions a year are performed, from a physician's office where 300 D&C's are performed, or from a physician's office where less than 300 abortions are performed. "I think [that] based on ACOG standards, they should be the same," she testified. "To protect the woman, they should have the same standards."

The defendants also introduced the testimony of Mark Jeffers, a registered nurse now employed by the health department. In 1997, he was in charge of organizing and guiding the task force members who were working to revise the abortion regulations. He stated that he tried to keep the committee focused on the goal of improving women's health. He discussed the various subcommittees that worked on different parts of the revisions, such as sterilization, quality of care, and qualifications of personnel. He helped to draft the quality control regulations, and he testified that quality assurance in a medical facility is important "no matter what kind of service they provide." He testified that the regulations require an LVN or RN to be on the quality control committee because "they are needed for their expertise."

Jeffers testified that the 1997 committee was focused only on the facilities covered by the statute at the time. Those physician offices affected by the 1999 amendments -- those who perform more than 300 abortions a year, but whose practice does not consist "primarily" of abortions

-- were not contemplated at the time the committee was drafting the regulations that became effective in August 1998, Jeffers said.

Jeffers admitted that there is no objective way to measure compliance with the "patient rights" regulation that requires physicians to "enhance" each patient's dignity and self-esteem. He agreed that people might have different interpretations of that language, and that a health department surveyor might have a different interpretation than a physician regarding whether the physician was in compliance. Jeffers acknowledged that it would be up to the surveyor's discretion and interpretation as to whether the physician would be subjected to civil or criminal penalties for not doing enough to "enhance. self-esteem." See 25 TAC § 139 51.

The defendants also introduced the deposition testimony of Julie Long, a registered nurse employed by the health facility licensing and compliance division of the Texas Department of Health. She has a master's degree in health care administration, and she has an obstetrical background. As an RN, she has assisted in abortion procedures. From 1990 to 1995, Long worked for the health department as an obstetrical nurse consultant. Her main job responsibility was scheduling and conducting surveys of licensed abortion facilities and licensed birthing centers. In fact, during part of this time she was the only surveyor in Texas, so she did virtually all of the surveys of licensed facilities. The regulations Long worked under were a different set of regulations than the ones now codified at Tex. Health & Safety Code §§ 245.001 et seq and 25 TAC §§ 139.1 et seq. "They were completely revised in August of 1998." Long testified. From 1990 to 1995, Long did annual surveys, conducted pre-survey conferences with facilities, investigated complaints, and reviewed the facilities' correction plans. She took phone calls from members of the public who had questions about particular facilities, and from facility owners who had questions

about the licensing regulations and the survey process. She also prepared a surveyor training manual for abortion facility surveys and trained other surveyors in the process. She also conducted investigations and surveys of other health care facilities other than abortion facilities.

A typical survey of an abortion facility during Long's tenure as a surveyor from 1990 to 1995 included a pre-survey conference with the physician or administrator, observation of an abortion procedure, listening to a counseling session, inspecting the laboratory, observing the staff members performing their various functions, and observing the sterilization of instruments and the examination of fetal tissue. She would also review personnel records, review policies and procedures, and randomly pull and review a sample of patient medical files from the last six months. In a facility that provides services other than abortion, she would identify and review only those personnel and patient records having to do with abortion. All information from the records is kept confidential.

During this period, Long paid special attention to the sterilization process, observing the employees as they worked on the sterilization of instruments, and interviewing them about their procedures. "And in many instances I found that there were problems with sterilization, that the staff were not adequately trained," she testified. The pre-1998 regulations did not contain any directions or requirements regarding sterilization, Long testified. "One of the problems that we had with the old set of regulations was that there was no set standard for processing instruments. There was no very specific guidelines that the facilities had to follow." Because of this lack of guidance, Long said, as a surveyor she observed errors in the way sterilization was done, for example, the employee would not know the correct temperature, pressure or length of time to run the sterilizer; employees would not properly wait for instruments to cool before taking them out of the autoclave:

there were problems with sharp instruments tearing through the packaging and compromising the sterility of the package; employees not putting enough water in the autoclave; and facilities were not running a biological control test often enough. In facilities with high staff turnover. Long testified, she might find that the person doing the sterilizing was a poorly trained medical assistant.

Long testified that the health department in 1993 investigated the case of a woman who had died after an abortion. That investigation led to major revisions in the abortion facility regulations, including amendments to include some discharge instructions and follow-up care. Long testified that the death occurred in a licensed facility which had a history of repeatedly failing to properly sterilize its instruments. The health department investigation into the woman's death led to civil penalties being assessed against the facility, and the facility was required to close.

Another change in the regulations that became effective in 1998 requires a facility administrator to have a bachelor's degree or two years' health care experience. The reason for this change, Long testified, was that "historically, a long time ago, not recently in the last few years, but historically," she found administrators who were not qualified, were inadequately supervising other staff members, and were giving bad medical advice over the phone. She said she read many hospital charts during this same time showing women who had severe post-abortion infections, who had to have operations, or whose health was permanently affected due to complications from an abortion.

Long stopped performing surveys in the field after 1995, but she worked on the 1997 revision of the regulations, and continued to train surveyors. After the new regulations became effective in August of 1998, Long continued to train surveyors, and she did pre-survey conferences over the phone, conducted a workshop for abortion facilities to familiarize them with the new rules, and served as a reference person for facilities to answer questions about compliance with the new

rules. During the period between August 1998 and December 1999, no person from an abortion facility contacted her and complained that he or she could not understand the regulations, or that the regulations were too burdensome or too detailed, or that the regulations were vague or ambiguous. During the telephone pre-survey conference, the facility representative has the opportunity to ask the health department about specific interpretation of the regulations, and discuss, for example, how to write the required policies and procedures. She said that it is common and helpful to use another licensed facility's policies as a model, revising as needed to apply to the second facility's operations. Long estimated that one person working full time could draft all of the required policies in "a few days."

Long testified that her relationship over the years with abortion facilities has been a cooperative one, and the facility staff were often grateful to her for pointing out a potential problem and helping them to correct it.

Long did not participate at all in the drafting or passage of the 1999 revision to the abortion regulations that is being challenged in this lawsuit.

She acknowledged that she has never inspected physicians' offices that are not currently licensed, so she has no knowledge of any sterilization problems or other issues in physicians' offices where outpatient surgery other than abortion is performed. She has no knowledge of whether physicians providing abortions in their offices who are currently exempt from abortion facility licensing have any more sterilization problems than private physicians who perform other types of surgeries in their offices. She said sterilization is not only an issue with abortion procedures, but is important for any surgery that invades a sterile body cavity. Long testified that sterilization issues do not change depending on the number of procedures a physician performs. "Sterilization

doesn't have anything to do with numbers," she said. She can think of no medical, safety, or health reason to regulate 300 abortion procedures differently from 299 abortion procedures, in terms of sterilization. The regulations on "inspection of surgical instruments" that she helped to draft in 1997 do not address anything unusual or unique about abortion, she said; the standards would be appropriate for any health care facility.

As of December 1, 1999, Long began a new job working on the complaint intake line for the health facility licensing and compliance division. Any member of the public can call the health department's 1-800 number and complain about abortion facilities or any other health care facility licensed by the health department. Long and the others who answer the toll-free line have a list of specific information that may be given regarding an abortion facility, including identification of the facility or the physician, if the patient is not sure of the name; the date and results of the last survey, and information about any deficiencies identified.

Long stated that the reason facilities are required to post their abortion facility license is so that women walking in to the facility can be sure that the facility has been inspected and meets the regulatory requirements. She said that personal information is required in the application process so that the department would be able to "track bad actors" from one facility to another, to prevent a facility owner who has been cited or shut down from just opening another facility under a different name. Regarding the patient rights section that requires physicians to enhance dignity and self-esteem, Long said that standard "is the same as the patient's rights in any other health care facilities."

The defendants also presented the testimony of Jan Melton-Kissel, an RN who has practiced in obstetrics and who currently works in the health department's bureau of licensing and

compliance. Melton-Kissel also has experience conducting surveys of licensed abortion facilities, including physician's offices devoted primarily to abortion. She was involved in the health department's input into and approval of the challenged 1999 amendments. She reviewed the 1997 abortion reporting statistics and determined that the 1999 amendment would affect 12 physicians.

She clarified that the current regulations (both before and after the 1999 amendment takes effect), provide for the charging of a physician with a criminal offense only if the physician is found to be running an abortion facility without a license. Licensed physicians who fail to comply with the regulation's specific requirements for running a facility are subject to civil penalties of \$100 to \$500 per violation, Melton-Kissel said. The regulations also provide for administrative penalties of \$1,000 per violation, with each day of noncompliance counting as a separate violation, and Melton-Kissel acknowledged that the decision of whether and to what extent administrative penalties will be imposed is "in the discretion of the health department." The regulations also provide for suspension and revocation of an abortion facility's license for various forms of noncompliance, and she testified that once a license is revoked, the physician can be criminally prosecuted for continuing to provide abortions to his patients.

To show the state's motivation and reason for adopting the 1999 amendments, the defendants offered an affidavit from Texas Senator Chris Harris, who filed a Senate bill in early 1999 that would have required all physicians performing more than 10 abortions a year to be licensed. That number was later amended to 300, and the amendment was ultimately passed into law by the legislature as part of a lengthy House bill dealing with general health department matters. Defendants also offered the deposition testimony of Texas Senator Leticia Van de Putte, who drafted the version of the amendment that became part of House Bill 2085 when she was a member of the

Texas House of Representatives, representing District 115 in San Antonio. Van de Putte was elected as a senator in November 1999. 11

Harris avers that in 1997, during the 75th legislative session. "the Texas Department of Health reported to the legislature a number of examples where young women had either died or been permanently injured due to the negligence of abortion facilities." In response to this information, Harris decided to author new legislation "because I felt the legislature had a responsibility to ensure that women who chose to have an abortion here in Texas are protected." Harris participated in authoring 1997 legislation that amended the previous abortion facility statute to give the health department the authority to report medical personnel to appropriate state licensing boards, impose administrative penalties, and revoke or suspend licenses in emergency situations. The 1997 legislation required the health department to provide a toll-free number "to allow individuals to call and find out if an abortion facility was licensed." The 1997 legislation also instructed the health department to adopt new rules to implement the abortion statute, which resulted in the ad hoc committee process in 1997 to promulgate the version of the rules that became effective in August 1998.

The legislative enactment being challenged in this lawsuit is the passage of the 1999 amendments to the abortion facility statute. Harris's affidavit describes the events leading up to the 1999 amendments as follows:

Prior to the 76th Legislative Session (1999), I reviewed the Texas Department of Health's implementation of these laws. In reviewing the data on abortions performed in the state, it became apparent to me that a number of physicians were circumventing the intent of the law that requires health and safety standards for

Plaintiffs moved to strike the testimony of Senators Harris and Van de Putte as "inadmissible subsequent legislative history." (Dkt. # 51). The Court has denied the motion to strike for the reasons stated in a separate order signed today.

abortion facilities. These doctors simply filled out a form which stated that abortions did not constitute a significant portion of their practice, even if the number of procedures was in the thousands. Furthermore, I found that many of these doctors were advertising in the yellow pages as abortion facilities. I felt that in order to protect the health and safety of the mother as much as possible, and to meet the intent of the current law, this loophole needed to be closed.

(See Harris affidavit, Dkt. # 41, Exh. A, page 2). Harris thus filed a Senate bill which would have amended the abortion facility licensing stature to require all physicians performing more than 10 abortions a year to be licensed as abortion facilities.¹² The Senate Human Services Committee held a public hearing on February 24, 1999, in which the amendment was considered. At the hearing, Harris explained the bill as follows:

Members, last Session we brought, made it to where the Texas Department of Health could inspect abortion clinics. We did this for the safety of women who were getting abortions because we'd had a number of cases where women had died as a result of improper hygiene, improper services being rendered. . . There has been, in essence, a little bit of a loophole created and again, this is not to do away with abortions or any of that type thing. The sole purpose of this bill is to give the department of health the, the right to go in and inspect and make sure that health standards are met for the safety of the patients.

(See Senate Human Services Committee February 24, 1999 transcript, Dkt. # 41, attachment to Exh. A, page 18). Harris explained to the committee that he perceived a loophole in the abortion licensing statute while reviewing the abortion reporting statistics, which all abortion providers are required to provide regardless of whether they are a licensed facility. Harris told the committee that the statistics reflected that some of the physicians claiming an exemption from licensing had reported high numbers of abortions. (There were) unlicensed facilities where physicians are doing as

Harris avers that he filed "Senate Bill 494," which was considered in a Senate Human Services Committee public hearing on February 24, 1999. However, the transcript from that hearing, which is attached to the affidavit, identifies Harris's bill as "Senate Bill 468." Because the record contains no explanation of this discrepancy in the bill number, the Court will assume it to be a typographical error.

¹³ The actual statistics to which Harris was referring do not appear to be in the record of this case.

providers for regulations that do not apply to other providers of similar procedures." McLaughlin said. "In light of the violence and terrorist activities surrounding clinics which provide abortion[,] the registration of a physician's office as a site for abortion is a public intimidation tactic." McLaughlin testified that "abortion is a[s] safe or safer than other out-patient surgeries that go unregulated."

Peggy Romberg, executive director of the Texas Family Planning Association, spoke against the bill, stating that her primary problem was with the number 10. Harris asked: "What number would you recommend?" Romberg replied that "my bottom ceiling would be about 300, of OB/GYN that provides abortion services that would be essentially about one a working day." Harris asked: "If it was at that amount would you be, would the bill be acceptable to you?" Romberg replied: "It would be more, certainly more acceptable. I, I certainly would work with you." Harris asked again, "Would it be acceptable?" Romberg did not answer directly, but went on to outline her other concerns about the bill. "I don't have the argument with you with the 2,900 abortions. . . . But ... we don't want to drive the private doctor who's providing this care out of business. We don't want him on a list. . . . [T]here's a 1-800 number where anyone could call and say, is Dr. Smith licensed to perform abortion and the answer is yes, puts Dr. Smith on a list to get these sort of things on his windshield in his parking lot, to have his private home picketed, to have threats made against his life." Romberg pointed out that she had supported the statutory amendments passed in 1997. which required licensing for clinics and physicians primarily doing abortions. But she testified that private physicians' offices don't generally have the security measures in place as most clinics do,

The plaintiffs introduced Romberg's deposition, in which she testified that she did suggest the number 300 when pressed by Senator Harris, because the abortion rights community would rather the threshold be 300 than 10, and they didn't have enough votes to completely kill the amendment. She testified that there was no health, safety, or medical basis for the number 300; it was just a "political compromise."

and she urged the health department licensing bureau to look carefully at which of the regulatory requirements would be appropriate to apply to small physician's offices. "[T]hese [regulations] are judged for hospitals and major medical facilities and not for small private doctor's offices," Romberg said.

J. Jacobson, executive director of the American Civil Liberties Union of Texas, testified that "this bill I think is more frankly about getting information out to the more radical anti-choice groups as to which physicians are performing abortions than it is about regulating the health and welfare of the patient. I don't think that there's a particular medical cause of alarm for the physicians who are currently performing this in their office. This bill has a chilling effect on the right to obtain an abortion by reducing the number of physicians who would be agreeable to performing abortions."

Kirk Overbey, a volunteer for the Greater Austin Right to Life Association, attended the hearing and registered in support of the bill, but stated that he did not wish to present oral testimony. At the end of the hearing, the bill was left pending, at Senator Harris' request.

Senate Bill 468 was not passed into law, but similar language amending the abortion statute to regulate physicians who perform 300 abortions or more a year was added by Representative Van de Putte to House Bill 2085, a lengthy bill dealing with general health department matters. House Bill 2085 was adopted by the House on May 27, 1999, and by the Senate on May 29, 1999. The amendment to the abortion facility licensing law became effective on September 1, 1999, but previously exempt physicians are not required to be licensed until January 1, 2000. There is no official legislative history on House Bill 2085. The defendants offered Van de Putte's deposition testimony to explain her motivations in backing the amendments:

died from that procedure," she testified. "I want to make sure that, as a legislator entrusted with the Health and Safety Code of this state, that we make sure that the state does all possible to make sure that the abortion facilities . . . provide quality care."

Van de Putte testified that her experience as a practicing pharmacist for 20 years in San Antonio also influenced her in supporting the bill. As a pharmacist, she dispenses prescriptions to women who have just come from having an abortion done, and provides counseling to "make sure they adhere to the treatment regimen of antibiotics and pain medication that are frequently given right after the procedure." She has counseled both patients who have had abortions at clinics and patients who have had abortions at private physicians' offices. Over time she got an idea of several nearby physicians' schedules, because on the days abortions were scheduled, she would see three or four women in the pharmacy who have come straight from having the abortion. Over 20 years, Van de Putte testified, she has only had concern about one particular physician, "because the women that walked into the pharmacy really seemed traumatized by their experience. . . . In particular, one physician[.] I do not believe, by the level of information that I have to impart as a professional pharmacist in patient counseling, I don't believe that those patients get adequate educational information about the procedure and their post-care from the procedure. This is not the case with other physicians who perform the procedure." Van de Putte said she does not know if that particular physician who caused her concern was subject to licensing or was licensed by the health department.

Van de Putte also answers phone calls to the pharmacy by women with questions about potential post-procedure problems or complications. "We get more phone calls from patients from this one physician than we do any other physician, calling because they can't ... get an answer from the physician's office," she said. These phone calls led Van de Putte to suspect that "because

of the number of procedures done in that office setting, I don't know if that physician or their staff has had the adequate follow-up care to those patients."

V. Conclusions of Law

A. Standard for Preliminary Injunction

To obtain a preliminary injunction, the plaintiffs must prove the following elements:

(1) a substantial likelihood that the plaintiffs will prevail on the merits;

(2) a substantial threat that the plaintiffs will suffer irreparable injury if an injunction is not issued; (3) proof that the threatened injury to the plaintiffs outweighs any harm that might result to the defendants; and (4) a showing that granting the preliminary injunction will not disserve the public interest. See Hoover v. Morales, 164 F.3d 221, 224 (5th Cir. 1998); Sunbeam Prods., Inc. v. West Bend Co., 123 F.3d 246, 251 (5th Cir. 1997), cert. denied, 118 S. Ct. 1795 (1998).

The Court will first examine the applicable law to determine if the plaintiffs have shown a substantial likelihood of success on the merits.

B. Due Process Claim

1. The Casey Decision and the Undue Burden Standard

The Supreme Court of the United States has determined that a woman's decision to terminate a pregnancy is entitled to constitutional protection. See Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833, 846 (1992); Roe v. Wade, 410 U.S. 113, 164 (1973). The protection "derives from the Due Process Clause of the Fourteenth Amendment," which declares that "no State shall 'deprive any person of life, liberty, or property, without due process of law." Casey, 505 U.S. at 846. Thus, Roe and Casey recognized "a realm of personal liberty which the government may not enter." Id. at 847. "It is settled now . . . that the Constitution places limits

on a State's right to interfere with a person's most basic decisions about family and parenthood, as well as bodily integrity." *Id.* at 849. But although the right recognized by *Roe* and *Casey* is a right "to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child," it must be noted that "[n]ot all governmental regulation is of necessity unwarranted." *Casey*, 505 U.S. at 875. The *Casey* decision set out the "undue burden" standard as "the appropriate means of reconciling the State's interest with the woman's constitutionally protected liberty." *Id.* at 876.

A finding of an undue burden is a shorthand for the conclusion that a state regulation has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus. A statute with this purpose is invalid because the means chosen by the State to further the interest in potential life must be calculated to inform the woman's free choice, not hinder it. And a statute which, while furthering the interest in potential life or some other valid state interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends.

Casey, 505 U.S. at 877. Similarly, Casey held that regulations "designed to foster the health of a woman seeking an abortion" are valid if they do not constitute an "undue burden." Id. at 878. "As with any medical procedure, the State may enact regulations to further the health or safety of a woman seeking an abortion. Unnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on that right." Id.

The Casey undue burden analysis was set out in a joint opinion by Justices O'Connor, Kennedy and Souter, which upheld several provisions of a Pennsylvania abortion regulation statute as not constituting an undue burden, but struck down another section that they found did constitute an undue burden. Justice Stevens wrote a separate concurring/dissenting opinion, in which he explains that the proper application of the undue burden test, in his view, would have resulted in the

Court overturning the entire challenged Pennsylvania statute rather than only a part of it. See Casey, 505 U.S. at 911-22. Justice Blackmun also wrote a separate concurring/dissenting opinion, in which he argues that the undue burden standard is not rigorous enough to protect the woman's constitutional rights. See id. at 922-43. Blackmun would retain Roe's strict scrutiny test, because "no other is more protective of the woman's fundamental right." Id. at 934. Under the strict scrutiny standards, regulations on abortion "can be upheld if they have no significant impact on the woman's exercise of her right and are justified by important state health objectives." Id. at 929 n. 5.

2. The "Large Fraction" Standard for Facial Challenges

In a section of the O'Connor-Kennedy-Souter joint opinion that was joined by Stevens and Blackmun, the Court held that the spousal notification provision of the Pennsylvania statute was "invalid on its face" because "in a large fraction of the cases in which [the provision] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion. It is an undue burden, and is therefore invalid." *Id.* at 895. In explaining why the provision was facially unconstitutional, the five justices held that "Legislation is measured for consistency with the Constitution by its impact on those whose conduct it affects. . . . The proper focus of a constitutional inquiry is the group for which the law is a restriction, not the group for whom the law is irrelevant." *Id.* at 894. The five justices rejected the respondents' argument that because "the statute affects fewer than one percent of women who obtain abortions, . . . the statute cannot be invalid on its face." *Id.* "The analysis does not end with the one percent of women upon whom the statute operates,"

¹⁵ The evidence before the court showed that the spousal notification provision "imposes almost no burden at all for the vast majority of women seeking abortions." *Id.* at 894. Only about 20 percent of the women who obtain abortions are married. Of that 20 percent, about 95 percent notify their husbands of their own volition. Therefore, "the effects of [the provision] are felt by only one percent of the women who obtain abortions. *Id.* Of that one percent who do not want to notify their husbands, some may be able to do so without adverse consequences or may qualify for one of the exceptions; therefore the provision will operate

the five justices stated, instead, "it begins there." *Id.* "The women most affected by this law -- those who most reasonably fear the consequences of notifying their husbands that they are pregnant -- are in the gravest danger." *Id.* at 897. Thus the "large fraction" language was applied by five justices to facially invalidate the Pennsylvania spousal notification provision.

Chief Justice Rehnquist, joined by Justices White, Scalia, and Thomas, wrote a concurring/dissenting opinion stating that "[w]e believe that *Roe* was wrongly decided, and that it can and should be overruled." *Id.* at 944-79. Rehnquist, White, Scalia and Thomas would hold that "States may regulate abortion procedures in ways rationally related to a legitimate state interest." *Id.* at 966.

3. The Salerno "No Circumstances" Test for Facial Challenges

Chief Justice Rehnquist, dissenting from the *Casey* joint opinion's conclusion that the spousal notification provision was facially invalid, recognized that the joint opinion had applied a "large fraction" test for facial challenges to abortion laws that differed from the general "no circumstances" test set out in *United States v. Salerno*, 481 U.S. 739, 745 (1987). Rehnquist thus dissented from the use of the "large fraction" test:

Furthermore, because this is a facial challenge to the Act, it is insufficient for petitioners to show that the notification provision "might operate unconstitutionally under some conceivable set of circumstances." [citing Salerno]. Thus, it is not enough for petitioners to show that, in some "worst case" circumstances, the notice provision will operate as a grant of veto power to husbands. Because they are making a facial challenge to the provision, they must "show that no set of circumstances exists under which the [provision] would be valid." [citing Salerno]. This they have failed to do.

Casey, 505 U.S. at 972-73 & n.2 (Rehnquist, J., dissenting, joined by White, Scalia and Thomas).

Several months after the Casey decision was released, two different panels of the

unconstitutionally for "fewer than one percent of women seeking abortions." Id.

Fifth Circuit issued seemingly contradictory decisions in facial challenges to abortion statutes. On August 17, 1992, a panel of the Fifth Circuit rejected a facial challenge of a Mississippi informed consent statute because — in light of Casev's holding that substantially identical provisions of the Pennsylvania Act were facially constitutional — the plaintiffs did not meet the Salerno "no circumstances" test. See Barnes v. Moore, 970 F.2d 12, 14 (5th Cir.), cert. denied, 506 U.S. 1021 (1992). "The Casey joint opinion may have applied a somewhat different standard in striking down the spousal notification provision of the Pennsylvania Act, not in issue here," Barnes, 970 F.2d at 14 (citing 112 S. Ct. at 2829, which contains the "large fraction" language). "Nevertheless," the Barnes panel wrote, "we do not interpret Casev as having overruled, sub silentio, longstanding Supreme Court precedent governing challenges to the facial constitutionality of statutes," Id at 14 n.2. However, even though it rejected Casev's "large fraction" language as inconsistent with Salerno, the Barnes panel stated that it was applying the Casey undue burden standard.

[I]n clarifying what they meant by an "undue burden," the authors of the [Casey] joint opinion stated that they were "set[ting] forth a standard of general application." Applying that standard, we conclude that the differences between the Mississippi and Pennsylvania Acts are not sufficient to render the former unconstitutional on its face.

Id. at 15 (citation omitted) In September 1992, about a month after the release of the Barnes opinion, another Fifth Circuit panel found that a Louisiana abortion statute was facially unconstitutional under Casey, even though the statute allowed abortions to save the life of the mother and therefore arguably passed muster under Salerno. See Sojourner Tv. Edwards, 974 F.2d 27, 31 (5th Cir. 1992). Sojourner T also recited and applied the undue burden standard.

¹⁶ See also Okpalobi v. Foster. 190 F.3d 337, 354 (5th Cir. 1999) (characterizing Sojourner T as an application of the Casey test for facial challenges rather than the Salerno test).

Individual Supreme Court justices subsequently expressed their views on what impact Casey had on the Salerno standard. In November 1993, the Supreme Court denied certiorari in Ada v. Guam Society of Obstetricians and Gynecologists, 506 U.S. 1011 (1992), in which the Ninth Circuit had struck down as facially unconstitutional a Guam statute outlawing all abortions except in cases of medical emergency. Justice Scalia, joined by Chief Justice Rehnquist and Justice White, dissented from the denial of certiorari, arguing that the law was not facially unconstitutional under Salerno because a set of circumstances existed under which it would be valid; namely, for abortions conducted after viability. Id. at 634. Scalia's dissent contended that "[t]he Court did not purport to change [Salerno's] well-established rule last Term in [Casey]."

In an April 1993 denial of application for stay of a pending appeal of a decision rejecting a facial challenge to a North Dakota abortion regulation, Justice O'Connor, joined by Justice Souter in a concurring opinion, expressed her disagreement with the Eighth Circuit's conclusions that "the Salerno standard applied" to facial challenges of abortion laws and that Casey "did not counsel a different result." See Fargo Women's Health Organization v. Schafer, 507 U.S. 1013 (1993) (discussing the Eighth Circuit's ruling in Fargo v. Schafer, 1993 WL 603600 (8th Cir. March 30, 1993)). "In my view," O'Connor wrote, "the approach taken by the lower courts is inconsistent with Casey. In striking down Pennsylvania's spousal-notice provision, we did not require petitioners to show that the provision would be invalid in all circumstances. Rather, we made clear that a law restricting abortions constitutes an undue burden, and hence is invalid, if, 'in a large fraction of the cases in which [the law] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." Id.

A month after O'Connor's statement, the Fifth Circuit rejected a facial challenge to a Mississippi parental consent statute, citing the "no circumstances" test previously followed in Barnes, 970 F.2d at 14. See Barnes v. State of Mississippi. 992 F.2d 1335, 1342–43 (5th Cir.), cert. denied, 510 U.S. 976 (1993). The court again, however, recited and applied the "undue burden" standard, holding that "[a]s long as Casey remains authoritative, the constitutionality of an abortion regulation thus turns on an examination of the importance of the state's interest in the regulation and the severity of the burden that regulation imposes on the woman's right to seek an abortion." Barnes, 992 F.2d at 1338.

In 1994, the Casey case itself, having been remanded to the Third Circuit for a hearing on severability, came back before Justice Souter -- in his capacity as Circuit Justice -- on an application for stay. See Planned Parenthood of Southeastern Pennsylvania v. Casey, 510 U.S. 1309, 1310-11 (1994). In his opinion denying the stay, Souter stated his approval of the Third Circuit's application of the "large fraction" test to the facial challenge, noting that "For the purposes of this opinion, I join the applicants and the court below in treating the joint opinion in Casey, [505 U.S. at 843], as controlling, as the statement of the Members of the Court who concurred in the judgment on the narrowest grounds." Id. at 1311 n.2.

In 1996, the Supreme Court denied certiorari in an Eighth Circuit case which invalidated a South Dakota parental notification statute. See Janklow v. Planned Parenthood, Sioux Falls Clinic, 517 U.S. 1174 (1996). The Eighth Circuit had applied the Casey "large fraction" test

¹⁷ The 1993 Barnes case involved a challenge by the same plaintiffs as the 1992 Barnes case, including Dr. Helen Barnes, to a different Mississippi statute. A dissent by Judge Johnson in the 1993 case asserted that "[i]n a case like this, the majority's application of the 'no-circumstances principle' is just plain wrong." Citing Casey, 112 S. Ct. at 2829, Judge Johnson argued that the "proper focus of constitutional inquiry is the group for whom the law is a restriction, not the group for whom the law is irrelevant." See Barnes, 992 F.2d at 1347 n.10 (Johnson, J., dissenting).

in finding that the statute was facially unconstitutional. See Planned Parenthood v. Miller, 63 F.3d 1452, 1463 (8th Cir. 1995). 18 Justice Stevens agreed with the denial of certiorari, noting that "Salerno's rigid and unwise dictum has been properly ignored" in Casey and in other cases "even outside the abortion context." Janklow, 517 U.S. at 1175-76 & n.1 (noting Casey's holding finding an abortion regulation "facially invalid as 'substantial obstacle' to exercise of right in 'large fraction' of cases"). Justice Scalia, joined by Chief Justice Rehnquist and Justice Thomas, dissented from the denial of certiorari, arguing that the Miller case's application of the "large fraction" standard "virtually cries out for our review" because "we have sent mixed signals on the question" of what standard should apply in facial challenges to abortion statutes. Janklow, 517 U.S. at 1585.

In April 1997, the Fifth Circuit discussed the issue in Causeway Medical Suite v. Ieyoub, 109 F.3d 1096, 1102-04 (5th Cir.), cert. denied, 118 S. Ct. 357 (1997), noting that the Supreme Court in Casey "appeared to temper the Salerno standard by suggesting that an abortion law is facially invalid if 'in a large fraction of the cases in which [the law] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." Id. at 1102 (quoting Casey, 505 U.S. at 895). However, the Fifth Circuit panel in Ieyoub considered itself bound by the holding of Barnes, 970 F.2d at 14 n.2, that Casey did not overrule Salerno. In addition, the Ieyoub opinion noted that "[a]s far as we can tell, the [Supreme] Court appears to be divided 3-3 on the Salerno-Casey debate, and it would be ill-advised for us to assume that the Court will abandon Salerno because three members of the Court now desire that result. We decline to speculate about the outcome of this disagreement among the Justices of the Supreme Court." Ieyoub. 109 F 3d at 1103-04 & n.5. "We also respectfully decline, for the reasons stated above, Justice Stevens invitation [in

¹⁸ In Miller, the Eighth Circuit departed from its previous determination that Salerno should apply. See Fargo v. Schafer, 1993 WL 603600 (8th Cir. March 30, 1993).

Janklow, 517 U.S. at 1176 n.2] to reconsider the wisdom of our decision in Barnes." The leyoub case went on to hold, however, that "whether viewed under Casey or Salerno. [the challenged Louisiana parental notification statute] is unconstitutional on its face." Id. at 1104.19

On June 16, 1997, the Supreme Court, in a per curiam opinion, applied the Casey undue burden standard in analyzing the lower court's denial of a preliminary injunction to enjoin the enforcement of a Montana statute restricting performance of abortions to licensed physicians. See Mazurek v. Armstrong, 520 U.S. 968, 976 (1997). The Court concluded that the respondents were not entitled to a preliminary injunction because they had not shown that either the purpose or the effect of the statute was to create a substantial obstacle to a woman seeking an abortion. Id. at 973-74. The Court did not discuss the Casey-Salerno issue regarding the proper standard for facial challenges. Justices Stevens, joined by Justices Ginsburg and Breyer, dissented, contending that the Court should have denied certiorari because of the procedural posture of the case.²⁰

In March 1999, Judge Porteus in the Eastern District of Louisiana struck down Louisiana's "partial birth abortion" statute as facially unconstitutional, noting that "[t]his Court

¹⁹ The Fifth Circuit, after a poll of the judges, denied rehearing en banc. See Causeway Medical Suite v. Ieyoub, 123 F.3d 849 (5th Cir. 1997).

Ten days after the issuance of the Mazurek decision, the Supreme Court issued the decision in Washington v. Glucksberg, 521 U.S. 702 (1997) (holding that asserted right to assistance in committing suicide was not a fundamental liberty interest protected by the due process clause). The Court, in an opinion written by Chief Justice Rehnquist and joined by Justices O'Connor, Scalia, Kennedy and Thomas, noted in a footnote that "[t]he District Court determined that Casey's "undue burden" standard, not the standard from United States v. Salerno, governed the plaintiff's facial challenge to the assisted-suicide ban. Washington, 521 U.S. at 708 n.5 (citations omitted). However, the Court did not further discuss the Casev-Salerno issue because the facial challenge was not a part of the case by the time it reached the high court. The only issue before the Court was the Ninth Circuit's "as-applied" holding, 1d. at 709 n.6, and the Court went on to decide that only a "rational basis" test should apply because the right at issue was not a fundamental liberty interest protected by the Due Process Clause. See Glucksberg, 521 U.S. at 728.

acknowledges that the Salerno standard is inconsistent with the rule set forth in Casey, however, the Fifth Circuit has not abandoned the Salerno standard and this court is compelled to follow such precedent." Causeway Medical Suite v. Foster, 43 F. Supp.2d 604, 611-12 (E.D. La. 1999). Judge Porteus went on to apply the undue burden standard and find the statute facially unconstitutional under Salerno. Id. at 612.

In a First Amendment case issued in June 1999, Justice Scalia characterized the Casey "large fraction" test for facial challenges to abortion laws as a Court-created exception to the general Salerno rule, an exception with which he heartily disagreed. City of Chicago v. Morales, 118 S. Ct. 1849, 1871 (1999):

I am aware, of course, that in some recent facial-challenge cases the Court has, without any explanation, created entirely irrational exceptions to the "unconstitutional in every conceivable application" rule, when the statutes at issue concerned hot-button social issues on which "informed opinion" was zealously united. See Romer v. Evans, 517 U.S. 620, 643, 116 S. Ct. 1620, 134 L.Ed.2d 855 (1996) (SCALIA, J., dissenting) (homosexual rights); Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833, 895, 112 S. Ct. 2791, 120 L.Ed.2d 674 (1992) (abortion rights).

Morales, 119 S. Ct. at 1871 (Scalia, J., dissenting). The Casey pinpoint citation, 505 U.S. at 895, which Scalia provides as an example of an exception to the Salerno rule, contains the Casey joint opinion's language (joined by five justices) which applies the "large fraction" test to the Pennsylvania spousal notification provision.

In September 1999, the Fifth Circuit issued Okpalobi v. Foster, 190 F.3d 337 (5th Cir. 1999), which struck down as facially unconstitutional a Louisiana statute which made abortion providers liable in tort for damages to the woman, and, arguably, for damages to the unborn fetus. The opinion in Okpalobi notes the "tension" between Casev and Salerno regarding "the proper standard of proof when a plaintiff asserts a facial challenge to a statute imposing restrictions on

abortion." *Id.* at 353. Additionally, *Okpalobi* acknowledged that "the Fifth Circuit jurisprudence on this question is not a model of clarity." *Id.* at 354 (citing *Barnes*, 970 F.2d at 14, and *Sojourner T*, 974 F.2d at 27). However, the court "decline[d] to address any internal inconsistency in this area of Fifth Circuit jurisprudence because, regardless of whether [the statute at issue] is tested under *Salerno* or under *Casey*, the Act is unconstitutional on its face." *Id*.

4. Application of Standards

This Court is now called upon to determine the proper standard to apply to this facial challenge to an abortion regulation. It appears that five justices, a majority of the Supreme Court, approved language in *Casey* holding that a law restricting abortions constitutes an undue burden, and hence is facially invalid, if, "in a large fraction of the cases in which [the law] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." *Casey*, 505 U.S. at 895. However, the Fifth Circuit points out that the *Salerno* standard for facial challenges was not explicitly overruled in *Casey*. *See Okpalobi*, 190 F.3d at 354; *Ieyoub*, 109 F.3d at 1103-04. In the last two cases to face the issue, the Fifth Circuit applied both standards and thus avoided having to definitively choose one standard or the other. *See Okpalobi*, 190 F.3d at 354; *Ieyoub*, 109 F.3d at 1103-04. Therefore, this Court will also undertake to analyze the instant case under both standards for facial challenges, noting that the "undue burden" standard will be applied in either instance.

After Okpalobi discussed the facial challenge issue, it then proceeded to examine the case under the Casey undue burden framework, holding that "under Casey and Sojourner T, we are directed to examine (1) the purpose and (2) the effect of [the challenged provision]. As the Sojourner T / Casey burden is disjunctive, a determination that either the purpose or the effect of the Act creates such an obstacle is fatal." Okpalobi, 190 F.3d at 354. The Court found that "the State's

proffered legislative purpose simply is not credible," and additionally that the statute would have the effect of unconstitutionally chilling physicians' willingness to provide abortions. *Id.* at 357. "A measure that has the effect of forcing all or a substantial portion of a state's abortion providers to stop offering such procedures creates a substantial obstacle to a woman's right to have a previability abortion, thus constituting an undue burden under *Casey*." *Id*.²¹

a. The Purpose of the Statute

In determining whether a statute has an impermissible purpose, the Fifth Circuit "has looked to various types of evidence, including the language of the challenged act, its legislative history, the social and historical context of the legislation, or other legislation concerning the same subject matter as the challenged measure." *Okpalobi*, 190 F.3d at 354. Regarding post-enactment testimony from individual legislators, the Fifth Circuit has not held that such evidence is inadmissible, but has held that post-enactment statements should be looked upon with caution and should not be relied exclusively or allowed to contradict the official legislative record. *See Foreman v. Dallas County*, 193 F.3d 314, 322 (5th Cir. 1999) ("No one legislator, or even a group of three legislators, has sufficient personal knowledge to declare the overall intent of the Texas legislature); *see also Quarles v. St. Clair*, 711 F.2d 691, 705 (5th Cir. 1983) (holding that "it is well accepted that even explicit post-enactment, retrospective, statements of intent are to be looked on with caution"). Accordingly, in determining whether the 1999 amendments were enacted with the purpose of placing a substantial obstacle in the path of a woman seeking an abortion, *Okpalobi*, 190 F.3d at 354,

Alternatively, the Court found that the Louisiana statute was unconstitutionally vague and facially invalid regardless of the *Casey-Salerno* issue "A vague law that chills the exercise of a constitutional right will succumb to a facial challenge "even when [the law] could have had some legitimate application. . . . Thus, the standard-of-proof question, see [Salerno], is not a factor in deciding the State's challenge to the district court ruling on vagueness." Okpalobi, 190 F.3d at 358.

this Court will rely primarily on the official legislative history in the record — the transcript of the February 24, 1999 Senate Human Services Committee meeting in which the amendments were introduced as a senate bill, and the materials documenting the 1997-98 ad hoc committee process to promulgate the regulations that the 1999 amendments will apply to the plaintiffs. Fifth Circuit precedent requires that Harris's and Van de Putte's testimony be given lesser weight than the official legislative history, but the Court notes that the challenged testimony in many respects merely confirms the official legislative history.

Even if the Court looks solely at the official legislative history, it cannot be concluded that the challenged 1999 amendments were passed for an improper purpose. Senator Harris, who first introduced the provision, emphasized that "this is not to do away with abortions" and explained his concerns that some physicians were evading the intent of the licensing statute by stating that their offices were not "used primarily for the purpose of performing abortions," when the reported statistics showed that they were performing 1,800 to 2,900 abortions a year. In addition, although the promulgation of the regulations themselves in 1997 and 1998 is not being directly challenged in this lawsuit, it is significant to note that the legislative history there shows that a diverse committee of medical experts and both abortion rights advocates and anti-abortion activists was assembled to draft a set of regulations that would improve the safety of women without decreasing access. The health care professionals who participated in the 1997-98 committee process were genuinely concerned about improper sterilization techniques and other problems in abortion clinics that had resulted in severe infections and even two deaths of women after abortions.

This Court, in a separate order signed today, denies the plaintiffs' motion to strike Harris's and Van de Putte's testimony, for the reasons stated therein.

Accordingly, the regulations effective in 1998 were "reasonably directed to the preservation of maternal health." Casey, 505 U.S. at 900. The 1999 amendment was intended to apply these carefully drafted regulations to physicians' offices providing a large number of abortions. Senator Harris was concerned about the possibility of improper sterilization that had the potential to cause injury and death in unregulated physicians' offices that were, for all practical purposes, operating like abortion clinics. Harris referred repeatedly to his goal to protect the "safety of women who were getting abortions because we'd had a number of cases where women had died as a result of improper hygiene, improper services being rendered." Although the number 300 is not tied to any particular medical evidence of increasing risk -- and the evidence contains no evidence of any infection or other problems with the specific 12 physicians affected by the 1999 amendments -- it appears that the intent was to come up with a specific cutoff number to provide a bright line for the enforcement of the licensing requirement. In addition, the number 300 appears to have been chosen at least in part after input from abortion rights advocates. There is no evidence of any intent or purpose to place obstacles in the path of women seeking abortions. On the contrary, the application of the already existing (and unchallenged) regulations to physicians' offices providing a large number of abortions appears to have been "designed to foster the health of a woman seeking an abortion." See Casey, 505 U.S. at 878.23 Accordingly, the Court concludes that the challenged legislation was not passed with an improper purpose.

The deposition testimony of Senator Van de Putte merely confirms the conclusions the Court has drawn from the official legislative history. Van de Putte testified that she discussed the number 300 with prochoice advocates and that she "felt very comfortable" with the number 300, which estimated to be approximately one abortion per working day. Van de Putte stated that she is "adamantly pro-choice," and that the amendment was "absolutely" not intended to limit access to abortion, but to ensure that physicians performing large numbers of abortions are regulated to the same extent as clinics, and to ensure that the women seeking abortions get high quality care.

b. The Effect of the Statute

The plaintiffs claim that the 1999 amendments will have the effect of placing a substantial obstacle in the path of women seeking abortions because the increased cost of compliance with the regulations will cause them to raise their prices for abortions, or in two cases, to stop providing abortions in their offices. Casey teaches that "at some point increased cost could become a substantial obstacle." Casey, 505 U.S. at 901. But Casey also indicates that a claim of. increased cost must be supported by a "showing on the record." Id. In this case, although the physicians cite increased costs, they have not provided any specific credible estimates on exactly how much those costs might be. Dr. Davis estimated that it would be necessary to raise his abortion fees by \$25 to \$50 per procedure, plus \$50,000 to \$60,000 in start-up costs to hire a consultant and close his office down for a week to train his employees. However, Davis admitted that his consultant did not review all of the regulations, but only heard him read part of the regulations over the phone. He testified that the consultant would cost \$1,000 a day, but he did not attempt to locate a less expensive consultant, and he has not taken the time to compare the various written manuals he currently uses in his office to see if he is already in compliance with some of the regulations required written policies. Davis estimated that drafting the required policies would take three weeks, but Julie Long, the RN who spent many years performing health department surveys of licensed abortion facilities, estimated that it would take one person working full time "a few days" to draft the required polices. The actual number of staff hours required to draft the policies will undoubtedly vary depending upon the size of the office and the written materials that are already on hand, but the Court finds Long's testimony to be credible due to her experience reviewing written policies at abortion facilities.

Dr. Robinson estimates that becoming licensed will cause him to incur costs up to \$100 per patient, but his testimony does not appear to support this figure. He will not have to add any staff, and he currently has many written policies already on hand. Dr. Kaminsky has not asked his staff to review the regulations, and he only reviewed them himself for about 45 minutes. Kaminsky admitted that he has not done a general cost estimate on how much it would cost him to comply with the regulations, and he testified that his abortion fees will likely have to be increased, but he did not estimate the amount of the increase. Dr. Smith also predicted increased costs, but admitted that she has not calculated exactly what the costs would be.

Dr. Hansen estimates that he will have to hire two staff members, an RN and a "regulation compliance officer," which will increase his costs about \$60,000 a year, or about \$60 per patient. But he testified that he would not necessarily raise his abortion fees. The Court finds that this \$60,000 estimate is somewhat high, because the evidence does not show that the regulations would require an additional full time employee solely devoted to compliance. Long testified that during the year-long period that the 1998 regulations have been in effect, no abortion facility staff members have complained to her that the regulations were unduly burdensome or were hard to understand. Long said the health department's relationship with abortion facilities is a cooperative one, in which both sides are trying to improve procedures for patients, and where the health department is available to explain or clarify the regulations. Therefore, although it undoubtedly will take some staff time to ensure compliance, the evidence before the Court does not establish that a permanent "regulation compliance officer" is necessary. The regulations would require Hansen to hire either an LVN or RN, but his estimate included the higher salary of an RN, when an LVN would satisfy the regulations.

Moreover, a court-considering an abortion regulation does not look at the regulation's burdens in isolation. The Fifth Circuit has held that "the constitutionality of an abortion regulation [under Casey] turns on an examination of the importance of the state's interest in the regulation and the severity of the burden that regulation imposes on the woman's right to seek abortion." Barnes v. Mississippi, 992 F.2d 1335, 1339 (5th Cir.), cert. denied, 510 U.S. 976 (1993). Under this balancing approach, the Court concludes that the benefits sought by the state in enacting the 1999 amendments justify the increased costs that might be incurred by the physicians. Texas already regulates abortion clinics and physicians' whose office are used primarily for abortion, and the state's evidence indicates that physicians' offices where large numbers of abortions are provided begin to resemble abortion clinics and should be subjected to the same regulations as abortion clinics. Davis has 15 employees, including another physician who also performs abortions. Kaminsky also has another physician helping him perform abortions, and 11 other staff members. Robinson has two other physicians helping him, and has 14 employees. Kaminsky's office provides about 1,500 abortions a year, and Robinson's office provides 2,211 abortions a year. The evidence indicates that these three offices, particularly, are large enough operations to benefit from, regulations appropriate for abortion clinics, and are large enough to potentially expose their patients to risks comparable to those risks associated with the high volume of abortions performed at abortion clinics. Dr. Hansen admitted that the abortion facility regulations have improved the health conditions for women in abortion clinics, and acknowledged that if a private physician is performing 2,000 abortions a year, then regulations requiring a more formal office administration could be of benefit. Dr. Lawson, who helped draft the 1999 regulations for the health department, testified that as more procedures are performed and more tasks are delegated to the physician's staff, the more

the office can benefit from a set of formal requirements and procedures. Long, the RN who performed surveys of abortion facilities for many years, testified that she observed many problems with sterilization in abortion facilities, especially before the regulations provided explicit directions on sterilization and required written sterilization and infection control policies. The Court concludes that the 1999 amendments will provide a benefit to Texas women seeking abortions by ensuring that proper sterilization procedures are in place at physicians' offices where 300-plus abortions are performed, just as the current regulations ensure the safety of women at abortion clinics. In addition, the health department's enforcement of the law will be aided by the establishment of a bright line cutoff of 300 for the number of procedures that will subject a physician to regulation. On the current record, the Court finds that the undetermined fee increases that the physicians predict, weighed against these enforcement and health benefits, do not constitute an undue burden on women seeking abortions. "Numerous forms of state regulation might have the incidental effect of increasing the cost or decreasing the availability of medical care, whether for abortion or any other medical procedure. The fact that a law which serves a valid purpose, not designed to strike at the right itself, has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it." Casey, 505 U.S. at 874.

The regulatory "fit" is less appropriate for the offices of Hansen and Smith, who have only four employees each, and whose practices do not resemble clinics to the same extent as the other plaintiffs' practices. Compliance with the regulations would undoubtedly impose costs on Smith and Hansen, although neither physician has estimated those costs precisely. Significantly, however, Hansen testified that even if he stops providing abortions in his private practice, he will continue providing abortions in Austin at the licensed abortion facility where he is medical director.

Similarly, even if Smith closes her practice in Denton, she will continue providing abortions in a Dallas clinic which is 45 to 90 minutes away from her office. Therefore, although Hansen and Smith are understandably upset at the possibility of having to stop providing abortions in a private office setting, it is important to note that even if the unknown increased costs will require them to close, their office abortion practices, their patients will not be left without a local abortion provider.

It should also be noted that the Court has before it a facial challenge to the 1999 amendments, not an "as-applied" challenge by Hansen or Smith. Under the Casey standard for facial standards, an abortion law is facially invalid if "in a large fraction of the cases in which [the law] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." Casey, 505 U.S. at 895. Although the increased costs of this regulation might force these two apparently very capable physicians to stop providing abortions in their offices,24 it must be noted that Smith and Hansen are only two abortion providers out of the 12 providers affected by the 1999 amendments, and only two out of the more than 50 providers in Texas. Additionally, both physicians will continue providing abortions in a clinic setting. Therefore, whether or not 1/6 could be considered a "large fraction," the Court concludes that Smith's and Hansen's decisions not to become licensed will not operate as a substantial obstacle to a woman's choice to undergo an abortion in Texas, or even in Denton or Austin. See Casey, 505 U.S. at 895. In contrast, the statute, overturned by the Fifth Circuit in Okpalobi would have had "the effect of forcing all or a substantial, portion of [Louisiana's] abortion providers to stop offering such procedures: "Okpalobi, 190 F.3d at 357. In that case, the Fifth Circuit found that "[t]he evidence shows that the Plaintiffs, who

The Court has insufficient evidence regarding specific anticipated costs before it to make a factual finding that Smith and Hansen would have no option but to close their practices. It does appear that both Smith and Hansen believe that they will have to close their practices.

currently provide approximately 80 % of all abortions in the state, will be forced to discontinue their abortion practice if Act 825 goes into effect." *Id.* There is no evidence in this record, however, that the 1999 amendments being challenged in this case would have anything near so drastic an effect.

The plaintiffs cite *Greenville Women's Clinic v. Bryant*, 66 F. Supp.2d 691 (D.S.C. 1999), in which a South Carolina district court struck down abortion facility regulations because, *inter alia*, they imposed excessive costs on physicians that would cause abortion fees to increase. The Court points out, however, that the plaintiff physicians in *Greenville* provided the court with very detailed and specific cost estimates, and the court specifically found that "the increased cost of providing abortions resulting from this regulation will prevent a significant number of women from obtaining an abortion or, at a minimum, delay them from obtaining the abortion." *See Greenville*, 66 F. Supp.2d at 716-718. In contrast, the record in this case does not show that the regulation will prevent a significant number of women from obtaining abortions. Accordingly, the

²⁵ Greenville also involved regulations which were significantly more onerous than the regulations: involved in this lawsuit; and which were imposed upon private physicians performing more than 60 abortions per year. See Greenville, 66 F. Supp.2d at 694-95. The South Carolina regulations mandated that all abortion patients receive specific medical tests that were not medically necessary, failed to provide for confidentiality of patient records, conferred broad discretion upon health department officials to impose additional case-bycase requirements to ensure the "best practices as interpreted by the department," and set out numerous "overwhelmingly" detailed requirements for the design and construction of abortion facilities that would have immediately required physical plant renovations costing up to \$27,000. In addition, evidence concerning the drafting of the South Carolina regulations indicated that the drafters did not seek -- and in fact affirmatively rejected -- the assistance of medical experts experienced in abortion practice to determine if the regulations were appropriate for a first-trimester abortion procedure. Finally, in Greenville, the record before the court. contained no evidence that any abortion providers were providing inadequate care to women, and the record. contained clear evidence that the regulations were not promulgated in response to any perceived public health problem in South Carolina. All of the witnesses in Greenville testified that they were unaware of any case where a woman suffered serious medical complications after an abortion in South Carolina. The court found that "[t]here is no evidence in this case that a first trimester suction curettage abortion has ever resulted in a woman's death in this state." See Greenville, 66 F. Supp.2d at 704. Accordingly, this Court finds Greenville's finding of an undue burden to be distinguishable from the case at bar.

Court concludes that the 1999 amendments are not facially unconstitutional as a violation of plaintiffs' patients' due process rights under the Casey "large fraction" test.

Applying the Salerno standard to this facial challenge would produce the same result. Salerno provides that "[a] facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid." Salerno, 481 U.S. at 745. In this case, the Court must conclude that circumstances exist under which this statute would not constitute an undue burden to women seeking an abortion. The evidence shows that the practices of Drs. Davis, Kaminsky and Robinson, with more than a dozen employees each and several physicians providing abortions, are large enough to potentially pose risks to patients comparable to risks encountered in abortion clinics, and are large enough both to benefit from a more formal administration and to absorb the costs of compliance with the regulation. The evidence in this record shows that the 1999 amendments, at most, would eliminate the office practices (but not the clinic practices) of only two out of the more than 50 abortion providers in Texas, and would, at most, cause abortion fees to increase an undetermined amount at the offices of three physicians out of the more than 50 abortion providers in Texas. The Court thus concludes on the evidence before it that the challenged amendments would not operate to create an undue burden in all circumstances and are therefore not facially unconstitutional under Salerno.

Because the Court has concluded on the current record that the challenged amendments do not have the purpose or effect of creating an undue burden on Texas women's right to seek an abortion, and are not facially unconstitutional under either Salerno or Casev, the Court

concludes that the plaintiffs (on behalf of their patients) have not shown a substantial likelihood of success on their Fourteenth Amendment due process claim.

C. Equal Protection Claim

The Equal Protection Clause commands that no state shall "deny to any person within its jurisdiction the equal protection of the laws." This provision creates no substantive rights. See Vacco v. Quill, 521 U.S. 793, 799 (1997). "Instead, it embodies a general rule that States must treat, like cases alike but may treat unlike cases accordingly." Id. However, courts must deal with "the practical necessity that most legislation classifies for one purpose or another, with resulting disadvantage to various groups or persons." Romer v. Evans, 517 U.S. 620, 631 (1996). The Supreme Court has "attempted to reconcile the principle with the reality by stating that, if a law neither burdens a fundamental right nor targets a suspect class, we will uphold the legislative classification so long as it bears a rational relation to some legitimate end." Id.

Classifications that involve a fundamental right require strict judicial scrutiny. See, e.g., Rublee v. Fleming, 160 F.3d 213, 217 (5th Cir.1998) (citing City of Cleburne, Tex. v. Cleburne Living Ctr., 473 U.S. 432 (1985)). Under strict scrutiny review, the classification must be narrowly tailored to serve a compelling state interest. Other classifications have been subjected to "intermediate" review. See, e.g., United States v. Virginia, 518 U.S. 515, 531 (1996) (classification based on sex); Clark v. Jeter, 486 U.S. 456, 461 (1988) (classification based on illegitimacy). Under intermediate scrutiny, the court examines whether the challenged classification is directly and substantially related to a legitimate and important governmental interest. See Mississippi Univ. for Women v. Hogan, 458 U.S. 718, 725 (1982).

The "rational basis" standard, although significantly less rigorous than the "strict scrutiny" standard, is not without teeth: "[E]ven in the ordinary equal protection case calling for the most deferential of standards, we insist on knowing the relation between the classification adopted and the object to be attained." Romer, 517 U.S. at 632. "By requiring that the classification bear a rational relationship to an independent and legitimate legislative end, we ensure that classifications are not drawn for the purpose of disadvantaging the group burdened by the law." Id. at 633. "[I]f the constitutional conception of 'equal protection of the laws' means anything, it must at the very least mean that a bare desire to harm a politically unpopular group cannot constitute a legitimate governmental interest." Id. at 634.

1. Casey's Effect on Equal Protection Analysis

This Court must determine which standard of review – strict scrutiny, intermediate review, or rational basis – should be used in this equal protection challenge to a state regulation on the abortion procedure. The case law on this issue, particularly post-Casey, is sparse and somewhat inconsistent. Cases pre-dating the Casey decision have held that because Roe v. Wade established a "fundamental" right to abortion during the first trimester, then any regulation classifying abortion differently from similar medical procedures must be justified by a "compelling reason." See, e.g., Friendship Medical Center v. Chicago Board of Health, 505 F.2d 1141, 1149-53 (7th Cir. 1974) (striking down state law that "regulate[d] comprehensively physicians who perform abortions, while at the same time leaving other medical procedures, often much more complex and dangerous in terms o[f] the patient's health, up to the good judgment of the physician"), cert. denied, 420 U.S. 997 (1975); Mahoning Women's Center v. Hunter, 610 F.2d 456, 460-61 (6th Cir. 1979) (affirming district court's finding that sweeping regulatory scheme applied only to abortions violated equal

protection because it was not justified by a compelling state interest), vacated on other grounds, 447 U.S. 918 (1980). The district court in Mahoning found that "[w]here fundamental rights are involved, a compelling interest is required in order to differentiate in treatment between two classes which do not differ on grounds related to the purpose of the challenged ordinance." Mahoning Women's Center v. Hunter, 444 F. Supp. 12, 17 (N.D. Ohio 1977), aff'd, 610 F.2d 456, 460-61 (6th Cir. 1979), vacated on other grounds, 447 U.S. 918 (1980).

Although the purpose of Chapter 98.00 is to effectuate "the highest standards of health care," such ordinance regulates only those physicians who would perform abortions while leaving other comparable medical procedures to the discretion of the attending physician. Thus, Chapter 98.00 differentiates between medical procedures which are without distinction as to surgical risk in a fashion which adversely affects the exercise of fundamental rights. Defendants have failed to demonstrate such a compelling interest as to warrant this regulation.

Mahoning, 447 F. Supp. at 17. Other pre-Casey decisions, although recognizing that Roe created a fundamental right to choose abortion, found that the challenged law did not "impinge" on that right, and that therefore rational basis review would apply. See Maher v. Roe, 432 U.S. 464, 474 (1977). Maher held that an indigent woman's difficulty in procuring an abortion was caused by her poverty, rather than by a state's policy decision not to fund abortions. Id at 473-74. Therefore, because "the indigenc[e] . . is neither created nor in any way affected by the Connecticut regulation," the regulation "places no obstacles, absolute or otherwise, in the pregnant woman's path to an abortion." Id. at 474. Accordingly, the Court "conclude[d] that the Connecticut regulation does not impinge upon the fundamental right recognized in Roe." Id. Because the regulation at issue did not "impinge" on the fundamental right, rational basis review applied. Id. The Eighth Circuit in Women's Health Center of West County, Inc. v. Webster, 871 F.2d 1377, 1380-81 (8th Cir. 1989), held that although "the Court has required that if a state law impinging on abortion is to be held

valid, it must further a compelling state interest -- a strict scrutiny test," application of the strict scrutiny test "is triggered only when the state law places 'sufficiently substantial and not de minimus' regulations on abortion." Id. at 1380 (finding that challenged law did not have a "significant impact" on women seeking abortion). The Webster decision, applying rational basis review, rejected the plaintiff physicians' equal protection challenge to the law requiring abortion doctors to have surgical privileges at certain hospitals, because the evidence showed that the requirement was equally applied to procedures other than abortion. Id. at 1381. The Court noted that abortion was not singled out for different treatment, because "the state requires that such backup care be available to patients undergoing any outpatient surgery." Id. Similarly, in Birth Control Centers, Inc. v. Reizen, 743 F.2d 352 (6th Cir. 1984), the Sixth Circuit, in an equal protection challenge to a regulation on "freestanding surgical outpatient facilities" ("FSOF"), held that "no suspect classification is involved here since the State has chosen to regulate all FSOF's, not just abortion clinics." Id. at 358 (also noting that the plaintiff physicians in that case were asserting only their own, not their patients', equal protection rights). The Reizen decision specifically distinguished Mahoning, supra, on the grounds that the regulation found unconstitutional in Mahoning targeted only abortion clinics, while the regulation in Reizen was generally applicable to all outpatient surgery procedures. Reizen, 743. F.2d at 358. n.4. Additionally, Reizen concluded that Michigan's decision to regulate FSOF's where abortions were performed, but not to regulate physicians' private offices where abortions were performed, had a "reasonable basis" due to actual differences between the two settings:

The trial court found, based on the evidence, that physician responsibility may differ depending upon the setting in which a physician practices. For example, the district court found that in a private office practice the physician will likely have direct control over the staff and the functioning of the office, but in a clinic owned and

operated by lay personnel, physicians may be mere employees lacking control over other areas of the clinic's functioning, such as the hiring, training and supervision of support personnel, the acquisition of medical equipment, or [the] design of the facility.

Reizen, 743 F.2d at 359. Reizen noted, however, that "[i]f compliance with the FSOF licensing requirements forced abortion clinics either to increase dramatically their charges for performing abortions or if the cost of compliance was so prohibitive that they ceased to perform abortions, then a woman's ability to exercise her fundamental right to choose to terminate her pregnancy would be seriously impaired." *Id.* at 358.

The issue now before the Court is whether and to what extent the Casey decision changed the analysis of equal protection claims to abortion regulations. Casey itself involved only a due process claim, not an equal protection claim. However, the Casey joint opinion held that the application of the strict scrutiny standard to all first-trimester abortion regulations created "tension" with regard to "the holding in Roe itself that the State has legitimate interests in the health of the woman and in protecting the potential life within her." Casey, 505 U.S. at 871. To address this contradiction, the joint opinion set out the undue burden standard as "the appropriate means of reconciling the State's interest with the woman's constitutionally protected liberty." Id. at 876 Therefore, Casey instructs us, "[r]egulations designed to foster the health of a woman seeking an abortion are valid if they do not constitute an undue burden." Id. at 878. "As with any medical, procedure, the State may enact regulations to further the health or safety of a woman seeking an abortion. Unnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on that right." Id.

After Casey, the Supreme Court continues to refer to a woman's right to choose abortion as one of "certain fundamental rights and liberty interests . . . specifically protected by the

Due Process Clause." See Washington v. Glucksberg, 521 U.S. 702, 720 (1997). In Glucksberg, the Court rejected the plaintiffs' claim that the right to commit suicide or to have assistance in committing suicide was one of the liberties protected by the Due Process Clause. Id at 727. The plaintiffs in Glucksberg and its companion case, Vacco v. Ouill, 521 U.S. 793 (1997), had relied on Casey to argue, for the purpose of their equal protection claim, that assistance in suicide was a "fundamental right" requiring strict scrutiny review. The Court reviewed Casey's discussion of fundamental rights, including the right to choose abortion, then distinguished Casey from the case at bar, concluding that the assisted suicide ban at issue did not implicate a fundamental right. Glucksberg, 521 U.S. at 727-28.26 In a concurring opinion, Justice Souter opines that "We have, made it plain, of course, that not every law that incidentally makes it somewhat harder to exercise, a fundamental liberty must be justified by a compelling counterinterest." Glucksberg, 521 U.S. at 767 n.8 (Souter, J., concurring) (citing Carey v. Population Services, 431 U.S. 678, 685 (1977) (liberty to choose contraception does not "automatically invalidate every state regulation in this area")). Souter then writes that "a state law that creates a 'substantial obstacle,' Casey, supra, at 877, 112 S. Ct. at 2820, for the exercise of a fundamental liberty interest requires a commensurably substantial justification in order to place the legislation within the realm of the reasonable." See Glucksberg, 521 U.S. at 767 n.8 (Souter, J., concurring).

Souter's "commensurably substantial justification" standard does not appear to have been accepted by the other members of the Supreme Court, or applied by any lower Court. But it shows the disagreement and confusion surrounding Casev's effect on the equal protection analysis.

In the companion case, Vacco, 521 U.S. at 799, the Court used rational basis review to analyze the equal protection challenge to the assisted suicide ban, relying on Glucksberg's holding that no fundamental right was infringed.

Very few post-Casey decisions in the federal courts contain analysis of an equal protection challenge to an abortion regulation. The Eighth Circuit in Planned Parenthood v. Dempsey, 167 F 3d 458, 463 (8th Cir.), cert. denied, 120 S. Ct. 501 (1999), rejected Planned Parenthood's argument that abortion regulations were still subject to strict scrutiny after Casey. See Dempsey, 167 F.3d at 464-65. Although its reasoning is not entirely clear, the Eighth Circuit appeared to hold that because Casey had set out a new standard of review, that standard, instead of "strict scrutiny," should be applied in the equal protection context as well as the due process context. See id (rejecting equal protection claim because statute did not constitute "undue burden" on abortion). In another case, a district court in Montana rejected an equal protection challenge to a parental notice statute under the "rational basis" standard. See Wickland v. Lambert, 979 F. Supp. 1285, 1289 (D. Mont. 1997). In Wickland, the plaintiffs had argued that an intermediate scrutiny should apply because the statute at issue applied only to female minors and thus was a "sex-based restriction on access to medical care." Id. at 1289. The court rejected this argument, relying on case law holding that a pregnancybased classification is not necessarily a sex-based classification, and held that the law was "rationally related to its legitimate state interest in protecting the well-being of minors." Id.

A district court in South Carolina recently struck down, on, *inter alia*, Equal Protection grounds, regulations similar in some respects to the Texas regulations at issue in this case. See Greenville Women's Center v. Bryant, 66 F. Supp.2d 691, 737-43 (D.S.C. 1999). Greenville held that "it has been established since Roe that a woman's decision to terminate her pregnancy prior to viability involves the exercise of a fundamental constitutional right." *Id.* at 739. The South Carolina regulation "applies only to abortion providers and directly impacts the exercise of a fundamental right. Furthermore. South Carolina imposes no similar requirements upon physicians or clinics

performing comparable procedures. Thus, the court ... concludes that [the regulation] must survive strict scrutiny analysis." *Id.* at 740 (striking down comprehensive abortion facility licensing and regulatory scheme "because it is not narrowly tailored to serve [the asserted] compelling state interest" of preserving the health and safety of women seeking abortion services). *Greenville* also held alternatively that the regulations at issue in that case would also be invalidated under rational basis review, because the regulations were not "based upon or designed to address" the "actual differences" between physicians who provide abortions and physicians who provide other similar surgical outpatient procedures in an office setting. *Id.* at 741.

2. Physicians' Assertion of Patients' Equal Protection Rights

The parties in the instant case disagree on what standard should be applied to analyze the plaintiffs' equal protection claim. The defendants contend that because physicians are not a suspect class, and because the physicians do not have a fundamental right to perform abortion, rational basis review should apply. The defendants also assert that the plaintiff physicians have no standing to assert their patients' rights in the equal protection context. Finally, the defendants contend that even if the physicians are allowed to assert patients' equal protection rights, the strict scrutiny standard no longer applies after *Casey*:

The Court first notes that no party has attempted to argue that physicians, or even physicians who perform abortions, are a "suspect class." The plaintiffs' equal protection argument rests upon the other reason to apply strict scrutiny review — the fact that the regulation implicates a fundamental right. Similarly, the plaintiffs do not appear to be claiming that they personally, as physicians, have a fundamental right to perform abortion, independent of their patients' right to seek an abortion. To the extent that the plaintiffs are asserting their own equal protection rights,

therefore, the Court must apply rational basis review. See Reizen, 743 F.2d at 358 (noting that because "the plaintiff physicians, in their equal protection argument, were raising their own equal protection rights, not the due process rights of their patients," rational basis review applied).

The question of whether, in general, a physician may assert the patient's equal protection rights as well as the patient's due process rights does not appear to have been squarely addressed by the courts. It is well established that physicians who perform abortions have standing to assert the due process rights of their patients when challenging regulations on abortion. See Singleton v. Wulff, 428 U.S. 106, 118 (1976); Okpalobi, 190 F.3d at 350-53. "The general rule, as formulated by the Supreme Court in Singleton, is that physicians have standing to raise challenges to laws regulating abortion based on the constitutional rights of their patients because they can adequately represent the patients' interest." Okpalobi, 190 F.3d at 353. The reasons for this general rule are that (1) a woman's exercise of her right to choose abortion is "inextricably bound up" with the activities of the physician challenging the regulation; (2) there are two obstacles to a woman's assertion of her own rights in an abortion case. "She may be chilled from such assertion by a desire to protect the very privacy of her decision from the publicity of a court suit," and each individual woman's claim is subject to "imminent mootness" due to the small window of time between a woman's discovery that she is pregnant and the time at which it is too late to have a safe abortion. See Okpalobi, 190 F.3d at 351 (quoting Singleton, 428 U.S. at 115-18).

These reasons for allowing a physician to assert the patient's due process rights would seem to apply equally in the equal protection context. Indeed, several pre-Casey equal protection cases, without discussion, allowed the physicians to assert both the patients' equal protection claims and the patients' due process claims. See, e.g., Mahoning, 610 F.2d at 458 n.2;

Friendship, 505 F.2d at 1152. The defendants have not directed the Court to a case that specifically draws any distinction between equal protection and due process regarding the physician's ability to assert the patient's rights. Moreover, the Supreme Court has cited Singleton as authorizing standing to raise third party equal protection rights in non-abortion cases. See, e.g., Campbell v. Louisiana, 523 U.S. 392, _____ 118 S. Ct. 1419, 1424 (1998) (citing Singleton, holding that white criminal defendant may assert equal protection rights of black grand jury members). Accordingly, it would appear that in general, Singleton and its progeny give physicians standing to raise their patients' equal protection rights.

However, the plaintiffs in this case have another obstacle to their ability to assert their patients' equal protection rights — they have not pleaded such a claim. Their amended complaint (Dkt. # 3) does not contain an assertion of the patients' equal protection rights. On the contrary, the amended complaint carefully states that the challenged provision violates "Plaintiffs' patients' constitutional guarantee of privacy in reproductive decision-making," and violates "Plaintiffs' right to equal protection." (Dkt. # 3, page 4) (emphasis added). In enumerating the four claims for relief, the complaint alleges that the regulatory scheme (1) "violates the right of privacy of Plaintiffs' patients" as an undue burden; (2) "violates the right of privacy of Plaintiffs' patients" in general; (3) "violates the Plaintiffs' right to equal protection of the laws"; and (4) "violates the Plaintiffs' due process rights" due to vagueness. (Dkt. # 3, pages 17-18) (emphasis added). Again, on page 5 of their motion for preliminary injunction (Dkt. # 4), the plaintiffs assert that "the regulatory scheme violates their rights to equal protection and the privacy rights of their patients."

Because the plaintiffs have not asserted their patients' equal protection rights in their amended complaint, they can only be asserting their own equal protection rights. Their equal protection claim is therefore subject to rational basis review. See Reizen, 743 F.2d at 358.²⁷

3. Application of Rational Basis Review

The Court must therefore examine the challenged classification to see if the classification bears "a rational relationship to an independent and legitimate state end." Romer, 517 U.S. at 632-33. "In the ordinary case, a law will be sustained if it can be said to advance a legitimate government interest, even if the law seems unwise or works to the disadvantage of a particular

Even if the plaintiffs had pleaded that they were asserting their patients' equal protection rights, it would not immediately follow that strict scrutiny review would apply. The Casey joint opinion held that many of the post-Roe decisions applying the strict scrutiny standard to all first-trimester abortion regulations can not be reconciled to "the holding in Roe itself that the State has legitimate interests in the health of the woman." Casey, 505 U.S. at 871. The joint opinion noted that the overzealous application of the strict scrutiny standard in the context of the trimester framework "has led to the striking down of some abortion regulations which in no real sense deprived women of the ultimate decision." Id. at 875. The undue burden standard was therefore articulated as "the appropriate means of reconciling the State's interest with the woman's constitutionally protected liberty." Id. at 876. Given this language, the continued application of the strict scrutiny test in analyzing abortion regulations -- even in an equal protection context -- might very well conflict with Casey. On the other hand, it is not clear that rational basis review should apply in light of Casey's decision to reaffirm the Roe holding that a woman has a constitutionally protected liberty interest to decide to terminate her pregnancy, and in light of the Supreme Court's continued acknowledgment that a woman's right to choose abortion is one of "certain fundamental rights and liberty interests... specifically protected by the Due Process Clause." See Glucksberg, 521 U.S. at 720.

It may be appropriate, in post-Casey equal protection challenges to abortion regulations, to apply some type of intermediate standard of review, as Justice Souter suggests. See Glucksberg, 521 U.S. at 767 n.8 (Souter, J., concurring) (advocating that "a state law that creates a substantial obstacle for the exercise of a fundamental liberty interest requires a commensurably substantial justification in order to place the legislation within the realm of the reasonable.") (citation omitted). Similarly, Justice O'Connor first articulated the undue burden standard in 1983 as a middle ground between strict scrutiny and rational basis. See Akron v. Akron Center for Reproductive Health, 462 U.S. 416, 454 (1983) (O'Connor, J., dissenting) (suggesting that if a regulation creates an undue burden, strict scrutiny applies; if no undue burden is created, then rational basis review should apply) Alternatively, a court might hold that Casey's requirement that medical regulations be "designed to foster the health of a woman seeking an abortion," and not be "unnecessary," could support the application of an intermediate standard. See Casey, 505 U.S. at 878. However, because the patients' equal protection rights are not currently before the Court, and because the Court finds in this order that the plaintiff physicians' own equal protection rights are violated by the challenged provisions, this issue need not be resolved today.

group, or if the rationale for it seems tenuous." *Id.* at 632. However, "even in the ordinary equal protection case calling for the most deferential of standards, we insist on knowing the relation between the classification adopted and the object to be attained." *Id.*

The plaintiffs are actually challenging two legislative classifications. The first classification is between physicians who perform abortions in their offices and physicians who perform other, comparable surgical procedures in their offices. The second challenged classification is between physicians who perform fewer than 300 abortions per year and physicians who perform more than 300 abortions per year.

The plaintiffs assert that imposing comprehensive regulations on physicians who perform abortions in their offices, while leaving unregulated physicians who perform other, comparable surgical procedures in their offices, violates equal protection. There is ample evidence in the record to support the proposition that there exist other surgical procedures performed in physicians' offices that pose similar or greater risks than abortion. All of the plaintiff physicians testified that they, and most physicians, routinely perform numerous types of invasive surgical procedures in their offices, many of which carry risks equal to, or even higher than, a routine first-trimester abortion procedure. Examples are endometrial biopsy, cervical biopsy, diagnostic hysteroscopy, D&C, conization, tummy-tucks, facelifts, liposuction, endoscopy, and laparoscopy. D&Cs, particularly, involve virtually the same instrumentation, sedation, techniques, duration, and risks as a first-trimester abortion. Yet only abortions subject physicians to regulation. Dr. Lawson, who participated in the 1997 committee process to draft the 1998 revisions to the abortion regulations, agreed that in some instances, the risks associated with a D&C are the same level as the risks of a vacuum aspiration or suction curettage abortion, and in that context, a woman going

into a physician's office for a D&C should have the same regulatory protection as if she were going in for an abortion. Dr. Hendricks, who specializes in infectious diseases and epidemiology, agreed that a first trimester abortion procedure is "quite similar" to a D&C procedure, in terms of both required instruments and level of invasiveness. She testified that the sterilization and infection control procedures she helped draft in the abortion regulations do not address any differences inherent in the abortion procedure, but are equally applicable to all invasive surgical procedures performed in a physician's office.

In light of the above testimony, a rational basis for this classification between office-based abortions and other comparable office-based surgery is not immediately apparent. However, it is important to remember that the overall regulatory scheme in Texas that subjects abortion providers to licensing and regulation -- leaving providers of other office-based surgical procedures unregulated -- has been in place (in some form) since 1985, and is not being challenged in this lawsuit. The 1999 amendments being challenged by the plaintiffs merely take this existing, unchallenged, regulatory scheme and apply it to additional providers that the legislature apparently believed needed regulation for the same reasons as the other 31 licensed abortion providers in Texas. Given that the regulatory scheme singling out abortion was already in place (and must be presumed to be constitutional), the Court cannot conclude that the legislature has no rational basis to regulate "high-volume" physicians' offices in the same way that abortion clinics are already regulated.

The plaintiffs have repeatedly asserted that they are challenging only the 1999 amendments, and not the entire regulatory scheme. The one exception is with regard to the due process vagueness challenge to the patient rights provision and the definition of "quality." This exception is not applicable here.

²⁹ "State legislatures are presumed to have acted within their constitutional power despite the fact that, in practice, their laws result in some inequality." *Harris County v. Carmax Auto Superstores, Inc.*, 177 F.3d 306, 321 (5th Cir. 1999).

Additionally, there is some basis in the record for a legislative belief that health regulations on abortion, as opposed to other procedures, may be justified. The evidence shows that the health department in 1993 investigated the case of a woman who had died from a post-abortion infection. That investigation led to major revisions in the abortion facility regulations, including amendments to include some discharge instructions and follow-up care. The evidence showed that the 1993 death occurred in an abortion facility which had a history of repeatedly failing to properly sterilize its instruments. A health department surveyor with years of experience surveying abortion facilities testified that problems with sterilization were very common in abortion facilities in the early 1990s, particularly those where inadequately trained staff members were performing the sterilization without direct physician supervision or written instructions. Hendricks, the infectious disease physician who has worked at the health department for 10 years, testified that she often gets calls about incidents or outbreaks of infection in various health care areas, but she has never been notified of any particular problems with infection following gynecology surgery or other outpatient surgeries performed in physicians' offices. Hendricks was, however, asked to be a witness in a lawsuit where a woman died from a severe infection following an abortion, and she was notified by a hospital about another death following an abortion.

It is not outside the realm of possibility that other office surgical procedures, such as liposuction and facelifts, have resulted in deaths and severe injuries to patients in Texas, but the plaintiffs in this case have not introduced evidence to this effect. The Fifth Circuit has "emphasized that in suits involving a challenge to a law's rational basis, the burden is not upon the state to establish the rationality of its statute, but is upon the challenger to show that the restriction is wholly arbitrary." Carmax Auto, 177 F.3d at 322-23. There is also testimony in the record that abortion "is

the most frequently performed surgery in the United States," and that more than 80,000 abortions are performed in Texas each year. No specific evidence was presented, however, as to whether other surgical procedures having similar risks to abortion are performed in similar numbers. There was also some discussion in the legislative history of the 1997 committee process that women who suffer complications or infections from abortion might be less likely to report their symptoms or make complaints than patients who suffer complications from other surgical procedures, because of the controversial, secret nature of abortion and the intense emotions that surround the abortion decision. Although there is scant support for this theory in the record, the Court cannot conclude that it is wholly irrational.

In light of the fact that the regulatory scheme singling out abortion providers has been in effect for nearly 15 years and is not being challenged in this lawsuit, and recognizing that the legislature could have reasonably believed that patients receiving abortions in high-volume physician offices are in more need of protection than patients receiving other surgical procedures, the Court must conclude that the classification between physicians who perform abortions in their offices and physicians who perform other, comparable surgical procedures in their offices can be said to bear a rational basis to a legitimate state end. See Romer, 517 U.S. at 632.

The second challenged classification — between physicians who perform fewer than 300 abortions per year and physicians who perform more than 300 abortions per year — presents more of a problem. The state advances several "legitimate government interests" that it claims are served by drawing the line at 300 abortions a year. First, the legislative history shows that Senator Harris introduced the provision because he was concerned about a perceived "loophole" in the physician exemption. The intent appears to have been to establish a bright line for the health

department to determine which physicians are subject to licensing and regulation. Senator Harris indicated at the Senate committee hearing that, in his review of the list of abortions reported by the state's physicians, he saw physicians who reported performing 1,800 to 2,900 abortions year, yet they had claimed an exemption — apparently evading the intent of the statute — by stating that their offices were not "primarily" used for abortion. Because physicians are not required to report the total number of patients treated, there is currently no immediate way for the health department to verify whether a physician who performed 2,000 abortions actually saw 4,000 patients that year. In contrast, if a numerical threshold for abortions is established, the health department already has the reported abortion statistics and will immediately know which physicians are subject to licensing and regulation.

The Court recognizes that, in general, creating a bright line for enforcement purposes is a "legitimate state end," and that legislative line-drawing, while often necessary, is always somewhat arbitrary. *Cf. Gregory v. Ashcroft*, 501 U.S. 452, 473 (1991) (upholding "arbitrary" provision providing for mandatory retirement of judges at age 70, even though such a classification did not necessarily correspond to a judge's actual loss of mental or physical facilities). However, the evidence in the record shows that the number 300 was not chosen by any rational thought process about increasing risk, but was simply a "raw political compromise." The legislature may have been justified in drawing a bright line to close a loophole, but by choosing the number 300, it drastically overshot the mark. Absolutely no evidence in the record indicates that any of the 12 physicians in the state who provide more than 300 abortions per year (but are currently exempt) ever gave substandard care to an abortion patient or had problems with infections. The state attempts to justify the number 300 by arguing generally that more abortions mean more risk to women. The state

contends that as the number of abortions increases, the physician tends to spend less time with each patient and is more likely to delegate tasks to staff members and not be able to adequately supervise activities like sterilization of instruments. Accordingly, as the number of abortions increases, the state asserts, it generally becomes more appropriate to impose safeguards appropriate for abortion clinics, like staff training and qualifications, written sterilization procedures, and regular inspections.

The Court agrees that, as a general proposition, when a physician's office starts to resemble an abortion clinic in the high volume of abortion procedures it provides, it would not be irrational to require that physician to submit to the same regulations as are applied to abortion clinics. However, the question then becomes, what is a "high volume"? The Court concludes that there is no evidence in the record that a physician's office performing 300 abortions a year resembles an abortion clinic. The record shows no rational connection between the number 300 and the "high volume" risks the state claims are associated with abortion clinics. In fact, the evidence amply supports the proposition that the cutoff would have to be significantly higher than 300 to be held rational. Dr. Hansen testified that it might be appropriate to regulate a physician performing 2,000 procedures. Senator Harris, when discussing the perceived loophole, mentioned numbers like 2,900, 2,100 and 1,800. The burdens of the 1999 amendments appear to fall most heavily on Dr. Smith, who performs 350 to 400 abortions a year, and Dr. Hansen, who performs approximately 1,000 abortions a year, but appear to pose less of a problem for Dr. Kaminsky, whose office provides about 1,500 abortions a year, and Dr. Robinson, whose office provides 2,211 abortions a year. There was testimony that abortion clinics might provide abortions to 15 to 35 women each working day, which would average out to a range of approximately 3,700 to 8,700 abortions per year. Dr. Robinson testified that the licenced clinic where he works on a part-time basis performs 3,600 to 3,700 abortions per year.

These figures show that it is not rational to assume that a physician providing 300 abortions per year will expose his patients to "high volume" risks similar to those of a typical abortion clinic. The evidence shows that Senator Harris originally suggested the number 10, and later negotiated the number 300 with pro-choice activists as a political compromise. The only rationale articulated for the number 300 in the official legislative history was to regulate a physician who performs more than one abortion per working day. This "one a day" rationale cannot be reconciled with the state's argument that some physicians may be providing so many abortions that they are unable to adequately take care of patients. It is irrational to assume that one abortion per day is a heavy workload, considering that a clinic might provide up to 35 abortions per day. The evidence shows that a physician might see and provide medical services to 20 patients overall during a typical day. Performing one abortion per day, then, would only constitute 5 percent of that physician's practice. It cannot be rational to conclude that a physician performing an average of one abortion a day as part of a general gynecological practice is thereby subjecting his patients to the "high volume" risks cited by the state. The Court must conclude that "the facts on which the classification is based could not reasonably be conceived to be true by the decisionmaker." See Gregory, 501 U.S. at 473 (quotation marks and ellipses omitted).

Indeed, the rationale that more abortions equals more risk is already tenuous; the evidence showed that any increased risk from physician inattentiveness, a heavy schedule, and more delegation to staff is not directly related only to the number of abortions performed, but may also depend upon the size of the physician's staff, the hours the office is open, and the number of total

patients seen and total procedures performed of all types. The defendants' witness, Dr. Long, testified that sterilization issues do not change depending on the number of procedures a physician performs. "Sterilization doesn't have anything to do with numbers," Long testified. Long said that she could think of no medical, safety, or health reason to draw the regulatory line at 300 abortions.

The Court recognizes that "[a] State does not violate the Equal Protection Clause merely because the classifications made by its law are imperfect." Arceneaux v. Treen, 671 F.2d 128, 134 (5th Cir. 1982). However, this is not a case where the classification is merely "imperfect" or "not made with mathematical nicety." Id. In this case, the legislature's choice of the number 300 as the point where risks start to increase is not just slightly inaccurate or arbitrary — it is not even remotely close to the numbers with which the "high volume" risks seem to be associated. All of the evidence in the record points to a much higher number. Although legislatures have the power to draw lines, the line drawn in this case "is so unrelated to the achievement of any combination of legitimate purposes that [the Court] can only conclude that the [legislature's] actions were irrational." See Gregory, 501 U.S. at 471; see also Greenville, 66 F.Supp.2d at 741 (holding, inter alia, that regulations on physicians who performed five or more abortions a month, but not on those who performed fewer abortions, violated equal protection even under rational basis review). 30

Accordingly, the Court must conclude that the classification drawing the line between physicians who perform fewer than 300 abortions per year and physicians who perform more than

To draw an analogy, it was not irrational for Missouri to draw the mandatory retirement line at age 70, based on the rationale that "physical and mental capacity sometimes diminish with age." *Gregory*, 501 U.S. at 472. However, the classification could not have been found rational if Missouri had drawn the mandatory retirement line at age 25, using the same rationale. If the required respect for legislative line-drawing means that a court cannot ever question the rationality of the relationship between the chosen classification and the stated purpose, then rational review is meaningless. Such a result would be incompatible with the Supreme Court's statement in *Romer* that "we insist on knowing the relation between the classification adopted and the object to be attained." *Romer*, 517 U.S. at 632.

300 abortions-per year does not bear a rational relationship to a legitimate state end, and therefore violates the physicians' right to equal protection under the law. The Court concludes that the plaintiffs have shown a substantial likelihood that they will succeed on the merits of their equal protection claim.

D. Vagueness Claim

Although they assert generally that they are attacking only the 1999 amendments and not the regulatory scheme in general, the plaintiffs assert that three provisions of the abortion regulations are unconstitutionally vague. Section 139.51(1) requires a physician licensed as an abortion provider to "ensure that all patients... are cared for in a manner and in an environment that enhances each patient's dignity and respect in full recognition of her individuality," and Section 139.51(2) requires the physician to ensure that all patients "receive care in a manner that maintains and enhances her self-esteem and self-worth." "Quality" is defined subjectively in the regulations as "the degree to which care meets or exceeds the expectations set by the patient." 25 TAC § 139.2 (43). These regulations are already applicable to licensed abortion facilities, but the 1999 amendments will apply them for the first time to the plaintiffs.

Due process prohibits laws so vague that persons of common intelligence must necessarily guess at their meaning and differ as to their application. See Okpalobi, 190 F.3d at 357. Vague laws offend due process in two respects. First, they fail to provide the persons targeted by the statutes with a reasonable opportunity to know what conduct is prohibited so that they may act accordingly. Id. Second, by failing to provide explicit standards for those who apply them, vague laws impermissibly delegate basic policy matters to the government representatives charged with enforcing the law, with the attendant dangers of arbitrary and discriminatory application. Id. The

imposition of criminal penalties requires a statute to provide an even higher level of certainty. *Id.* at 358 n.10. "A vague law is especially problematic, and the standard of a court's review is therefore more stringent" when the uncertainty induced by the statute "threatens to inhibit the exercise of constitutionally protected rights." *Id.* at 358.

The testimony in the record indicates that there is no objective way to measure compliance with the provision that requires physicians to "enhance" each patient's dignity and self-esteem. Jeffers, the health department representative who helped draft the provision, agreed that people might have different interpretations of that language, and that a health department surveyor might have a different interpretation than a physician regarding whether the physician was in compliance. Jeffers acknowledged that it would be up to the surveyor's discretion and interpretation as to whether the physician would be subjected to civil or criminal penalties for not doing enough to "enhance... self esteem."

In addition, several of the plaintiffs testified that although they certainly strive to treat all patients with dignity and respect, they are concerned about health department surveyors who can fine them or suspend their licenses, subjecting them to criminal charges, if the surveyors conclude that this vague standard has not been satisfied. Abortion is a traumatic and difficult life decision under any circumstances, so it appears unrealistic to require physicians, under the threat of discretionary civil and criminal penalties, to "enhance" dignity and self esteem in connection with an event that is virtually always a negative experience despite a physician's best efforts to provide emotional support

"The Supreme Court has invalidated laws that alter the standard of care a physician owes an abortion patient on vagueness grounds because of the potential for chilling the providing

of the vague provisions will infringe the plaintiffs' constitutional right to due process. Therefore, the Court finds a substantial threat that the plaintiffs will suffer irreparable injury absent an injunction. See Okpalobi v. Foster, 981 F. Supp. 977, 987 (E.D. La. 1998) (holding that when a constitutional right is impaired, no further showing of irreparable injury is necessary), aff'd, 190 F.3d 337 (5th Cir. 1999).

Furthermore, the Court finds that the threatened injury to the plaintiffs outweighs any harm that might result from an injunction. Enjoining the effect of the 1999 amendments will only preserve the status quo until a full trial on the merits can be had. Nothing in the record suggests that any harm will result from allowing the 12 physicians to whom the amendments apply to continue to provide abortions (as they have done for years) without obtaining an abortion facility license during the pendency of this case. The risks the state was seeking to address with the 1999 amendments are general, not specific to the five plaintiff physicians, or even to the other seven physicians affected by the amendments. Absolutely no evidence in the record indicates that any of the 12 physicians in the state who provide more than 300 abortions per year (but are currently exempt) have ever given substandard care to an abortion patient or had problems with infections.

In addition, there is evidence that two of the plaintiffs will cease performing abortions (and in Dr. Smith's case, completely close down her private practice) on January 1, 2000 if the 1999 amendments are not enjoined. The Court concludes that the injury that will accrue to physicians who will have to choose whether to immediately close down all (or a significant portion) of their practices, or to seek licensing under a law that this Court has found to be unconstitutional, is greater than the unlikely risk that any women will be harmed by the state's inability to apply the abortion facility licensing scheme to 12 physicians pending trial on the merits. See, e.g., Women's Medical

Professional Corp. v. Voinovich, 911 F. Supp. 1051, 1092 (S.D. Ohio 1995) (enjoining abortion regulation; holding that "[a]s far as the Defendants' interests are concerned, a preliminary injunction will merely maintain the status quo while the constitutionality of this legislation is decided.")

Finally, the Court concludes that a preliminary injunction will not disserve the public interest. See Ingebretsen v. Jackson Pub. Sch. Dist., 88 F.3d 274, 280 (5th Cir. 1996) (holding that enjoining the enforcement of an unconstitutional provision does not disserve the public interest). The public does not have an interest in enforcing an unconstitutional law. Id. at 280. Additionally, there is evidence in the record that if Dr. Smith and Dr. Hansen cease their private abortion practices, Dr. Smith's abortion patients (the majority of whom are college students with few resources) will face the prospect of having to find transportation to a Dallas abortion clinic 45 to 90 minutes away, and Dr. Hansen's "medically indicated" abortion patients will be subjected to the less personal atmosphere of abortion clinics. The Court has held that such hardships do not, on this record, rise to the level of an undue burden under Casey. However, the potential effect on Smith's and Hansen's patients finds enough support in the evidence to constitute evidence that a preliminary injunction will not disserve the public interest.

Accordingly, the defendants will be enjoined from enforcing the 1999 amendments to the Texas abortion regulatory scheme, pending a full review of this case on the merits.

VI. Conclusion

For the reasons set out in this order, the plaintiffs' motion for preliminary injunction (Dkt. # 4) is GRANTED with regard to the claims that the 1999 amendments violate the plaintiffs' equal protection rights; is GRANTED with regard to the three provisions found to be unconstitutionally vague; but is DENIED with regard to the claims that the 1999 amendments violate the plaintiffs' patients' due process rights. Therefore, it is ORDERED that Texas Commissioner of Health William R. Archer, III, and Texas Attorney General John Cornyn, in their official capacities, are hereby enjoined from enforcing the 1999 amendments to Texas's abortion licensing statute and regulations, and 25 TAC Sections 139.51(1), 139.51(2), and 139.2(43), pending a full trial on the merits.

SIGNED on December 29, 1999.

JOHN D. RAINEY

UNITED STATES DISTRICT JUDGE