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IMPLICATIONS OF CONSCIENCE CLAUSE LEGISLATION ON ACCESS TO CONTRACEPTIVE PILLS

By: Alicia D. Massidas

Introduction

It is easy to equate the phrase “conscience clause” with a medical provider’s right in the context of *Roe v. Wade*¹ to refuse to provide abortion services. Less commonly considered is the legislation that, in some states, allows for doctors and pharmacists to refuse to prescribe or fill prescriptions for contraceptive pills.² Additionally, there are “conscience clause” implications for pharmacists dispensing oral contraceptives including emergency contraception such as the “morning-after” or Plan B pill.³

Oral contraceptives or birth control pills usually contain the hormones, estrogen and progestin.⁴ These contraceptives prevent a woman’s egg from fully developing each month and from being able to accept sperm, effectively preventing fertilization.⁵ There are several different types of oral contraceptives.⁶ Additionally, there are several options for women seeking emergency contraception.⁷ In general, Plan B, which is designed to be taken seventy-two hours after intercourse, contains the same hormones found in birth control pills but in higher doses.⁸ Specifically, “[p]rogestin prevents the sperm from reaching the egg and keeps a fertilized egg

¹ *Roe v. Wade*, 410 U.S. 113 (1973).

² Jane W. Walker, *The Bush Administration’s Midnight Provider Refusal Rule: Upsetting the Emerging Balance in State Pharmacist Refusal Laws*, 46 HOUS. L. REV. 939, 941-948 (2009).

³ *Id.* at 941-948.

⁴ Estrogen and Progestin Oral Contraceptives (Oral Route), <http://www.mayoclinic.com/health/drug-information/DR602119> (last visited May 6, 2010).

⁵ *Id.*

⁶ *Id.*

⁷ Morning-after Pill: Emergency Birth Control, <http://www.mayoclinic.com/health/morning-after-pill/AN00592> (last visited May 6, 2010).

⁸ *Id.*

from attaching to the wall of the uterus (implantation)” and “[e]strogen stops the ovaries from releasing eggs (ovulation) that can be fertilized by sperm.”⁹ The Plan B pill “is available to women and girls age 17 and older without a prescription at most pharmacies.”¹⁰

Because contraceptives are designed to prevent pregnancy, there are some who oppose their use for moral and/or religious reasons. As a result of doctors or pharmacists who have moral or religious objections to prescribing or dispensing contraceptives, legislatures have recognized a need to protect these health care providers from adverse or discriminatory action. However, there is also a need to protect the rights of patients seeking contraceptives from their health care providers. Due to the inherent tension between the rights of patients and health care providers in this instance, there is a need for balanced legislation. Unfortunately, with the enactment of the Department of Health and Human Services Refusal Rule regulation in 2008, this balance has grossly shifted to the benefit of health care providers at the detriment of patient’s rights. In light of public policy, a better stance would be to enact legislation that is more protective of patient’s rights.

The following is a review of pertinent constitutional cases and an overview of federal and state conscience clause legislation as well as an in depth discussion of two important conscience clause cases. Further, arguments on both sides of the debate will be explored.

Origin of Legal Rights

There are several important constitutional law cases implicated in the controversy surrounding conscience clause or refusal legislation. The first among these is *Roe v. Wade*,¹¹

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Roe v. Wade*, 410 U.S. 113 (1973).

which prompted the federal government to pass the Church Amendment¹² and state governments to pass their first conscience clause legislation in the 1970's. This initial decision gave women the right to choose to legally terminate a pregnancy prior to the fetus's viability or the time when a fetus can survive outside of the womb.¹³

The Court's position on this right was further clarified by their decision in *Planned Parenthood v. Casey*.¹⁴ In pertinent part, the Court in that case held that women have a right to access abortion services without an "undue burden" imposed by the government.¹⁵ Both *Roe v. Wade*¹⁶ and *Planned Parenthood v. Casey*¹⁷ balance the state's interest in protecting the fetus with a woman's right of personal autonomy and privacy.¹⁸

With regard access to contraceptives, the two major cases in American jurisprudence are *Griswold v. Connecticut*¹⁹ and *Eisenstadt v. Baird*.²⁰ In *Griswold*, the Court held that a constitutional right to privacy legally allowed married couples to have access to contraceptives,²¹ and in *Eisenstadt*²² expanded this right to include unmarried people. Further, the Court held that people have the 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."²³ As a result, "patients...have expectations when it comes to their medical care, including: access to prescribed medications, respect for their personal autonomy and privacy, and confidence that their medical

¹² 42 U.S.C. § 300a-7 (2010).

¹³ *Roe v. Wade*, 410 U.S. 113 (1973).

¹⁴ *Planned Parenthood v. Casey*, 505 U.S. 833 (1992).

¹⁵ *Id.*

¹⁶ *Roe v. Wade*, 410 U.S. 113 (1973).

¹⁷ *Planned Parenthood v. Casey*, 505 U.S. 833 (1992).

¹⁸ Jane W. Walker, *The Bush Administration's Midnight Provider Refusal Rule: Upsetting the Emerging Balance in State Pharmacist Refusal Laws*, 46 HOUS. L. REV. 939, 948 (2009).

¹⁹ *Griswold v. Connecticut*, 381 U.S. 479 (1965).

²⁰ *Eisenstadt v. Baird*, 405 U.S. 438 (1972).

²¹ *Griswold v. Connecticut*, 381 U.S. 479 (1965).

²² *Eisenstadt v. Baird*, 405 U.S. 438, 454 (1972).

²³ *Id.*

needs will guide their care. Specifically, patients expect that their providers' decisions will be based upon prevailing medical knowledge, rather than on personal religious beliefs.”²⁴ Further, this case law advances the argument that "a health care provider's autonomy cannot be exercised in a way that violates a patient's autonomy in making her own choices” and that “neither should the patient's autonomy be exercised in a way that would trump the values and choices of the health care provider as a human being.”²⁵ As is evident from these cases, an approach that balances a health care provider’s religious beliefs and moral convictions with the rights of patients most accurately reflects the spirit of the Court’s decisions in cases dealing with access to contraceptives. The basis of conscience clause legislation as it relates to the access to contraceptives is explicated below.

What is Conscience Clause legislation?

A. Basic Definition

In general, “conscience clause” or “refusal clause” legislation protects health care providers who refuse to perform or provide a service that violates their religious or moral consciences.²⁶ These health care providers are protected from possible disciplinary action or legal liability for failing to provide a service that would otherwise be legally or ethically required of them.²⁷

²⁴ Jane W. Walker, *The Bush Administration’s Midnight Provider Refusal Rule: Upsetting the Emerging Balance in State Pharmacist Refusal Laws*, 46 HOUS. L. REV. 939, 954-955 (2009).

²⁵ *Id.* at 955.

²⁶ *Id.* at 941-944.

²⁷ *Id.*

B. Refusal Legislation in the Federal Context

Subsequent to the *Roe v. Wade* decision, Congress enacted the first federal refusal legislation in 1973.²⁸ This legislation, known as the Church Amendment,²⁹ contains two provisions.³⁰ The conscience provision allows individuals and health care entities to refuse to perform or participate in any sterilization procedure or abortion if doing so would be contrary to their religious beliefs or moral convictions.³¹ The nondiscrimination provision protects health care providers from being discriminated against for participating in a lawful sterilization procedure or abortion or for refusing to participate in such procedure if it is contrary to their religious beliefs or moral convictions.³² This amendment was further expanded in 1974 through the National Service Award Act of 1974, which says that no individual will be forced to perform an activity that is part of a health service program or research activity if doing so would be contrary to that individual's religious beliefs or moral convictions.³³ As a result of the Church Amendment³⁴ and its expansion in 1974, the foundation for federal refusal legislation was set. Health care providers who refused to participate in sterilization or abortion procedures on the basis of religious beliefs or moral convictions were protected from discrimination as well as health care providers who chose to perform such procedures. Additionally, individuals involved in health service programs or research activities were prohibited from being forced to perform any activity that would be contrary to his or her religious beliefs or moral convictions.

²⁸ *Id.* at 948-949.

²⁹ 42 U.S.C. § 300a-7 (2010).

³⁰ Jane W. Walker, *The Bush Administration's Midnight Provider Refusal Rule: Upsetting the Emerging Balance in State Pharmacist Refusal Laws*, 46 Hous. L. Rev. 939, 949 (2009).

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ 42 U.S.C. § 300a-7 (2010).

Federal refusal legislation was expanded in 1996 with the Coats Amendment³⁵ to the Public Service Act. The Coats Amendment prohibits federal, state, and local governments from basing the accreditation and certification of medical schools and physicians on whether it provides training in abortion procedures and techniques.³⁶ Specifically, the Coats Amendment protects a health care entity that refuses to provide training of the “performance of induced abortions, to require to provide such training, to perform such abortions, or to provide referrals for such training for such abortions.”³⁷

Additionally, with the Weldon Amendment that has been added to the Department of Health and Appropriations Act since 2004, “none of the funds made available in this Act may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.”³⁸ Further, the Weldon Amendment provides for the termination of funds appropriated by the Department of Health and Human Services for noncompliance with its nondiscrimination provision.³⁹ As a result of this additional legislation, there is further protection for health care providers as well as insurance companies. In the federal context, there is vast discrimination and liability protection for health care entities that choose not to perform, teach techniques about, or provide referrals for abortion procedures.

C. Refusal Legislation in the State Context

³⁵ Jane W. Walker, *The Bush Administration’s Midnight Provider Refusal Rule: Upsetting the Emerging Balance in State Pharmacist Refusal Laws*, 46 Hous. L. Rev. 939, 952 (2009).

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.* at 952-953.

³⁹ *Id.*

Subsequent to the federal Church Amendment⁴⁰ of 1973, many states enacted refusal clause legislation with regard to sterilization and abortion procedures. However, the refusal statutes of Georgia, Mississippi, Arkansas, and South Dakota expressly give pharmacists a right of refusal.⁴¹ For example, Mississippi explicitly includes pharmacists within the definition of “health care provider” in its refusal statute⁴² while Georgia’s statute states “it shall not be considered unprofessional conduct for any pharmacist to refuse to fill any prescription based on his/her professional judgment or ethical or moral beliefs.”⁴³

While other states do not specifically include pharmacists in their conscience clause statutes, pharmacists in those states have generally based their right of refusal on concepts having to do with when a pregnancy begins and which drugs could possibly abort that pregnancy.⁴⁴ This has put the impetus on state legislatures to ensure that women will have access to legal contraceptives without infringing on the rights of pharmacists.⁴⁵ One such approach is taken in Illinois’s Health Care of Conscience Act.⁴⁶ This state legislation protects “any nurse, nurses’ aide, medical school student, professional, paraprofessional or any other person who furnishes, or assists in the furnishing of, health care services.”⁴⁷

In August 2005, an emergency rule was established that requires that “upon receipt of a valid, lawful prescription for a contraceptive, a pharmacy must dispense the contraceptive, or a suitable alternative permitted by the prescriber, to the patient or the patient’s agent without delay,

⁴⁰ 42 U.S.C. § 300a-7 (2010).

⁴¹ Jane W. Walker, *The Bush Administration’s Midnight Provider Refusal Rule: Upsetting the Emerging Balance in State Pharmacist Refusal Laws*, 46 HOUS. L. REV. 939, 959 (2009).

⁴² MISS. CODE ANN. §§41-107-3.

⁴³ GA. COMP. R. & REGS. r. 480-5-.03(n) (2010).

⁴⁴ *Id.* at 959.

⁴⁵ *Id.*

⁴⁶ 745 ILCS 70/3 (2010).

⁴⁷ 745 ILCS 70/3(c) (2010).

consistent with the normal timeframe for filling any other prescription.”⁴⁸ The rule also established a toll-free number for Illinois residents to report pharmacist refusals.⁴⁹ As a result of the emergency rule, Illinois’s refusal legislation puts the burden for the filing of prescriptions on the pharmacy rather than the individual pharmacists. In this way, the refusal clause respects an individual pharmacist’s rights without interfering with women’s rights to obtain legal contraceptives.⁵⁰ It seems that this approach would work best in a situation where multiple pharmacists are available at one pharmacy. It also appears that as a result of this legislation, a pharmacy solely consisting of pharmacists who refuse to dispense contraceptives based on religious beliefs or moral convictions could face adverse action. Additionally, this legislation does not address the Plan B pill, which is to be dispensed at pharmacies without a prior prescription. It would appear that patients do not have as strong protection with regard to access to emergency contraception. Despite possible difficulties in the execution of this legislation due to a lack of pharmacists willing to dispense contraceptives in a particular location, the idea behind the legislation is commendable. It aims to protect the autonomy of individual pharmacists without harming patient’s rights or infringing on the patient’s right to privacy and personal autonomy.

Another example of a state approach to refusal legislation is in California. While doctors, nurses, hospital employees, and certain hospitals are allowed to refuse to participate in abortions based on moral or religious objection through the California Health and Safety Code, pharmacists are protected by another statute.⁵¹ The approach of California’s Business and

⁴⁸ Jane W. Walker, *The Bush Administration’s Midnight Provider Refusal Rule: Upsetting the Emerging Balance in State Pharmacist Refusal Laws*, 46 Hous. L. Rev. 939, 959(2009).

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.* at 960.

Profession Code⁵² closely resembles the approach of the American Pharmacists Association in its “dispense or refer” policy.⁵³ The California statute “requires licensed pharmacists to dispense all legal prescriptions, unless... (3) the pharmacist has given prior written notice of religious or moral objection to the pharmacist's employer so that that employer may make a "reasonable accommodation" to "establish protocols that ensure that the patient has timely access to the prescribed drug.”⁵⁴ The California statute is another example of legislation that tries to balance the refusal rights of health care entities with the personal autonomy rights of patients. This statute puts the impetus on the refusing pharmacist to notify his or her employer of a possible religious or moral objection. The burden then shifts to the pharmacist’s employer to come up with reasonable accommodations that ensure that, despite the pharmacist’s objection, the patient will receive his or her prescription in a timely manner. It would be interesting to find out what would happen in the instance of a small town with only one pharmacy whose pharmacists all object to dispensing the contraceptives. What would the “reasonable accommodation” be? Would it require the pharmacy to dispense the prescribed medicine or force the patient to go to another pharmacy which may be several miles away? Regardless of possible problems in the nuance of the application of this statute, it aims to safeguard patients’ rights without infringing on the rights of pharmacists. While there are explicit pharmacist protections in some states such as Illinois and California, pharmacist in some other states do not have any refusal clause protection and are required to dispense contraceptive medicines.⁵⁵

⁵² CAL BUS & PROF CODE § 733 (2009).

⁵³ Jane W. Walker, *The Bush Administration’s Midnight Provider Refusal Rule: Upsetting the Emerging Balance in State Pharmacist Refusal Laws*, 46 HOUS. L. REV. 939, 960 (2009).

⁵⁴ *Id.*

⁵⁵ *Id.* at 961.

D. Department of Health and Human Services Provider Refusal Rule⁵⁶

In 2008, new federal refusal regulation was introduced that effectively changed the game.⁵⁷ The Department of Health and Human Services Provider Refusal Rule went into effect on January 20, 2009.⁵⁸ It extends the same protections afforded to health care providers who object to sterilization and abortion procedures to health care providers who object to the prescribing and dispensing of contraceptives.⁵⁹ The HHS Refusal Rule,⁶⁰ which includes pharmacists in its definition of health care entities,⁶¹ “goes beyond abortion and sterilization to prohibit “any entity, including a State or local government, that carries out any part of any health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services,” from requiring “any individual to perform or assist in the performance of any part of a health service program or research activity funded by the Department if such service or activity would be contrary to his religious beliefs or moral convictions.”⁶² Additionally, this refusal rule leaves the definition of abortion open so that, conceivably, the statute’s prohibition on discrimination against health care providers or entities who refuse to “assist in the performance” of an abortion could be read to include the writing or dispensing of prescriptions for certain types of contraceptives.⁶³ Another concern is that the HHS Refusal Rule⁶⁴ conflicts with many of the aforementioned state refusal statutes and may

⁵⁶ 73 FED. REG. 78072.

⁵⁷ *Id.* at 962.

⁵⁸ White House set to reverse health care conscience clause, <http://www.cnn.com/2009/POLITICS/02/27/conscience.rollback/index.html> (last visited May 8, 2010).

⁵⁹ Jane W. Walker, *The Bush Administration’s Midnight Provider Refusal Rule: Upsetting the Emerging Balance in State Pharmacist Refusal Laws*, 46 HOUS. L. REV. 939, 965 (2009).

⁶⁰ 73 FED. REG. 78072.

⁶¹ Jane W. Walker, *The Bush Administration’s Midnight Provider Refusal Rule: Upsetting the Emerging Balance in State Pharmacist Refusal Laws*, 46 HOUS. L. REV. 939, 964 (2009).

⁶² *Id.*

⁶³ *Id.* at 963-964.

⁶⁴ 73 FED. REG. 78072.

render them effectively void.⁶⁵ *Stormans v. Selecky*,⁶⁶ which will be discussed later in greater depth, is an example of some of the issues created by the HHS Refusal Rule.⁶⁷ Inherent in that case are issues dealing with basic rights guaranteed by the First and Fourteenth Amendments.⁶⁸

Examples of Tension between Health Care Providers and Patients

The following cases, which are discussed at length, are two of the most fundamental cases to this controversy. *Noesen v. State Dep't of Regulation & Licensing*⁶⁹ has received a great deal of press with regard to this issue; and the opinion explores what the correct balance between patient and health care provider rights should be. Specifically, the court in that case discusses how a pharmacist can conscientiously object while respecting patients' rights. *Stormans v. Selecky* is an important case dealing with pharmacists' right of refusal for emergency contraception and is unresolved.⁷⁰ This case is so important because once it is finally resolved it will be an example of how the HHS Refusal Rule⁷¹ will be employed by the courts.

A. *Noesen v. State Dep't of Regulation & Licensing*⁷²

This case arising out of Wisconsin involved a registered pharmacist, Noesen, who worked for a pharmacy placement service and had subsequently been placed at two K-Mart pharmacy locations. After his placement at the pharmacy locations, Noesen sent a letter

⁶⁵ Jane W. Walker, *The Bush Administration's Midnight Provider Refusal Rule: Upsetting the Emerging Balance in State Pharmacist Refusal Laws*, 46 HOUS. L. REV. 939, 968-969 (2009).

⁶⁶ *Stormans, Inc. v. Selecky*, 524 F.Supp.2d 1245 (W.D. 2007) *rev'd, rem'd, vac'd*, 586 F.3d 1109 (2009).

⁶⁷ 73 FED. REG. 78072.

⁶⁸ *Stormans, Inc. v. Selecky*, 524 F.Supp.2d 1245 (W.D. 2007) *rev'd, rem'd, vac'd*, 586 F.3d 1109 (2009).

⁶⁹ *Noesen v. Wis. Dep't of Regulation & Licensing, Pharmacy Examining Bd.*, 751 N.W.2d 385 (2008).

⁷⁰ *Stormans, Inc. v. Selecky*, 524 F.Supp.2d 1245 (W.D. 2007) *rev'd, rem'd, vac'd*, 586 F.3d 1109 (2009).

⁷¹ 73 FED. REG. 78072.

⁷² *Noesen v. Wis. Dep't of Regulation & Licensing, Pharmacy Examining Bd.*, 751 N.W.2d 385 (2008).

detailing his various conscientious objections. Specifically, “Noesen stated he wished to ‘exercise my right not to participate in’ certain tasks, including dispensing birth control pills for contraceptive purposes.”⁷³ Additionally, Noesen’s letter proposed that “When confronted with an objectionable situation, which most likely would be a refill or new prescription for an oral contraceptive, I understand the necessity of responding in a professional manner with the patient(s), medical staff, and pharmacy staff. I will *immediately* notify the patient of my conscientious objection and offer to call the prescriber or give the original prescription to the patient if it has not yet been filled.”⁷⁴ Upon hearing about Noesen’s objections, the managing pharmacist at one of the K-Mart locations agreed that in situations where Noesen would not fill prescriptions, he would come into the store to fill them if no other pharmacists were available in the store.

In July 2002, Amanda Renz attempted to refill her prescription for birth control pills at the K-Mart pharmacy where Noesen was working. Noesen asked Renz if she intended to use her birth control pills for contraceptives purposes and advised her of his objection and refused to refill the prescription, when she answered that in the affirmative. There were no other pharmacists available that in the K-Mart pharmacy to fill Renz’s prescription and the managing pharmacist was unable to make it into the store. Renz left without Noesen giving her any information as to where or how should could get her prescription filled since he refused to do it.

Renz later took her empty prescription to a Wal-Mart pharmacy in a second attempt to get it filled. However, “when the pharmacist there called Noesen to transfer the prescription, Noesen refused to give the information necessary for Wal-Mart to fill the prescription, believing

⁷³ *Id* at 389.

⁷⁴ *Id* at 390.

it would constitute participating in contraception.”⁷⁵ Renz was finally able to have her prescription filled two days later. As a result of Noesen’s refusal to transfer her prescription, Renz filed a complaint with the Department of Regulation and Licensing. Specifically, the complaint stated that “by refusing to transfer [the] prescription order in these circumstances, [Noesen] engaged in a pharmacy practice which constitutes a danger to the health, welfare, or safety of a patient by practicing in a manner which substantially departs from the standard of care ordinarily exercised by a pharmacist and which could have harmed a patient.”⁷⁶

The administrative law judge said that the central issue was “whether, by refusing to transfer the patient's prescription on the basis of his conscientious objection, [Noesen] departed from a standard of care ordinarily exercised by a pharmacist and which harmed or could have harmed the patient.”⁷⁷ On appeal, Noesen argued “that, by disciplining him for failing to transfer a prescription, the Board has violated his right of conscience.”⁷⁸ Further he suggested that “the State could “establish standards for accommodating the religious and moral beliefs of pharmacists” and “adopt policies regarding access to prescription records that would not require a pharmacist to violate his right of conscience.”⁷⁹

The court stated that in Wisconsin, “when an individual makes a claim that state law violates his or her freedom of conscience, we apply the compelling state interest/least restrictive alternative test...Under this test, the challenger must prove (1) that he or she has a sincerely held religious belief, (2) that is burdened by application of the state law at issue. Upon such a showing, the burden shifts to the state to prove (3) that the law is based in a compelling state

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.* at 392.

⁷⁸ *Id.* at 394.

⁷⁹ *Id.* at 393.

interest, (4) which cannot be served by a less restrictive alternative.”⁸⁰ The court reasoned that although Noesen had sincerely held religious beliefs under the first prong, he was not “burdened by the application of a standard of care, WIS. ADMIN. CODE § Phar 10.03(2), or the discipline imposed by the Board” is satisfaction of the second prong of the compelling state interest/least restrictive alternative test.⁸¹

It is interesting to consider whether Noesen would have been subject to disciplinary action under Wisconsin’s refusal legislation in 2002 if he had merely refused to fill Renz’s prescription without refusing to cooperate in the transfer of her prescription to another pharmacy. In fact, the Board in making their decision to institute formal disciplinary proceedings rather than just give Noesen an administrative warning noted that “testimony gave the distinct impression that satisfying his own personal moral code was his only concern. [Noesen] *did not even acknowledge that he had caused or could have caused harm to a patient.*”⁸² The Board further noted that “respondent is allowed to work as a pharmacist and to exercise his beliefs about contraception; he is merely prevented from doing so in a manner where he deprives patients of their legal health care rights... The imposition of the proposed discipline, training and practice guidelines strike the appropriate balance between the interests of an objecting pharmacist *and the need for protection of the public in this action.*”⁸³ It is clear that the Board did not object to Noesen’s exercise of his right to conscientiously object. Rather, they took issue with the fact that Noesen exercised his right without any express concern for Renz’s rights. Instead of balancing their competing interests, Noesen only acted in accordance with his own interests.

⁸⁰ *Id* at 394.

⁸¹ *Id* at 395.

⁸² *Id* at 394.

⁸³ *Id* at 395.

Another consideration in analyzing this case is what the outcome would have been under the relatively new HHS Refusal Rule.⁸⁴ As previously discussed, this regulation expanded federal refusal legislation for protect health care entities from discrimination when refusing to participate in the assistance of an abortion. While parts of this statute can be read to protect pharmacist from filling or even transferring certain types of contraceptives, it would be interesting to see if a court would find that this applies to routine birth control pills in addition emergency contraception, such as the Plan B pill. Such a finding would illustrate that the HHS Refusal Rule⁸⁵ has diminished patient's rights in favor of health care entities. It would fly in the face of the spirit of the court's ruling in the *Noesen*⁸⁶ as well as the findings of the Board in that case.

B. *Stormans v. Selecky*⁸⁷

The plaintiffs in this case are Storman's Stores, a pharmacy, and two pharmacists. They alleged that regulations adopted by the Washington State Board of Pharmacy in April 2007, "violated their free exercise, equal protection, and due process rights under the First and Fourteenth Amendments because the regulations' enforcement interfered with the free exercise of their religion."⁸⁸ Specifically, they sought to "enjoin the enforcement of regulations making it sanctionable for a pharmacy to permit a pharmacist-employee to refuse to fill a lawful prescription because of religious or moral objections. Specifically, they ask the Court to enjoin enforcement of provisions contained within certain regulations as applied to "Plan B"

⁸⁴ 73 FED. REG. 78072.

⁸⁵ *Id.*

⁸⁶ *Noesen v. Wis. Dep't of Regulation & Licensing, Pharmacy Examining Bd.*, 751 N.W.2d 385 (2008).

⁸⁷ *Stormans, Inc. v. Selecky*, 524 F.Supp.2d 1245 (W.D. 2007) *rev'd, rem'd, vac'd*, 586 F.3d 1109 (2009).

⁸⁸ Jason R. Mau, *Stormans and the Pharmacists: Where have all the Conscientious Rx gone?*, 114 PENN ST. L. REV. 293, 298 (2009).

contraceptives, also known as the "morning after" pill."⁸⁹ The plaintiffs argued a right to "refuse and refer" the patient by claiming a right of refusal to dispense the Plan B or "morning after" pill and instead referring the patient to another pharmacy to have the prescription filled.⁹⁰ According to the court, the plaintiffs' conscientious objection was derived from the fact their "faith informs them that life begins at conception, when an egg from the female is fertilized by the sperm from the male."⁹¹ As, "Plan B prevents the fertilized egg from adhering to the wall of the uterus, one result attained when the morning after pill is administered within 72 hours after unprotected sex, "[p]laintiffs believe that it is wrong to terminate that life."⁹² The plaintiffs also argued that the regulations were not intended to be neutral and instead were created to target "any pharmacist or pharmacy who objects to Plan B for religious reasons."⁹³

The originally sought preliminary injunction was reversed and vacated and the case was remanded to the district court. The opinion states "that the district court abused its discretion in applying an erroneous legal standard of review, failing to properly consider the balance of hardships and the public interest, and entering an overbroad injunction. On remand, the district court must apply the rational basis level of scrutiny to determine whether Appellees have demonstrated a likelihood of success on the merits."⁹⁴ Further, "the district court must also determine whether Appellees have demonstrated that they are likely to suffer irreparable harm in the absence of preliminary relief, whether the balance of equities tips in the favor of the three Appellees, and whether the public interest supports the entry of an injunction. If the court finds in favor of Appellees, it must narrowly tailor any injunctive relief to the specific threatened

⁸⁹ *Id.* at 302-303.

⁹⁰ *Id.* at 329.

⁹¹ *Stormans, Inc. v. Selecky*, 524 F.Supp.2d 1245, 1249 (W.D. 2007) *rev'd, rem'd, vac'd*, 586 F.3d 1109 (2009).

⁹² *Id.*

⁹³ *Id.* at 1259.

⁹⁴ *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1142 (2009).

harms raised by Appellees.”⁹⁵ The final resolution of this matter will likely shed light on the practical enforcement of state refusal statutes in light of the HHS Refusal Rule.⁹⁶

As well as demonstrating the fundamental issues on both sides of the conscience clause debate, *Noesen*⁹⁷ and *Stormans*⁹⁸ along with the HHS Refusal Rule⁹⁹ have reignited the debate with great fervor beyond the legal community and into the general population.

Conscience Clause Debate in the Media

Because the issues surrounding the conscience clause debate deal with fundamental issues of moral and religious beliefs as well as personal privacy and autonomy, it is a subject that has received impassioned debate in the media. An introduction to the complex issues at the heart of the controversy surrounding conscience clause/refusal legislation can readily be found in the media. For example, in October 2009, USA Today published an article exploring the practical implications of the HHS Refusal Rule,¹⁰⁰ which was enacted in 2008.¹⁰¹ It also includes an anecdote from a doctor who refused to write a birth control pill prescription for an unmarried female patient.¹⁰² The doctor, who is an Evangelical Christian, was quoted saying “I’m not going to give any kind of medication I see as harmful.”¹⁰³ Additionally, she said that the contraceptives would not protect her patient from “emotional trauma from multiple partners” and that she “could not ethically give that type of medication to a single woman.”¹⁰⁴ The article

⁹⁵ *Id.*

⁹⁶ 73 FED. REG. 78072.

⁹⁷ *Noesen v. Wis. Dep't of Regulation & Licensing, Pharmacy Examining Bd.*, 751 N.W.2d 385 (2008).

⁹⁸ *Stormans, Inc. v. Selecky*, 524 F.Supp.2d 1245, 1249 (W.D. 2007) *rev'd, rem'd, vac'd*, 586 F.3d 1109 (2009).

⁹⁹ 73 FED. REG. 78072.

¹⁰⁰ 73 FED. REG. 78072.

¹⁰¹ Conscience clauses not just about abortion anymore, http://www.usatoday.com/news/religion/2009-10-24-conscience-doctors_N.htm (last visited May 8, 2010).

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ *Id.*

provides a simplified summary of the debate, with a proponent of conscience clause legislation arguing that he wants to be able to be a pharmacist in a way that allows him to do it “with a good, clear conscience and sleep well at night,” and an opponent of such legislation saying “putting barriers in their way to access those medications only hurts public health.”¹⁰⁵ These are the issues at the basis of the debate. Health care providers want their right to practice their profession in a way that coincides with their religious beliefs and moral convictions protected. At the same time, patients want safeguards on their ability to have access to contraceptives.

Arguments by Proponents of Conscience Clause Legislation

As briefly introduced, there are impassioned arguments on both sides of the conscience clause debate. Indeed, even the names by which these statutes are referred can be indicative of the controversy itself. “Proponents refer to [such legislation] as “conscience clauses” and argue that health care providers have a right to refuse to participate in activities that violate their religious or moral consciences” while “[o]pponents...refer to these laws as “refusal clauses” to emphasize that they allow health care providers to refuse to perform what would otherwise be a legal or ethical duty.”¹⁰⁶

A. Free Exercise, Equal Protection, and Due Process

As previously discussed, the decades-old foundation of this debate lies in *Roe v. Wade*¹⁰⁷ and the subsequent passage of the Church Amendments,¹⁰⁸ which were enacted to protect health care providers who refused to perform or participate in medical sterilization or abortion

¹⁰⁵ *Id.*

¹⁰⁶ Jane W. Walker, *The Bush Administration’s Midnight Provider Refusal Rule: Upsetting the Emerging Balance in State Pharmacist Refusal Laws*, 46 HOUS. L. REV. 939, 942 (2009).

¹⁰⁷ *Roe v. Wade*, 410 U.S. 113 (1973).

¹⁰⁸ 42 U.S.C. § 300a-7 (2010).

procedures on the basis of the religious beliefs or moral convictions. The debate was renewed with great fervor following the enactment of the HHS's Provider Refusal Rule¹⁰⁹ in 2009.¹¹⁰ The HHS Provider Refusal Rule¹¹¹ expanded existing conscience clause legislation. Specifically, “[u]nder the rule, workers in health-care settings -- from doctors to janitors -- can refuse to provide services, information or advice to patients on subjects such as contraception, family planning, blood transfusions and even vaccine counseling if they are morally against it.”¹¹²

Proponents of conscience clause legislation generally couch their arguments in the First and Fourteenth Amendments as is evident by cases such as *Stormans*.¹¹³ Specifically, health care providers and other proponents of conscience clause legislation make arguments about the violation of their free exercise, equal protection, and/or due process rights because suffering discrimination and/or legal liability on the basis of their refusal to perform or participate in certain procedures that are contrary to their individual religious beliefs and/or moral convictions is a violation of the free exercise of their religion.¹¹⁴ In this context, there are doctors and pharmacists who look to conscience clause legislation for protection when refusing to prescribe or dispense contraceptives.

B. Religious Arguments

There are many people, from health care providers to special interest groups to religious organizations, who support conscience clause legislation and its expansion by the HHS. In

¹⁰⁹ 73 FED. REG. 78072.

¹¹⁰ White House set to reverse health care conscience clause, <http://www.cnn.com/2009/POLITICS/02/27/conscience.rollback/index.html> (last visited May 8, 2010).

¹¹¹ 73 FED. REG. 78072.

¹¹² White House set to reverse health care conscience clause, <http://www.cnn.com/2009/POLITICS/02/27/conscience.rollback/index.html> (last visited May 8, 2010).

¹¹³ *Stormans, Inc. v. Selecky*, 524 F.Supp.2d 1245 (W.D. 2007) *rev'd, rem'd, vac'd*, 586 F.3d 1109 (2009).

¹¹⁴ Jane W. Walker, *The Bush Administration's Midnight Provider Refusal Rule: Upsetting the Emerging Balance in State Pharmacist Refusal Laws*, 46 Hous. L. Rev. 939, 942 (2009).

general, religious organizations support conscience clause legislation on the basis of their religious beliefs and their view of the effect of contraceptives in relation to those beliefs. One such proponent organization is the Family Research Council, which has given comments to CNN on this topic.¹¹⁵ According to their website, the Family Research Council “champions marriage and family as the foundation of civilization, the seedbed of virtue, and the wellspring of society. FRC shapes public debate and formulates public policy that values human life and upholds the institutions of marriage and the family. Believing that God is the author of life, liberty, and the family, FRC promotes the Judeo-Christian worldview as the basis for a just, free, and stable society.”¹¹⁶ With regard to “conscience protection,” the Family Research Council’s website says “FRC supports the right of health care professionals and organizations who have conscientious objections to reject participation in or cooperation with the delivery and marketing of abortion or abortifacients, sterilization, contraception, embryo-destroying research or treatments, or euthanasia. Neither the state nor professional licensing bodies can be permitted to impose treatment or referral mandates which violate this right of conscience.”¹¹⁷ As is evident by their website, the Family Research Council’s support of conscience clause legislation is based on their mission to promote “the Judeo-Christian worldview.”¹¹⁸

As illustrated by the Family Research Council, an important part of the reason behind the objections of some health care providers relating to access to contraceptives is religious beliefs about the origin of human life and the role of sexual intercourse. An example of this is the Roman Catholic Church’s teachings on birth control and abortion. The Catholic Church defines contraception as “any action which, either in anticipation of the conjugal act [sexual intercourse],

¹¹⁵ *Id.*

¹¹⁶ About FRC, <http://www.frc.org/about-frc> (last visited May 8, 2010).

¹¹⁷ Human Life & Bioethics, <http://www.frc.org/life--bioethics#conscience> (last visited May 8, 2010).

¹¹⁸ About FRC, <http://www.frc.org/about-frc> (last visited May 8, 2010).

or in its accomplishment, or in the development of its natural consequences, proposes, whether as an end or as a means, to render procreation impossible.”¹¹⁹ On its website the Church adds that their definition of contraception includes “sterilization, condoms and other barrier methods, spermicides, *coitus interruptus* (withdrawal method), the Pill, and all other such methods.”¹²⁰ The Church’s specific teaching on contraception is “Contraception is wrong because it’s a deliberate violation of the design God built into the human race, often referred to as “natural law.” The natural law purpose of sex is procreation... God’s gift of the sex act, along with its pleasure and intimacy, must not be abused by deliberately frustrating its natural end—procreation.”¹²¹ Based on the Catholic Church’s stance on birth control, it is easy to understand that someone who staunchly adheres to the Catholic religion would be opposed to the use of contraceptives. Indeed, this objection might not be limited to a Catholic’s own personal life as the Church’s teaching describes contraception as going against God and nature. By forcing a health care provider with these religious beliefs to prescribe or dispense medication that he or she believes is against God could convincingly be construed as a violation of the health care provider’s rights of free exercise, equal protection, and due process.

With regard to access to the Plan B pill, the Church’s stance on abortion seems pertinent. Specifically, in 1995 Pope John Paul II explicated “I declare that direct abortion, that is, abortion willed as an end or as a means, always constitutes a grave moral disorder, since it is the deliberate killing of an innocent human being. This doctrine is based upon the natural law and upon the written word of God, is transmitted by the Church’s tradition and taught by the ordinary and universal magisterium. No circumstance, no purpose, no law whatsoever can ever make licit an act which is intrinsically illicit, since it is contrary to the law of God which is written in every

¹¹⁹ Birth Control, http://www.catholic.com/library/Birth_Control.asp (last visited May 8, 2010).

¹²⁰ *Id.*

¹²¹ *Id.*

human heart, knowable by reason itself, and proclaimed by the Church.”¹²² For Catholics and other health care providers who believe that human life begins at conception, abortion procedures and, to some, the Plan B pill effectively constitute the act killing a human being.

Such health care providers who believe that human life begins at conception may also believe that because the Plan B pill prevents implantation it causes the end of an already conceived life. Based on this theory, opponents of the use of the Plan B pill “equate it with RU-486,¹²³ which is an abortifacient that changes the uterine lining and expels the implanted embryo.”¹²⁴ It is not difficult to imagine that health care provider with similar beliefs would not only object to participating in abortion procedures but also to prescribing or dispensing the Plan B pill. While religious and moral objections related to contraceptives are not limited to Judeo-Christian beliefs, the preceding provides an example of how such beliefs related to the origin of life and the purpose of sexual intercourse contribute to the need for and use of conscience clause legislation.

Arguments by Opponents of Refusal Clause Legislation

A. Privacy, Personal Autonomy & Public Policy

On the opposite end of the spectrum, opponents of refusal clause legislation are impassioned, too. The trend of cases that preserve and protect women’s health and personal autonomy started with *Roe v. Wade*.¹²⁵ Of the cases that followed, *Grisowld*¹²⁶ and *Eisenstadt*¹²⁷ are both the most pertinent and the most fundamental with regard to the issue of access to

¹²² Abortion, <http://www.catholic.com/library/Abortion.asp> (last visited May 8, 2010).

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Roe v. Wade*, 410 U.S. 113 (1973).

¹²⁶ *Grisowld v. Connecticut*, 381 U.S. 479 (1965).

¹²⁷ *Eisenstadt v. Baird*, 405 U.S. 438 (1972).

contraceptives. As previously discussed, the Court in *Eisenstadt*¹²⁸ held that people have the 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.”¹²⁹ This case was particularly important because it expanded the privacy rights already recognized for married couples and their access to contraceptives to include unmarried couples. Based on *Eisenstadt*¹³⁰ alone, many people would not expect to have their right to have access to contraceptives infringed upon.

In fact, when the Bush Administration’s plan to expand refusal legislation under the current HHS Provider Refusal Rule¹³¹ came to light, there was a great deal of protest from organizations such as the “National Association of Chain Drug Stores, the American Hospital Association [and] the American Medical Association” as well as “28 senators, more than 110 representatives and the attorneys general of 13 states.”¹³² In fact, even officials from the Equal Employment Opportunity Commission opposed the HHS rule arguing that “the proposal would overturn 40 years of civil rights law prohibiting job discrimination based on religion.”¹³³ They “also said that the rule was unnecessary for the protection of employees and potentially confusing to employers.”¹³⁴ Additionally, as the EEOC’s legal counsel explained to the New York Times, “Title VII of the Civil Rights Act of 1964 already prohibits employment discrimination based on religion...and the courts have defined ‘religion’ broadly to include

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ 73 FED. REG. 78072.

¹³² Protests Over a Rule to Protect Health Providers, www.nytimes.com/2008/11/18/washington/18abort.html?_r=2&partner=rss&emc=rss (last visited May 8, 2010).

¹³³ *Id.*

¹³⁴ *Id.*

‘moral or ethical beliefs as to what is right and wrong, which are sincerely held with the strength of traditional religious views’.”¹³⁵

Even prior to the enactment of the HHS Provider Refusal Rule in 2009, there was a growing controversy surrounding the increasing denial of access of contraceptives. *Prevention* magazine explored this issue in an article written in 2004.¹³⁶ The article highlighted the circumstance of a woman who was informed by her gynecologist that not only would she not be able to renew her birth control prescription but that she could also not go to her primary care physician for the prescription because that doctor would be unwilling to do it, too.¹³⁷ These physicians as well as other health care providers “adhere to a controversial belief that birth control pills and other forms of hormonal contraception--including the skin patch, the vaginal ring, and progesterone injections--cause tens of thousands of "silent" abortions every year.”¹³⁸ Their view is based on the fact that “[a]lthough it is designed to suppress ovulation and prevent fertilization, both can--and do--occur in rare cases.”¹³⁹ Additionally, “[w]hile mainstream experts say ovulation happens only 2 to 3 percent of the time and fertilization is rare, anti-Pill groups claim both happen frequently. They say most of these fertilized eggs--in their view, nascent human lives--are unable to attach to the hormonally altered uterine lining. Instead of implanting and growing, they slough off. This theoretical action, which scientists can't confirm, is called the post-fertilization effect.”¹⁴⁰

Further, the article explicates that “[a]t the heart of the debate between anti-Pill forces and mainstream medicine lies a profound difference of opinion about when pregnancy and life

¹³⁵ *Id.*

¹³⁶ Access Denied, <http://www.prevention.com/health/health/healthy-living/the-new-birth-control-ban/article/a9a466263d803110VgnVCM20000012281eac> (last visited May 8, 2010).

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ *Id.*

begin.”¹⁴¹ While, “[t]he long-standing medical definition of pregnancy, held by the American College of Obstetricians and Gynecologists, is that it starts not when an egg is fertilized, but when the fertilized egg implants in the uterine lining”, as previously noted, “anti-Pill doctors and pharmacists say life begins...at fertilization.”¹⁴² Therefore, they view the sloughing off of a fertilized egg as a chemical abortion.¹⁴³ However, the view that contraceptive pills discourage implantation has not been scientifically proven and is even regarded by the American Association of Pro-Life Obstetricians and Gynecologists as speculation.¹⁴⁴ As highlighted by this article, there are a number of health care providers who refuse to prescribe and dispense contraceptives based on views rooted in speculative science.

For opponents to refusal care legislation, this represents a serious problem furthering the infringement of a woman’s right to privacy and personal autonomy in accessing contraceptives. In this regard, the article quoted a reproductive rights ethicist and an assistant professor of obstetrics and gynecology at Duke University Medical Center who said “I have a hard time with people who market themselves as women's health care physicians but who won't prescribe such a basic part of women's health care... We're seeing a growing trend among pharmacists and medical practitioners who consider it acceptable to impose their morality on women's bodies. I don't think moral aspects should be a concern. Imagine a pharmacist asking a customer whether his Viagra prescription is to enhance sexual performance in his marriage or in an extramarital affair. Never!”¹⁴⁵ This quote highlights the views of people in the health care industry who believe that the use of refusal clauses has been taken too far. Additionally, it forces the reader to consider the striking inequality of the treatment of women’s health issues as compared to issues

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

relating to male sexuality. Would a physician who devoutly believes that intercourse should be reserved as an act between a married couple advocate denying a Viagra prescription to a man in an adulterous relationship as well as advocating denying contraceptive pills to an unmarried woman? Additionally, much of the anti-contraceptive debate surrounds the morality of sexual behavior and the inception of human life while ignoring the fact that birth control pills “also widely prescribed by gynecologists and family doctors for other uses, such as clearing up acne, shrinking fibroids, reducing ovarian cancer risk, and controlling endometriosis.”¹⁴⁶ What about the rights of these women?

B. A more balanced approach

Prominent medical organizations have also given their input with regard to access to contraceptives. In 2005, the American Medical Association’s House of Delegates voted to adopt a resolution that is described as “as an attempt to address the concern some physicians have regarding pharmacists objecting to dispensing prescription medications for moral or religious reasons—using what’s often referred to as a ‘pharmacist’s conscience clause’.”¹⁴⁷ According to their website, the American Pharmacists Association “has had a policy supporting a pharmacist’s conscience clause since 1998, around the time when Oregon enacted its physician assisted suicide law. APhA’s two-part policy supports the ability of the pharmacist to step away from participating in activity to which they have personal objections—but not step in the way. The Association supports the pharmacist’s right to choose not to fill a prescription based on moral or ethical values. But recognizing the pharmacist’s important role in the health care system, APhA

¹⁴⁶ *Id.*

¹⁴⁷ AMA rules on pharmacist conscience clauses, <http://www.pharmacist.com/AM/Template.cfm?Section=Search1&template=/CM/HTMLDisplay.cfm&ContentID=8688> (last visited May 8, 2010).

supports the establishment of systems to ensure that the patient's health care needs are served."¹⁴⁸ The stance of the American Pharmacists Association is similar to the stance taken by many of the state refusal statutes that were previously discussed. While the American Pharmacists Association can certainly not be described as in opposition to refusal clause legislation, their position on the appropriate handling of patient's health care needs shows a respect for the role that pharmacists play in the health care system and the responsibility pharmacists have to ensure that patient's health care needs are served. Much of the debate surrounding refusal clause legislation is not attributed to their existence as much as it is the abuse of the use of refusal legislation at the expense of patients' rights.

Analysis and Conclusion

The preceding discussion has focused on the origin of conscience clause or refusal clause legislation in the both the federal and state contexts. This legislation was expanded in 2009 with the enactment of the HHS Provider Refusal Rule.¹⁴⁹ And, with this enactment came a renewed discussion of the controversy surrounding conscience clause legislation in general as well as patient access to contraceptives.

Examples of situations wherein women have been denied access to contraception in various ways are readily available in both litigation and the media. Additionally, impassioned arguments on the both sides of the issue have been made by various groups including political organizations and medical associations.

The reason that this issue invokes such passionate responses is because for health care providers who object to the access of the contraceptives on the basis of their religious beliefs or

¹⁴⁸ *Id.*

¹⁴⁹ 73 FED. REG. 78072.

moral convictions, conscience clause legislation protects their free exercise, equal protection, and due process rights. For women who have been denied access to oral contraceptives, refusal clause legislation represents an infringement on their rights of privacy and personal autonomy. This controversy involves the balancing of fundamental and, at times, opposing rights. Health care providers do not want to be forced under threat of adverse employment action or legal liability to take part in medical procedures, which go against their strongly held religious beliefs and moral convictions. On the other hand, patients do not want to be denied access to medication that they are medically and legally entitled to receive.

Since the Church Amendment¹⁵⁰ was enacted in 1973, state and federal legislation has tried to strike a balance between the rights. However, as a result of 2009's HHS Provider Refusal Rule,¹⁵¹ many experts agree that the balance has been shifted too far in the favor of health care providers to the detriment of patient's rights. It goes against public policy and a respect for women's health to allow such imbalanced legislation. Not only does the HHS Provider Refusal Rule¹⁵² put state conscience clause legislation in flux but it also seems contrary to the methods favored by both the American Medical Association and the American Pharmacists Association.¹⁵³ While refusing to prescribe or dispense contraceptives and then referring the patient to another health care provider who can help them is certainly not a perfect resolution; it is a better one than the current state of conscience clause legislation. In ideal circumstances, there will always be another physician or pharmacist who can step up and assist with patients' health care needs. However, this is not always the case; and the balance of the

¹⁵⁰ 42 U.S.C. § 300a-7 (2010).

¹⁵¹ 73 FED. REG. 78072.

¹⁵² *Id.*

¹⁵³ AMA rules on pharmacist conscience clauses,

<http://www.pharmacist.com/AM/Template.cfm?Section=Search1&template=/CM/HTMLDisplay.cfm&ContentID=8688> (last visited May 8, 2010).

conscience clause legislation needs to be skewed in favor of patients' rights. This position is that which most accurately reflects the spirit of past conscience clause legislation, legal precedent, and the positions of prominent medical associations and adequately respects patient's health care needs.