No. 15-862

IN THE

Supreme Court of the United States

STORMANS, INC., DOING BUSINESS AS RALPH'S THRIFTWAY, *et al.*,

Petitioners,

v.

JOHN WIESMAN, *et al.*,

State Respondents,

and

JUDITH BILLINGS, *et al.*

Intervenor Respondents,

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF FOR THE INTERVENOR RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether the Free Exercise Clause compels a state, at the risk of patient health and safety, to grant pharmacies a religious exemption from their general regulatory obligation to fill all lawful prescriptions.

PARTIES TO THE PROCEEDINGS

Petitioners Stormans, Inc. (doing business as Ralph's Thriftway), Rhonda Mesler, and Margo Thelen are a corporate pharmacy and two individual pharmacists in Washington State. Their lawsuit seeks a religiously based exemption from state regulations that require pharmacies to timely deliver all lawfully prescribed medications to patients.

Those rules were adopted by the Washington Pharmacy Quality Assurance Commission ("Commission"). The State Respondents are current and former members of the Commission and other state government officials: John Wiesman, Dan Rubin, Elizabeth Jensen, Emma Zavala-Suarez, Sepi Soleimanpour, Christopher Barry, Nancy Hecox, Tim Lynch, Steven Anderson, Albert Linggi, Maureen Simmons Sparks, Maura C. Little, Kristina Logsdon, and Martin Mueller.

The Intervenor Respondents are Judith Billings, Rhiannon Andreini, Dr. Jeffrey Schouten, Molly Harmon, Catherine Rosman, Emily Schmidt and Tami Garrard. They are Washington residents, who rely on prescription medications.

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BRIEF FOR THE INTERVENOR RESPONDENTS IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals reversing the district court's order entering a preliminary injunction is reported at *Stormans, Inc.* v. *Selecky* (*Stormans I*), 586 F.3d 1109 (2009), and reproduced at Petitioners' Appendix ("Pet. App.") 265a-332a. The opinion of the court of appeals reversing the district court's order entering a permanent injunction is reported at *Stormans, Inc.* v. *Wiesman* (*Stormans II*), 794 F.3d 1064 (2015), and reproduced at Pet. App. 1a-48a.

JURISDICTION

The judgment of the court of appeals was entered on July 23, 2015. Pet. App. 1a-4a. A petition for panel rehearing and rehearing en banc was denied on September 10, 2015. Pet. App. 261a. The petition for a writ of certiorari was filed on January 4, 2016. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

PERTINENT REGULATIONS

Three provisions of the Washington Administrative Code are involved in the case and reproduced at Pet. App. 344a-350a: Wash. Admin. Code §§ 246-869-150(1) (the "Stocking Rule"), 246-869-010 (the "Delivery Rule"), and 246-863-095 (the "Responsibility Rule").

INTRODUCTION

Pharmacies play a critical role in the nation's health system. Every day, in every state, patients and physicians rely on pharmacies to dispense needed medicines, and to do so safely, accurately, and promptly. That public responsibility necessarily entails an exercise of professional judgment to protect patients' health. But it does not give a pharmacy the right to refuse to fill a lawful, accurate, medically appropriate prescription for private reasons that are entirely its own. Ethically and constitutionally, the paramount interest is the patient's right to health care. A pharmacy's refusal to provide needed medicine puts patient health at risk, disrupts the market for prescription drugs, and interferes in the doctor-patient relationship.

For those reasons, Washington and other states require as a condition of licensure that pharmacies deliver to patients all lawfully prescribed medications. That across-the-board duty covers all prescription drugs and devices, applies to all retail pharmacies (but not to individual pharmacists), and broadly prohibits a pharmacy's refusal to dispense medication, whether for religious or secular reasons. Because Washington's rules are neutral, generally applicable, and designed to protect patients' rights rather than to religiously discriminate against pharmacies, two separate panels of the court of appeals have upheld them under this Court's settled free exercise precedents. Those decisions were correct. The Constitution does not give pharmacies a veto over the health care needs of others.

STATEMENT OF THE CASE

A. Rulemaking history

All 50 states require pharmacies and pharmacists to obtain state licenses and follow regulations promulgated by a state agency. Note, *State Regulation of Drugs: Who May Sell "Patent and Proprietary" Medicines*, 63 Yale L.J. 550, 550 & n.2 (1954). In Washington, the Commission develops and enforces state pharmacy regulations, Wash. Rev. Code § 18.64.005(4), primarily through a complaint-driven process. Pet. App. 37a.

In 2004, the Commission (then called the Board of Pharmacy) began to receive complaints that pharmacists were "refusing to dispense drugs and devices" when presented with valid prescriptions. Intervenor Respondents' Appendix ("Int. App.") 95a, 144a. Those refusals involved a variety of medications, but they represented a particular problem for time-sensitive medications such as hormonal contraceptives. Int. App. 95a-97a. At that time, the Commission's rules did not expressly cover pharmacy delivery refusals. Although the Commission had long required pharmacies to *stock* certain medications, it did not then require actual *delivery* to patients: Since 1967, the Stocking Rule has required pharmacies to "maintain at all times a representative assortment of drugs" approved by the FDA. Wash. Admin. Code § 246-869-150(1). But as of 2006 no Commission rule specifically required pharmacies to *deliver* lawfully prescribed medication to patients as a condition of pharmacy licensure.

To provide clear notice of the rights and responsibilities of pharmacies, pharmacists, and

patients, in 2006 the Commission commenced a 16-month public rulemaking process. Int. App. 87a-91a; Pet. App. 268a. The Commission held 12 public hearings and received more than 21,000 public comments. Pet. App. 268a. Significant testimony focused on pharmacists' refusals for personal, non-clinical reasons to deliver "a variety of prescription medicines and devices" such as contraceptives, "syringes, prenatal vitamins, . . . and AIDS medications." Pet. App. 23a-24a (internal citation omitted); *see also* Int. App. 143a ("We heard about people [who] were not getting access to their diabetic syringes, their insulin, . . . concerns from HIV patients that they may not be getting access to lawful medications."). Commission members expressed concerns that allowing pharmacies to refuse to fill lawful prescriptions would imperil patient' timely access to any number of medications. Int. App. 123a-124a, 135a-136a, 144a-147a. Although Petitioners focus single-mindedly on their own objections to contraceptives, the problem of access addressed by the Commission was much broader. Int. App. 92a-93a.

Adopted unanimously, the final rules were designed to protect patients' rights to access their medications, while simultaneously accommodating individual pharmacists' private objections. *See* Int. App. 94a-120a (Commission's Final Significant Analysis). The rules do not permit a retail pharmacy to refuse to sell lawfully prescribed medications to patients.

B. The rules

The Commission made two changes to its regulations. First, the Commission amended the

"Responsibility Rule" (which applies to *pharmacists* only) to clarify that a pharmacist may be subject to discipline for destroying or refusing to return an unfilled lawful prescription, violating a patient's privacy, or intimidating, harassing, or discriminating against a patient. Pet. App. 350a. The Responsibility Rule, however, "does *not* require an individual pharmacist to dispense medication if the pharmacist has a religious, moral, philosophical, or personal objection to delivery." Pet. App. 12a. Rather, the amendments to the Responsibility Rule "allow[] a pharmacy to 'accommodate' a pharmacist who has a religious or moral objection" to filling a certain prescription. Pet. App. 274a.

Second, the Commission adopted the "Delivery Rule" (which applies to *pharmacies* only) to "require[] pharmacies to deliver lawfully prescribed drugs or devices to patients." Pet App. 344a. A pharmacy must sell a lawfully prescribed medication to the patient unless one of five exceptions applies: (a) an "obvious or known error" in the prescription itself; (b) "national or state emergencies" affecting medical supplies; (c) lack of "specialized equipment or expertise"; (d) "[p]otentially fraudulent prescriptions"; or (e) a drug is out of stock despite a pharmacy's good faith compliance with the Stocking Rule. *Id.*

Under the decades-old Stocking Rule, "[p]harmacies are expected to stock all medications in demand by their patients," but not "to stock all medications on the market," which "would be prohibitively expensive." Int. App. 92a. The Delivery Rule also makes clear that a pharmacy need not deliver a prescribed drug or device without proper payment. Pet. App. 345a.

With those changes, the Commission struck a simple and reasonable balance between pharmacists' personal beliefs and the Commission's primary objective to ensure that patients promptly receive their medications: individual pharmacists may refuse to fill a prescription for personal reasons (including religious objections), but pharmacies may not. Pet. App. 274a.

In striking that balance, Washington State is not alone. Eight states specifically require pharmacies or pharmacists to deliver all lawfully prescribed medications. *See* Cal. Bus. & Prof. Code § 733(a); N.J. Stat. § 45:14-67.1; Wis. Stat. § 450.095(2); Ill. Admin. Code tit. 68, § 1330.500(f) (effective Apr. 23, 2015), *prior version invalidated on state statutory grounds by Morr-Fitz, Inc. v. Quinn*, 976 N.E.2d 1160 (2012); 02-392-19 Me. Code R. § 11 (interpreting 32 Me. Rev. Stat. § 13795(2)); 247 Mass. Code Regs. 6.02(4); Nev. Admin. Code § 639.753(1). Washington's rules closely correspond to the laws of four of those states—Illinois, Massachusetts, Nevada, and Wisconsin—in that they all impose a general duty to dispense medications and do not permit pharmacies to avoid that obligation by referring a patient elsewhere or refusing to stock the drug. Far from an outlier, Washington's rules are actually more solicitous of pharmacists' personal abstentions than New Jersey's statute, which expressly *rejects* as a basis for non-delivery a pharmacist's "sincerely held moral, philosophical, or religious beliefs." N.J. Stat. § 45:14-67.1(a).

Other states have chosen different policy approaches. Six states have broad refusal clauses for health care providers, which may apply to pharmacists, and six others permit pharmacists to

refuse to dispense contraceptives specifically. *See* Guttmacher Institute, *State Policies in Brief: Refusing to Provide Health Services* (Feb. 1, 2016), https://www.guttmacher.org/statecenter/spibs/spib_RPHS.pdf. In the remaining 30 states, however, the laws provide neither a general duty to fill prescriptions nor a right of refusal. *Id.*

As for Washington's rules, the Commission has yet to enforce them and, as the district court acknowledged, no pharmacy or pharmacist has ever been disciplined for violating any of them. Pet. App. 225a.

C. The preliminary injunction

The day before the rules took effect, Petitioners filed this lawsuit, challenging them as unconstitutional under the Free Exercise, Equal Protection, and Due Process Clauses.

The Intervenor Respondents, Washington residents who rely on prescription medications, moved to intervene pursuant to Federal Rule of Civil Procedure 24(a). Dr. Jeffrey Schouten is HIV-positive, and Judith Billings has AIDS. Int. App. 126a, 137a. They depend on physician-prescribed drug regimens to manage their illnesses, and serious health consequences would attend any obstacle to or delay in access. Int. App. 94a, 126a-130a, 137a-140a. Rhiannon Andreini and Molly Harmon were denied emergency contraceptives by Washington pharmacists in separate incidents. Only after enduring harassment, embarrassment, and delay, were these women eventually able to obtain the drug—Andreini, after driving to another pharmacy 60 miles away. Int. App. 74a-76a, 140a-142a, 158a-163a. The Intervenor Respondents

intervened to defend the rules, which protect their significant interests in timely access to prescription medications. The district court granted intervention as a matter of right. Pet. App. 277a.

The district court then entered a preliminary injunction against enforcement of the rules. In its opinion (which Petitioners' appendix omits), the district court looked beyond the "platitudes enunciated by established precedent." Int. App. 52a. The court applied strict scrutiny to the rules because, in its view, the Commission's "overriding objective" was to "target[] the religious practices of some citizens." Int. App. 42a. Dismissing the asserted state interest in promoting timely delivery of prescription medicines, the district court opined that "the regulations have more to do with convenience and heartfelt feelings." Int. App. 50a. The court diminished the Intervenor Respondents' rights to access medications as "not want[ing] to drive farther than the closest pharmacy" and "not want[ing] to be made to feel bad when they get there." Int. App. 51a. According to the district court, the Commission's hidden objective was to "intentionally place a significant burden on the free exercise of religion for those who believe life begins at conception." Int. App. 49a. That "nefarious" regulatory purpose, Int. App. 39a, was inferred not from the text of the rules, nor even the rulemaking record, but from the "prominent role" supposedly played behind the scenes by various bogeymen—namely "Planned Parenthood, the Northwest Women's Law Center," (now called Legal Voice), and then-Governor Christine Gregoire, Int. App. 41a.

Although Petitioners sought to enjoin the rules as applied to themselves only, the district court

enjoined the Commission from enforcing the rules against *any* pharmacy in Washington that objected to dispensing Plan B on religious grounds. Int. App. 57a. The district court noted that it "look[ed] forward to trial of the merits." Int. App. 58a. All Respondents appealed.

D. The court of appeals' decision in *Stormans I*

The court of appeals unanimously reversed the district court's preliminary injunction. Under binding Free Exercise Clause precedents, the *Stormans I* court explained, rational basis review applies to a neutral law of general applicability, even where it incidentally burdens religious practice. Pet. App. 299a-300a (citing *Church of Lukumi Babalu Aye, Inc.* v. *City of Hialeah*, 508 U.S. 520, 531 (1993); *Emp't Div., Dep't of Hum. Res.* v. *Smith*, 494 U.S. 872, 879 (1990)). Washington's rules are neutral and generally applicable, the court held, because they "do not suppress, target, or single out the practice of any religion because of religious content" and because they are "not substantially underinclusive." Pet. App. 306a, 315a. The district court therefore erred in imputing to the Commission a "design to burden religious practice." Pet. App. 312a. The administrative record shows the opposite: the Commission "was motivated by concerns about the deleterious effect on public health that would result" from a broad religious refusal clause for pharmacies. Pet. App. 313a.

Because the district court had not yet made "the appropriate factual findings as to whether the new rules are rationally related to a legitimate governmental purpose," Pet. App. 322a, the court of

appeals "remand[ed] to the district court for consideration of whether the new rules pass rational basis review," Pet. App. 330a.

The court of appeals denied Petitioners' en banc petition, with no judge calling for a vote. Pet. App. 266a.

E. The stay

After the remand, in 2010 the State Respondents and Petitioners agreed to stay the district court proceedings while the Commission considered amending the rules. One proposed amendment would have allowed *pharmacies* "to refuse to dispense" a medication to which they had a personal objection and "instead refer the patient to a nearby pharmacy that will dispense the drug"—a practice the district court called "refuse and refer," *e.g.,* Pet. App. 63a, and which Petitioners call a "facilitated referral," Pet. 7. As part of the stay agreement, the State Respondents and Petitioners also entered a stipulation regarding refuse-and-refer. Pet. App. 334a-337a. The Intervenor Respondents opposed the stipulation and are not parties to it. The district court approved the stipulation only after Petitioners agreed that Intervenors were not "bound by the stipulation[]" and are "free to challenge [its] accuracy." Int. App. 169a-170a.

The Commission eventually declined to amend the rules after receiving additional public testimony highlighting the risks refusals pose to patients' timely access to medications. Multiple physicians testified about pharmacists' refusals to fill prescriptions for a variety of drugs, Int. App. 78a-79a,83a-84a, 147a-158a, including the refusal

to deliver HIV medications because of a patient's perceived homosexuality, Int. App. 156a-158a. A rape survivor testified that after she was first assaulted it took her a "long time" to obtain Plan B, that she was "told no" by multiple pharmacies, and that she had to wait several days to obtain it. Int. App. 77a-78a. Emergency contraception "becomes less effective with each passing hour." Pet. App. 269a. Traumatized by the repeated refusals, the rape survivor testified that was "so upset by the process" that, after being sexually assaulted again later in life, she was discouraged from attempting to obtain Plan B. She became pregnant. Int. App. 77a-78a.

Other witnesses testified to the obstacles refuse-and-refer poses to patients with limited English proficiency or who are unable to drive. *See, e.g.*, Int. App. 60a-73a, 77a-86a; *see also id.* 1a-14a (describing importance of emergency contraception for rape victims). Petitioners acknowledge that they have refused to dispense Plan B to patients, Pet. 7, and have no idea whether those patients ever received the medications Petitioners denied them, Int. App. 164a-168a, 171a-174a.

After the Commission elected not to amend the rules, the district court lifted the stay.

F. The trial

The district court disregarded the court of appeals' remand instruction to apply rational basis review in the first instance, Pet. App. 330a, electing instead to conduct a full-blown trial on the merits. The district court reexamined the neutrality and general applicability issues anew, as though the

court of appeals' decision in *Stormans I* did not exist.

The 12-day trial was an evidentiary free-for-all. In the district court's words, "everything comes in." Int. App. 121a-122a, 124a. For instance, the district court allowed Petitioners to ask countless speculative questions, *see, e.g.*, Int. App. 121a ("It is speculative . . . , but you can ask the question."), and admitted into evidence every one of the hundreds of exhibits offered, *see, e.g.*, Int. App. 132a, 163a-164a. Even witnesses who had never served on the Commission were given free rein to hypothesize how the Commission might interpret the rules in the future. *See, e.g.*, Int. App. 130a (asking non-Commission member "if the Board was confronted with such a complaint . . . , what would the Board's response be?").

Most troublingly, the district court openly aligned itself with Petitioners, announcing that it had "contemplated . . . little more than [this case] for four or five years." Int. App. 132a-135a. The district court advanced arguments against the rules that Petitioners had not raised, and derided the rules as "stupid," "misguided," and a "train wreck." Int. App. 135a-136a. The district court suggested that women's rights organizations were "vigilant," "demanding," and "militant." *See, e.g.*, Int. App. 125a, 134a.

The judgment of the district court was a foregone conclusion. Adopting Petitioners' proposed findings almost verbatim and ignoring the court of appeals' direction in *Stormans I*, the district court again found the rules non-neutral and not generally applicable, applied strict scrutiny, and held that

they failed to meet that exacting standard. Once again, the district court perceived "the purpose" of the rules as "discriminatory"—that is, "to target conscientious objections to Plan B"—despite the court of appeals' contrary holding in *Stormans I*. Pet. App. 242a.

Most perplexingly, the district court found "no evidence" that religiously-based pharmacy refusals "have ever impeded timely access to Plan B," and that enforcing the rules against Petitioners "serves no public interest." Pet. App. 257a. Those findings contradicted Petitioners' admissions throughout the litigation that they personally had "refuse[d] to provide Plan B to patients who request it." Pet. App. 275a; *see* Pet. App. 290a-291a. And the findings usurped the expert judgment of the Commission, the agency charged with regulating Washington's pharmacy industry to protect "public health, safety, and welfare." Wash. Rev. Code § 18.64.005(7). After years of administrative rulemaking, the Commission had concluded that the rules "are needed to minimize barriers to health care and to reduce risks for patients' health." Int. App. 102a.

The district court enjoined not only the Delivery Rule but the Stocking Rule, too, which Petitioners had never challenged. Pet. App. 18a n.2. The court also made the unusual choice to orally deliver its entire 62-page opinion from the bench. Although the court said the "case is a simple decision to make," it was necessary to issue a "lengthy, scholarly decision aimed at a skeptical appellate court." Int. App. 176a.

G. The court of appeals' decision in *Stormans II*

A new panel of the court of appeals unanimously reversed the district court a second time. In *Stormans II*, the court of appeals reiterated that the rules are neutral because they "prescribe and proscribe the same conduct for all, regardless of motivation." Pet. App. 25a. And the rules are generally applicable because they have not been "selectively enforced," their few enumerated exemptions are "tied directly to limited, particularized, business-related, objective criteria," and accordingly they do not allow the Commission to exercise "unfettered discretion." Pet. App. 29a, 36a-37a.

The district court also "clearly erred in finding [that] discriminatory intent" motivated the Commission. Pet. App. 28a. Reiterating its clear instruction in *Stormans I*, the court of appeals noted that the "Commission did not act solely in response to religious objections to dispensing emergency contraception," but was "also concerned with the safe and timely delivery of many other drugs," including AIDS and HIV drugs, prenatal vitamins, and devices used to treat diabetes. Pet. App. 27a. "Nothing in the record developed since *Stormans I* alters that conclusion." Pet. App. 28a.

Because the rules are neutral and generally applicable, the court of appeals applied rational basis review and concluded that the "rules are rationally related to Washington's legitimate interest in ensuring that its citizens have safe and timely access to their lawful and lawfully prescribed medications." Pet. App. 41a.

Petitioners filed a second petition for rehearing en banc. Once again, no judge voted to take the case en banc. Pet. App. 262a.

ARGUMENT

I. THE COURT OF APPEALS CORRECTLY APPLIED THIS COURT'S FREE EXERCISE PRECEDENTS.

The court of appeals upheld the rules in a straightforward application of *Smith* and *Lukumi*, the pillars of this Court's modern free exercise jurisprudence. The decision below breaks no new ground, in no way deviates from this Court's precedents, and neither creates nor exacerbates any circuit split. Nothing about the decision warrants this Court's review, much less summary reversal: Far from a "clear misapprehension" of the applicable legal standards, *Brosseau* v. *Haugen*, 543 U.S. 194, 598 n.3 (2004) (per curiam), the court of appeals' decision faithfully and logically applied the central holding of *Smith*, 494 U.S. at 879, that a neutral, generally applicable law does not violate the Free Exercise Clause just because it incidentally burdens religiously motivated conduct. Because that rule easily resolves this case, both the petition and Petitioners' bold request for summary reversal should be denied.

As explained below, Petitioners distort this Court's precedents in at least two respects. First, they ignore *Smith* (which they fail to cite directly a single time), and instead construct a flawed analogy to *Lukumi*. In *Lukumi*, 508 U.S. at 535, the Court unanimously struck down ordinances prohibiting "ritual" animal "sacrifice" because their unmistakable "design" was to "target" Santeria

believers "and their religious practices." Petitioners say the Commission adopted the rules to suppress their religious practice, but that myopic view ignores the rules' text, their history, and common sense, which all confirm the Commission's secular, legitimate purpose: to ensure patients' timely access to prescription medications. The court of appeals properly upheld the rules under *Smith* and *Lukumi*.

Second, Petitioners ask the Court to do something it has never done: to carve out a free exercise exemption from general state regulatory duties, to the detriment of the very persons the rules seek to protect. Under the Free Exercise Clause, however, a religious exemption is not constitutionally required where it would injure the rights of nonadherents. *See, e.g.*, *Estate of Thornton* v. *Caldor, Inc.*, 472 U.S. 703, 710 (1985) ("'The First Amendment gives no one the right to insist that in pursuit of their own interests others must conform their conduct to his own religious necessities.'") (ellipsis omitted) (quoting *Otten* v. *Baltimore & Ohio R. Co.*, 205 F.2d 58, 61 (2d Cir. 1953) (L. Hand, J.)); *United States* v. *Lee*, 455 U.S. 252, 261 (1982) ("When followers of a particular sect enter into commercial activity as a matter of choice, the limits they accept on their own conduct as a matter of conscience and faith are not to be superimposed on the statutory schemes which are binding on others in that activity.").

Apart from Petitioners' request to refashion established free exercise law, they seek review on two even more dubious bases. They claim the court of appeals "flagrant[ly] disregard[ed] the district court's extensive factual findings." Pet. 22. In addition to being untrue, Petitioners' argument

sidesteps the "independent appellate review" standard that applies in First Amendment cases, *Bose Corp.* v. *Consumers Union of U.S., Inc.*, 466 U.S. 485, 509 (1984), and misconstrues this Court's role as one of routine error correction, *see* Sup. Ct. R. 10.

Finally, Petitioners and various amici ask the Court to decide a question that is not before it, trying to transform this into a case about a pharmacist's purported right not to "participate in what they consider to be an abortion." Pet. 38. Their argument is a misdirection. The rules do not implicate abortions in any way. A Washington statute allows health care providers to decline to participate in abortions, but Petitioners do not rely on that law in support of their requested exemption. Wash. Rev. Code § 9.02.150. Petitioners did earlier press a similar substantive due process claim, but the district court *rejected* it, Petitioners did not appeal, and they did not list it as a question presented in their petition. This case does not involve abortion or substantive due process.[1]

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[1] As a matter of medical science, the emergency contraceptive drugs to which Petitioners object are not abortifacients. Plan B and Ella are synthetic hormones that, like regular hormonal contraception, delay or prevent ovulation. It is well established in the scientific community that Plan B does not prevent implantation of a fertilized egg. *See* U.S. Nat'l Library of Med., Nat'l Insts. of Health, *Med. Encycl.: Emergency Contraception* (Mar. 11, 2014), https://www.nlm.nih.gov/medlineplus/ency/article/007014.htm. And even if emergency contraception did somehow prevent implantation, that would not make it an abortifacient as defined by physicians. *See* Am. Cong. of Obstetricians & Gynecologists, *Facts are Important: The Start of Pregnancy*

A. The rules are valid under *Smith* and *Lukumi*.

The *Smith* rule is clear and, in this case, dispositive: "generally applicable, religion-neutral laws that have the effect of burdening a particular religious practice need not be justified by a compelling governmental interest." *Smith*, 494 U.S. at 886 n.3. If burdening religion is "not the object" but an "incidental effect" of a neutral, generally applicable law, strict scrutiny does not apply. *Id*. at 878; *Lukumi*, 508 U.S. at 531.

Neutrality and general applicability are "interrelated," and provide a judicial mechanism for smoking out the government's forbidden "object or purpose" to "suppress[] religion." *Id*. at 531, 533; *accord Johnson* v. *Robison*, 415 U.S. 361, 384 (1974). *See generally* Elena Kagan, *Private Speech, Public Purpose: The Role of Governmental Motive in First Amendment Doctrine*, 63 U. Chi. L. Rev. 413, 414 (1996).

In this light, both *Smith* and *Lukumi* were clear-cut cases. In *Smith*, 494 U.S. at 878, the Court applied rational basis review to a state drug law that criminalized use of peyote, because the statute was "not specifically directed" at individuals who used peyote for sacramental purposes, and was "concededly constitutional as applied to those who use the drug for other reasons." No religious exemption was required because the drug law did not "represent[] an attempt to regulate religious

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(May 15, 2014), https://www.acog.org/-/media/Departments/Government-Relations-and-Outreach/FactsAreImportantPreg.pdf?dmc=1&ts=20160303T0128531456.

beliefs." *Id.* at 882. As with Washington's rules, in *Smith* any burden to religious practice was an "incidental effect" rather than the "object" of the law. *Id.* at 878.

Lukumi presented the opposite scenario. A city enacted ordinances banning "ritual" animal "sacrifice" shortly after a Santeria church announced plans to open there. 508 U.S. at 527. Suppression of religion was not simply an "incidental effect" of the ordinances, it was the "*exclusive* legislative concern." *Id.* at 536 (emphasis added). All nine Justices agreed that the ordinances purposely targeted Santeria. *See id.* at 524 (majority opinion); *id.* at 559 (Souter, J., concurring in part and in judgment); *id.* at 577 (Blackmun, J., concurring in judgment). Because the city had "single[d] out" Santeria rites so transparently, *Lukumi* was an "easy [case] to decide." *Id.* at 580.

By contrast, here the rules bear none of *Lukumi*'s four hallmarks of discriminatory purpose:

1. Unlike the ordinances at issue in *Lukumi*, which specifically targeted "ritual" animal "sacrifice," here the text of the rules is facially neutral, suggesting no purpose to discriminate against religion. Pet. App. 80a (district court stating that "[t]he rules are facially neutral, and if the [Commission] applied those rules to all pharmacies as written, there is little doubt that the rules would pass constitutional muster").

2. Unlike *Lukumi*, the record reveals no "pattern [of] . . . animosity" to Petitioners or their "religious practices." *Lukumi*, 508 U.S. at 542 (majority opinion). To the contrary, the rules *accommodate*

individual pharmacists by allowing them to decline to fill prescriptions to which they personally object. That accommodation of pharmacists would make no sense if the Commission's goal were to discriminate on the basis of their religious beliefs. Pet. App. 22a-23a. Nothing in the record casts doubt on the Commission's asserted, legitimate purpose to ensure timely access to medications. The Commission was confronted with documented obstacles to the safe and timely provision of a range of medications, including HIV drugs and diabetes devices. Addressing that secular, social harm is a "legitimate concern of government for reasons quite apart from discrimination" and altogether "unrelated to religious animosity." *Lukumi*, 508 U.S. at 535.

3. Next, the rules' few discrete exceptions do not resemble a "religious gerrymander" or render the rules underinclusive. In *Lukumi*, the ordinances were "gerrymandered with care" to prohibit Santeria animal killing "but almost no others"—exempting "hunting, slaughter . . . for food, eradication of insects and pests, . . . euthanasia," and, in a catch-all, any other animal killing deemed "necessary." *Id.* at 542, 537. But here the rules contain no such "pattern of exemptions parallel[ing] [a] pattern of narrow prohibitions." *Id.* at 537. On the contrary, the rules impose a *broad* prohibition of all refusals, whether religiously or secularly motivated, subject to five *narrow* exceptions: the rules do not require pharmacies to permanently stock the many thousands of drugs approved by the FDA; or dispense medications for no payment; or promptly deliver scarce medicines during a federal emergency; or fill prescriptions that are obviously erroneous or fraudulent. Pet. App. 344a. But those common-sense exceptions do not undermine

Washington's legitimate interest in ensuring timely access to medications. They "further" that goal. Pet. App. 31a. "All laws are selective to some extent," *Lukumi*, 508 U.S. at 542, and the "First Amendment does not require States to regulate for problems that do not exist," *McCullen* v. *Coakley*, 134 S. Ct. 2518, 2532 (2014) (internal quotation marks and citation omitted). The rules are not underinclusive under *Lukumi*.

The "circuit split" Petitioners see regarding secular exemptions is illusory. No circuit (nor any other court of which the Intervenor Respondents are aware) has endorsed Petitioners' theory that a law triggers strict scrutiny whenever it exempts some "narrow slice of secular conduct." Pet. 27. *See, e.g.*, *Grace United Methodist Church* v. *City of Cheyenne*, 451 F.3d 643, 651 (10th Cir. 2006) (rejecting "proposition that a secular exemption automatically creates a claim for a religious exemption" under the Free Exercise Clause). The constitutional test is whether exemptions of equivalent secular conduct render a law "underinclusive to a *substantial extent* with respect to each of the [asserted state] interests." *Lukumi*, 508 U.S. at 547 (emphasis added); *accord id.* at 539-40, 543. That "substantial underinclusion" standard is what the court of appeals correctly applied here in finding the rules generally applicable. Pet. App. 29a-32a. And every other circuit to reach that issue—including the Third and Sixth Circuits—has applied the same test under the Free Exercise Clause. *See, e.g.*, *King* v. *Governor of New Jersey*, 767 F.3d 216, 242 (3d Cir. 2014) (rejecting Free Exercise Clause challenge to ban on providing "sexual orientation change" therapy to minors; "[n]one of [the law's] five exemptions . . . demonstrate that [it] covertly

targets religiously motivated" counseling and "nothing in the record suggests that [exempted] forms of counseling are equally harmful to minors") (internal quotation marks omitted); *Mich. Catholic Conference & Catholic Family Servs.* v. *Burwell*, 755 F.3d 372, 394 (6th Cir. 2014) (under Free Exercise Clause, Affordable Care Act's contraceptive coverage requirement was generally applicable despite exemptions for grandfathered plans and small businesses; "[a] law need not apply to every person or business in America to be generally applicable") (citing *Stormans I*, 586 F.3d at 1134), *vacated sub nom. Mich. Catholic Conference* v. *Burwell on statutory grounds*, 135 S. Ct. 1914 (2015); *Blackhawk* v. *Pennsylvania*, 381 F.3d 202, 209 (3d Cir. 2004) (Alito, J.) ("A law fails the general applicability requirement if it burdens a category of religiously motivated conduct but exempts or does not reach a *substantial* category of conduct that is not religiously motivated and that undermines the purposes of the law *to at least the same degree* as the covered conduct that is religiously motivated.") (emphasis added).

In support of the extreme "no-secular-exemption" position in the purported circuit split, Petitioners invoke *Midrash Sephardi, Inc.* v. *Town of Surfside*, 366 F.3d 1214 (11th Cir. 2004). Pet. 24. But *Midrash* is not even a Free Exercise Clause case. Expressly declining to reach the constitutional question, the court applied the "equal terms" provision of the Religious Land Use and Institutionalized Persons Act of 2000 (RLUIPA), 42 U.S.C. § 2000cc(b)(1). *Midrash*, 366 F.3d at 1219 n.1. Under RLUIPA, according to *Midrash*, a zoning ordinance that permits any secular "assembly" (defined broadly) to locate in a neighborhood must also allow a house of worship

there. *Id.* at 1230-31. To the extent *Midrash* is part of a circuit split, it is one over statutory construction, not the Free Exercise Clause. *See, e.g.*, *River of Life Ministries* v. *Village of Hazel Crest*, 611 F.3d 367, 369-70 (7th Cir. 2010) (en banc) (rejecting *Midrash*'s RLUIPA test). It says much about Petitioners' constitutional argument that the best authority they can muster is not a Free Exercise Clause case at all.

There is no circuit split over the constitutional consequences of secular exemptions—nor, as the State Respondents explain in detail, on any other issue. *See* Wash. State Respondents' Br. in Opp. at 24-35.

4. Finally, unlike in *Lukumi*, 508 U.S. at 542, the rules are not overinclusive; they do not "suppress much more religious conduct than is necessary in order to achieve the legitimate ends asserted in their defense." As the court of appeals explained, the rules actually "*protect* religiously motivated conduct" by providing for accommodation of individual pharmacists who personally object to dispensing particular medications. Pet. App. 22a. Unsatisfied, Petitioners seek a further exemption that would allow a retail *pharmacy* to refuse patients and send them elsewhere to procure their medication. Pet. 26. Petitioners make much of the State Respondents' stipulation regarding refuse-and-refer, but the Intervenor Respondents are not bound by it and, as the court of appeals noted, the 2010 stipulation hardly provides "evidence of discriminatory intent by *the Commission* when it adopted the rules in *2007*." Pet. App. 41a. The Commission later considered Petitioners' proposed refuse-and-refer exemption but rejected it, precisely because of its concern the practice would

undermine patients' *timely* access to medications. Pet. App. 26a. Allowing a pharmacy to refuse and refer would not equally "achieve" the Commission's legitimate regulatory interests, *Lukumi*, 508 U.S. at 539, it would compromise them.

In sum, *Lukumi* does not support Petitioners' claim for a religious exemption, and *Smith* forecloses it. "Conscientious scruples [do] not . . . relieve[] the individual from obedience to a general law not aimed at the promotion or restriction of religious beliefs." *Smith*, 494 U.S. at 879 (emphasis added, internal quotation marks and citation omitted).

B. Petitioners are not entitled to an exemption that would injure the rights of third parties.

Washington's rules are not the "rare example of a law actually aimed at suppressing religious exercise." *Lukumi*, 508 U.S. at 564 (Souter, J., concurring in part and in judgment). Rather, the rules' secular, legitimate end stands wholly apart from any religious creed, ritual, or activity. This case, then, falls among the more "typical" free exercise cases, like *Smith*, involving claims for faith-based exemptions from general regulatory obligations. *Id.*

Both before and after *Smith*, this Court has almost uniformly denied such religious exemption claims under the Free Exercise Clause. *See, e.g.*, *Christian Legal Soc'y Chapter of Univ. of Cal., Hastings Coll. of Law* v. *Martinez*, 561 U.S. 661, 697 n.27 (2010) (no religious exemption from university take-all-comers policy); *Hernandez* v. *Comm'r*, 490 U.S. 680, 698-99 (1989) (no

religious exemption from income tax); *Lee*, 455 U.S. at 258-61 (no religious exemption from Social Security tax); *Gillette* v. *United States*, 401 U.S. 437, 461-62 (1971) (no religious exemption from military conscription); *Braunfeld* v. *Brown*, 366 U.S. 599, 609 (1961) (plurality opinion) (no religious exemption from Sunday closing laws); *Prince* v. *Massachusetts*, 321 U.S. 158, 166-71, 166 n.12 (1944) (no religious exemption from child labor laws) (citing *Jacobson* v. *Massachusetts*, 197 U.S. 11 (1905) (no religious exemption from compulsory vaccination laws)). Those cases show that religious beliefs do not "relieve[] an objector from any colliding duty fixed by a democratic government." *Gillette*, 401 U.S. at 461. That clear constitutional rule precludes Petitioners' claim for a religious exemption.

The free exercise claim here is particularly weak because, as the court of appeals explained, Petitioners' requested exemption would endanger patients' timely access to prescription medications. Pet. App. 25a-26a. "To maintain an organized society . . . requires that some religious practices yield to the common good." *Lee*, 455 U.S. at 259. In a community of many faiths, the "limits" on free exercise "begin to operate whenever [religious] activities . . . affect or collide with liberties of others or of the public." *Prince*, 321 U.S. at 177 (Jackson, J., concurring in judgment). This Court has long adhered to that principle: in no decision of which the Intervenor Respondents are aware has the Court exempted a religious objector from a general regulatory duty to the detriment of the law's intended beneficiaries. *See, e.g.*, *Catholic Charities of Sacramento, Inc.* v. *Superior Court*, 85 P.3d 67, 93 (Cal. 2004) ("We are unaware of any decision in which . . . the United States Supreme Court . . .

exempted a religious objector from the operation of a neutral, generally applicable law despite the recognition that the requested exemption would detrimentally affect the rights of third parties.").

Nor, when third-party rights are at stake, has the Court ever employed a balancing test to weigh the regulatory burden to a religious claimant against the costs an exemption would impose on nonadherents. The task of "reconcil[ing] the various competing demands on government, many of them rooted in sincere religious belief," is for "legislatures and other [political] institutions," not for courts. *Lyng* v. *Nw. Indian Cemetery Protective Ass'n*, 485 U.S. 439, 452 (1988). When a claimed religious liberty comes "into collision with rights asserted by any other individual," it is for the "State to determine where the rights of one end and those of another begin." *W. Va. State Bd. of Educ.* v. *Barnette*, 319 U.S. 624, 630 (1943).

The Commission carefully made that determination without sacrificing its goal to ensure timely access to medications: it required pharmacies to deliver all lawfully prescribed drugs while allowing an accommodation for pharmacists with personal objections to filling particular prescriptions. Petitioners dislike the balance it struck, but the Constitution does not give them a "veto over public programs" designed to protect the rights of others. *Lyng*, 485 U.S. at 452. As this Court has explained, "The mere possession of religious convictions which contradict the relevant concerns of a political society does not relieve the citizen from the discharge of political responsibilities." *Smith*, 494 U.S. at 872 (internal quotation marks, citation, and parenthetical omitted).

II. PETITIONERS' REAL DISAGREEMENT IS WITH THE COURT OF APPEALS' REASONABLE APPLICATION OF THE GOVERNING LAW TO THE FACTS.

Petitioners repeatedly assail the factual predicates of the court of appeals' opinion, but their criticism is doubly flawed. First, it overlooks the fact that the Supreme Court is not a court of "error correction." *See* Sup. Ct. R. 10. Even if Petitioners could identify any error in the court of appeals' review of the record (and they cannot), it would not provide a valid basis to grant the petition. Second, in any event the court of appeals' analysis of the voluminous evidentiary record was correct. This case satisfies none of the Court's certiorari criteria, for it presents at most a dispute over the application of the right legal rules to a unique set of facts.

As an initial matter, Petitioners' fact-intensive attacks conceal an important threshold issue—the applicable standard of review of key facts under the Free Exercise Clause. In First Amendment cases, an appellate court must conduct an "independent examination of the whole record," *Bose Corp.*, 466 U.S. at 499 (quotation marks and citations omitted), and a "fresh examination of crucial facts," *Hurley* v. *Irish-Am. Gay, Lesbian & Bisexual Grp. of Boston*, 515 U.S. 557, 567 (1995). In the court of appeals, Petitioners maintained that this *Bose* standard does not extend to free exercise cases, Pet. App. 19a n.5, though Petitioners' own counsel had concluded otherwise when he served on the bench. *See United States* v. *Friday*, 525 F.3d 938, 950 (10th Cir. 2008) (McConnell, J.) ("Although this Circuit has not yet considered whether *Bose*

extends to the Free Exercise Clause, . . . [w]e see no reason for free exercise to be left behind.").

The court of appeals did not resolve the *Bose* review question because the district court's most unfounded factual findings failed to meet even a deferential standard of review for clear error. Pet. App. 19 n.3. If this Court sees closer questions of fact, however, resolving them would require it to address whether *Bose* review applies in free exercise cases. Petitioners skip over that lurking question entirely, and little wonder: the precedents of this Court and the courts of appeals resolve it against them. *Rosenbloom* v. *Metromedia, Inc.*, 403 U.S. 29, 54 (1971) (plurality opinion) ("First Amendment questions of 'constitutional fact' compel this Court's de novo review."), *abrogated on other grounds by Gertz* v. *Robert Welch, Inc.*, 418 U.S. 323 (1974); *United States* v. *Israel*, 317 F.3d 768, 770 (7th Cir. 2003) (independent review of facts in free exercise case); *Tenafly Eruv Ass'n, Inc.* v. *Borough of Tenafly*, 309 F.3d 144, 156-67 (3d Cir. 2002) (same); *New Life Baptist Church Acad.* v. *Town of E. Longmeadow*, 885 F.2d 940, 941-42 (1st Cir. 1989) (Breyer, J.) (same).

In any event, the court of appeals' finding of clear error here was proper—particularly in light of the district court's disregard of the remand instruction to consider the rules under rational basis review. Instead, the district court conducted a 12-day trial largely for show: the district court adopted Petitioners' proposed factual findings almost verbatim and came to the exact "inescapable conclusion" it had reached at the preliminary injunction phase—that the rules "discriminate intentionally" against Petitioners on the basis of religion. Pet. App. 108a. The district court's

decision reflected a highly partial view of rules it considered "stupid" and "misguided." Int. App. 135a. Recognizing the obvious contradictions and deficiencies in the district court's reasoning, the court of appeals rejected the finding of discriminatory intent a second time. Pet. App. 28a.

Three factual issues bear specific mention:

1. The district court interpreted the rules to permit numerous "unwritten" secular exemptions, Pet. App. 89a, but no evidence showed that the Commission would actually apply the rules in the way the court imagined. The court of appeals rejected the district court's grafting of untold exemptions onto the rules. Pet. App. 32a. The district court derived those hypothetical exemptions not from the text of the rules, nor from the authoritative guidance of the Commission, but from selective excerpts of testimony—including witnesses not on the Commission—"about how the Commission might act if it received a complaint" in the future. Pet. App. 32a. Accordingly, the district court "clearly erred by concluded that the Commission permitted those practices or exempted them from enforcement." *Id.* The court of appeals correctly interpreted the regulations to mean what they say.

2. Incongruously, the district court found that "there was no problem of access to Plan B or any other drug" while acknowledging evidence before the Commission that pharmacists (including Petitioners themselves) had repeatedly refused to deliver lawfully prescribed medications. Pet. App. 95a. As the court of appeals noted, the Commission "heard testimony that patients were

not getting access to prescription medications and devices used to treat diabetes and HIV." Pet. App. 27a (internal quotation marks omitted). As a matter of logic, "the immediate delivery of a drug is always a faster method . . . than requiring a customer to travel elsewhere," which "may reduce the efficacy of [the] drugs." Pet. App. 26a. Petitioners acknowledge they have personally refused to fill prescriptions for emergency contraception. Pet. 7; Pet. App. 290a-291a. Given their candid admissions, it is disingenuous to assert that "[n]o customer in Washington has ever been denied timely access to any drug due to religiously motivated" refusals. Pet. at i.

3. Finally, the district court found that the rules have been "selectively enforced" against pharmacies with religious objections to dispensing medications—even though the rules have never been enforced against *anyone*, including Petitioners. Pet. App. 225a. Given that fact, as well as the Commission's legitimate reliance on a complaint-driven enforcement process, the court of appeals rightly found "no evidence of selective enforcement." Pet. App. 40a.

On those bases and others, the court of appeals properly considered the whole record and concluded that the district court had "clearly erred in finding discriminatory intent." Pet. App. 28a. As the court of appeals explained, "even if" the rules were largely in "response to incidents of refusal to deliver Plan B," it would not mean that the Commission harbored an "intent of discriminating against religiously motivated conduct." Pet. App. 28a n.6. Protecting women's health is not discrimination; it is responsible government.

III. THIS CASE DOES NOT IMPLICATE ABORTION OR SUBSTANTIVE DUE PROCESS.

Finally, Petitioners' attempt to make this case about abortion is misguided. Contrary to Petitioners' repeated assertions, neither the rules nor the court of appeals' decision require anyone to participate in abortion. As the district court acknowledged, "pharmacists have a right under state law *not* to participate in an abortion." Pet. App. 155a (emphasis added) (citing Wash. Rev. Code § 9.02.150). At no point in this nine-years-long litigation have Petitioners contended that the rules conflict with that Washington statute.

In their complaint, Petitioners did raise a similar "abortion-refusal" theory based on substantive due process. But even the district court rejected that claim. Pet. App. 254a. Petitioners did not appeal the district court's ruling, nor does their petition arguably raise the forfeited argument as a question presented. Pet. at i; *see* Sup. Ct. R. 14.1(a) ("Only the questions set out in the petition, or fairly included therein, will be considered by the Court."); *United States* v. *Jones*, 132 S. Ct. 945, 954 (2012) (issues not raised in court of appeals are forfeited).

This case is not about abortion. It is not even about contraception, despite Petitioners' best efforts to frame it that way. The religious exemption they seek under the Free Exercise Clause would sweep far more broadly than they acknowledge. It would permit a pharmacy to deny patients *any* medication on account of personal scruples. As this Court's cases show, no such constitutional right exists. The Free Exercise Clause does not compel a state to exempt

pharmacies from general regulatory obligations at the expense of patient welfare.

CONCLUSION

The petition should be denied.

Respectfully submitted.

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APPENDIX

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ER470-480
Expert Report of Karil Klingbeil, MSW

The Honorable Ronald B. Leighton

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON

STORMANS, INCORPORATED doing business as RALPH'S THRIFTW AY; RHONDA MESLER; and MARGO THELEN, Plaintiffs, v. MARY SELECKY, Acting Secretary of the Washington State Department of Health, et al., Defendants.	Case No. C07-5374-RBL **EXPERT REPORT OF KARIL KLINGBEIL, MSW** **September 26, 2008**

1. My name is Karil Klingbeil. I am a former Associate Professor at the University of Washington's School of Social Work and Adjunct Associate Professor in the Department of Psychiatry and Behavior Sciences at the University of Washington Medical School. I am also the former Director of Social Work at Harborview Medical Center and the founder of the Harborview Center for Sexual Assault and Traumatic Stress, the first

trauma center of its kind in the nation. I have more than 36 years of clinical experience evaluating and treating survivors of rape, incest, and intimate partner violence. I have been retained by the Defendant-Intervenors in this litigation.

I. Assignment

2. Counsel for the Defendant-Intervenors asked me to provide a report explaining the prevalence of rape and intimate partner violence in the United States and Washington State; the help-seeking behaviors of women and girls who have been raped; the effect of post-traumatic stress symptoms and/or the disorder on women and girls who have been raped; the significance of emergency contraception in treating rape survivors; and the impact of a refusal to provide emergency contraception to survivors of rape.

3. This report sets forth my opinions on this matter and describes the data and information that underlie my opinions. I reserve the right to present demonstrative exhibits containing my analysis at trial, supplement my opinions as I continue to refine my analysis as new evidence becomes available and in response to opinions expressed and analyses introduced by plaintiffs' experts, depositions and trial testimony. I have waived my usual fee of $150 per hour and am providing my services without charge.

II. Qualifications

4. I received my Masters of Social Work at the University of Washington School of Social Work in 1960 and my undergraduate degree in

Sociology and Psychology at the University of Washington in 1957.

5. I am retired from my positions as Associate Professor at the University of Washington School of Social Work, Director of Social Work at Harborview Medical Center, and Adjunct Associate Professor in the Department of Psychiatry and Behavioral Sciences at the University of Washington School of Medicine. However, I have maintained a part-time practice in forensic social work and continue to testify as an expert witness. My complete CV is attached as Appendix A.

6. My special area of academic interest is interpersonal violence. I have written articles and presented extensively throughout the United States on various aspects of domestic violence and trauma. In 1973, I founded the first sexual assault trauma center in the country at the Harborview Medical Center in Seattle, Washington. I also helped write Washington State's rape statute.

7. In the course of my career, I have testified as an expert witness in hundreds of cases, both civil and criminal, in state and federal courts throughout the Pacific Northwest, on the effects of post-traumatic stress syndrome and the symptoms suffered by trauma survivors, including rape victims.

8. In the late-l980s I participated in an invitational conference in the area of family violence called by former Surgeon General C. Everett Koop. My work for that conference, including recommendations for hospital-based assessment and detection of family violence and

community prevention, was incorporated into his recommendations to the Center for Disease Control's section on Violent Crime.

9. At the University of Washington School of Social Work, I taught graduate courses on Family Violence, including child abuse, incest, spouse/partner abuse, rape, sibling abuse, elder abuse, and stalking behavior. I also taught child development courses and seminars on ethics in health care and jury debriefing. Much of the course content was repeated in my lectures in the medical school for psychiatry residents, medical, and nursing students.

10. My opinions offered in this case are based on my own research and study, my decades of clinical experience, and my review of current literature and research on trauma, sexual assault, and intimate partner violence.

III. Opinion

A. Definition of Rape

11. Rape is forceful sexual intercourse whether oral, anal, or vaginal penetration, committed against a person's will and without their permission. Sexual assault is the legal term for rape.

B. Prevalence of Rape

12. The United States Department of Justice, through its National Institute for Justice, completed a comprehensive national study of rape

prevalence in 2006 ("DOJ Rape Study").[1] That study indicated that, as of 2006, almost 18 million American women had been raped. More than half of those women were raped before the age of 18. While the DOJ Rape Study attempted to address the problem of underreporting, most experts in the field of sexual assault believe that this number is low, and suggest that 1 in 6 (or sometimes 1 in 4) women are likely to be raped in her lifetime.

13. As elsewhere in the United States, women and girls in Washington experience high rates of rape, with the majority of those rapes occurring before the age of 18. The Harborview Sexual Assault & Trauma Center conducted a study on the prevalence of sexual assault in Washington State.[2] The study, completed for the Washington State Office of Crime Victim Advocacy in October 2001, indicated that 23% of the Washington State women surveyed indicated they had been raped in their lifetime. Consistent with the national figures, the majority of those rapes were committed against girls under the age of 18.

C. Prevalence of Intimate Partner Violence and Rape Within Intimate Partner Violence

14. "Domestic violence" is a term commonly used to describe abuse by a spouse or

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[1] P. Tjaden & N. Thoennes, U.S. Dept. of Justice, Extent, Nature and Consequences of Rape Victimization: Findings from the National Violence Against Women Survey (Jan. 2000).

[2] L. Berliner et al., Office of Crime Victims Advocacy, Sexual Assault Experiences and Perceptions of Community Response to Sexual Assault (Oct. 2001).

intimate partner. However, because that term includes other types of abuse within a family, such as child abuse or elder abuse, "intimate partner violence" is the more accurate term to describe abuse by a spouse, intimate partner, or someone a woman is dating.

15. Intimate partner violence refers to a spectrum of behaviors designed to maintain power and control over an intimate partner. Physical assault, sexual assault, and threats of murder or suicide are, short of murder, the most extreme forms of intimate partner violence. However, intimate partner violence may also include other behaviors designed to control a partner, including stalking, threats to children or other family members, isolating a victim from family and friends, or limiting a victim's access to money and work.

16. As with sexual assault, intimate partner violence is an all-too-common experience for women nationally and in Washington State. A national survey, also conducted by the Department of Justice, indicated that almost one-quarter of American women have been victims of intimate partner violence.[3] A study in 2006 of women in Idaho and Washington indicated that 44% of women in those two states had experienced such abuse.[4]

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[3] P. Tjadden and N. Thoennes, U.S. Dept. of Justice Office of Justice Programs, Full Report of the Prevalence, Incidence, and Consequences of Violence Against Women (Natl. Institute of Justice 27 Nov. 2000).

[4] Bonomi, A., et al., *Intimate Partner Violence: Prevalence, Types, and Chronicity in Adult Women*, 30 Am.

17. Not all intimate partner abuse includes rape, but rape commonly co-occurs with intimate partner violence. In my clinical experience, rape by an intimate partner is an overwhelmingly common aspect of intimate partner violence, but the women who experience it are very unlikely to tell anyone about it. There are many complex reasons that women do not report sexual assault by intimate partners, but one significant aspect for women, across cultural backgrounds, is the heightened sense of shame and degradation of self-worth that they experience after rape within a marriage or by an intimate partner.

18. Of late, researchers have paid increasing attention to the experience of teen girls in abusive relationships. A 2007 study, published in Ambulatory Pediatrics, indicates that men who abuse teenage girls use pregnancy – coerced through sexual assault or birth control sabotage – as a means of maintaining control of their victims.[5] A 2000 study of pregnant and parenting teenagers receiving public assistance benefits showed similar results. [6] Both school and work sabotage are strongly related to behavioral birth control

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Jml of Preventative Med. 447 (2006).

[5] E. Miller, et al, *Male Partner Pregnancy Promoting Behaviors and Adolescent Partner Violence: Findings from a Qualitative Study with Adolescent Females*, 7 Ambulatory Pediatrics 360 23 (2007).

[6] Center for Impact Research, Domestic Violence and Birth Control Sabotage: A Report from the Teen Parent Project, (Feb. 2000), *available at* http://www.issuelab.org/research/domestic_violence_and_birth_control_sabotage_a_report_from_the_teen_parent_project.

sabotage, a suspected factor before the research, but now confirmed.[7]

D. Women and Girls Who Are Raped Generally Do Not Report the Rape or Seek Medical Care

19. Rape is a vastly underreported crime. The Washington State study of rape prevalence indicated that only 15% of women and girls who had been raped in this state reported the rape to law enforcement.[8] National statistics reported in August of 2002 by the United States Department of Justice showed that only 36% of rapes were reported to law enforcement.[9] My clinical experience working with rape victims reflects these findings.

20. There are a whole host of reasons for this lack of reporting. Children and young girls who are the victims of incest or rape are frequently threatened by the perpetrator and are afraid that if they report, they or someone they care for will be injured or killed. Adult women frequently do not report rapes because of the societal understanding that their report will not be believed, or that they will be blamed in some way for the rape. Unfortunately, this reticence reflects reality: rape victims are frequently re-traumatized by the response of untrained police officers, prosecutors,

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[7] *See supra* n.2.

[8] Callie Marie Rennison, U.S. Dept. of Justice, Office of Justice Programs, Rape and Sexual Assault: Reporting to Police and Medical Attention, 1992-2000 (Aug. 2002), *available at* www.ojp.usdoj.gov/b js/pub/pdf/rsamOO.pdf.

[9] *Id.*

and courts (as well as disbelieved by juries) when they report a rape.

21. In 2002, the United States Department of Justice studied whether women who have been raped sought medical care.[10] The study looks at women who were injured physically during the rape. Again, despite physical injury, most women did not receive treatment for their injuries. Women who did not report rape to the police were the most likely not to get treatment for their injuries - only 17% of those women were treated.

E. Consequences of Rape

22. Rape is the most devastating crime for its victims. Some have referred to it as the ultimate savagery. It damages the physical, mental, and social well-being of its victims. As if the attack itself isn't traumatic enough, it carries with it significant sequelae that are both threatening and terrorizing. Women subject to rape have numerous traumatic and psychological reactions, including grief, anger, shame, and debilitating moments of reliving the experience of a rape. Women may react after a rape by engaging in self-destructive behaviors including suicide, substance abuse, and eating disorders. They may also experience fear of sexually transmitted disease, pregnancy, or having lasting scars or physical damage from the rape.

23. Those reactions can range, clinically, from a variety of symptoms associated with post-traumatic stress to full-blown Post Traumatic Stress Disorder (PTSD). Many women who have been raped also experience Rape Trauma

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[10] Rennison, Rape Reporting Study (Aug. 2002).

Syndrome (RTS), a subset of PTSD. Most rape victims exhibit at least some of the symptoms of post-traumatic stress.

24. PTSD is a condition that arises when a person is exposed to a traumatic event(s) involving actual or threatened death or serious injury, or a threat to the physical integrity of self or others. The event results in specific definable characteristics which include re-experiencing symptoms, avoidant symptoms, and arousal symptoms. Re-experiencing symptoms include but are not limited to recurrent and intrusive distressing recollections of the event, including images, thoughts or perceptions. Avoidant symptoms include efforts to avoid thoughts, feelings or conversations associated with the trauma; efforts to avoid activities, places, or people that arouse recollections of the trauma; inability to recall an important aspect of the trauma; diminished interest or participation in significant activities; feeling of detachment or estrangement from others; restricted range of affect; and a sense of a foreshortened future. Arousal symptoms include difficulty falling or staying asleep; irritability or outbursts of anger; difficulty concentrating; hyper-vigilance; and exaggerated startle response.

25. Rape Trauma Syndrome is similar to PTSD and considered a sub-set of PTSD. It refers to a system of responses seen in most people who suffer the trauma of sexual assault. There are three components of RTS: the Acute Phase, the Adjust Phase, and the Reorganization Phase. In the acute or shock phase which may last for days to several weeks, the victim's life has been drastically disrupted and she is usually experiencing shock

and some disorientation, along with physical reactions and potential injuries from the assault. The Adjustment Phase involves the lessening of both physical as well as psychological symptoms. She may talk less about the event, or if she hasn't talked to someone at all, she may now begin to do so. Her life starts to make sense and she is less anxious. The Reorganization Phase begins usually as the victim starts to integrate the experience into their daily life. The phase varies in time and will usually depend on the age, personality style and support system. A strong support system is critically important.

26. While many women recover from these symptoms or PTSD, some women continue to experience debilitating symptoms for many years or a lifetime after being raped.

27. The fear of pregnancy compounds the trauma of rape. Women can and do become pregnant as a result of rape. A 3-year longitudinal study of American women estimates that approximately 5% of rapes result in pregnancy.[11] Extrapolating from the national rate of rape per year indicates that about 32,000 women become pregnant as a result of rape each year. The fear of pregnancy increases a victim's susceptibility to PTSD and RTS.

28. Even if the rapist is a husband or partner, the victim may have many reasons for not wanting to be impregnated. In particular,

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[11] M.M. Holmes, et al., Rape-related Pregnancy: Estimates and Descriptive Characteristics from a National Sample of Women, 175 Am. Jml of Obstetrics & Gynecology 320 (1996).

pregnancy is often used by abusers to keep their partners dependent on them, essentially keeping them at "home in the kitchen." Even if she tries to leave her abuser, having a child with an abusive intimate partner usually means a lifetime of contact, giving the abusive partner multiple opportunities to continue the abuse. This also puts a child at great risk of harm.

F. Significance of emergency contraception to rape victims

29. Having access to emergency contraception may alleviate the trauma of the rape. Quite simply, the possibility of pregnancy becomes one less problem the victim has to deal with. She can then go on to seek support, treatment, and hopefully resolution of other issues.

30. Provision of emergency contraception is the standard of care for rape victims. A copy of the protocol for treatment of sexual assault victims from the Harborview Center for Sexual Assault and Traumatic Stress is attached as Appendix D (see page 21). In fact, hospital emergency rooms in Washington State are required, by law, to provide emergency contraception to rape victims. But, as noted above, the vast majority of rape victims do not report the crime or seek medical treatment.

31. Accordingly, the only source of emergency contraception for a rape victim may be a pharmacy. Going to a pharmacy may be very difficult for a rape victim. If the victim is young, she may have never been to a pharmacy for anything, so going now to seek emergency contraception could be very intimidating. The victim may be embarrassed to ask for help and

fearful that she will have to disclose the assault to a stranger and this may increase any shame and low self-esteem that she experienced as a result of the rape. People of different cultures may have strong customs or taboos regarding sex and therefore not know how to talk about it or find it impossible to explain what they want from the pharmacy.

32. If a victim has faced these fears and gone to a pharmacy for help, if the pharmacist then refuses to provide emergency contraception to the victim, it may re-traumatize her, promoting PTSD and RTS. She may abruptly leave the counter. She may experience feelings of rejection, anger, low self-esteem, feeling dirty, feeling not wanted or respected, or bewilderment. She may conclude that no one will help her and become suicidal. This is especially true if she has not received any medical assistance and wants to take care of her concerns herself. If the refusal is accompanied by a pharmacist imposing his or her own ideas, beliefs and thoughts (whether religious or not) on the victim, it can be a defining moment for her at a time when she is most vulnerable to serious and potentially debilitating re- traumatization.

33. The impact of a refusal to provide emergency contraception may not be alleviated by a referral to another pharmacy. Trauma symptoms may prevent the victim from going to another pharmacy. Victims of intimate partner violence may find it hard or dangerous to get away again to seek help, as control of a victim's access to money, transportation, and time commonly co-occur with intimate partner violence.

34. Prevention of all rape and intimate partner violence should be a goal for all hospitals, clinics, social service programs, criminal justice programs, towns, cities, and the country as a whole. These crimes are considered by most researchers and clinicians to be a major public health epidemic and presents a real threat to individuals and communities. Rape, of course, is one of the more serious of these crimes. Like all treatment providers and systems, pharmacists are a vital and much needed component of the health care team. Their role in the provision of emergency contraception after a rape is critical.

35. After participation in former Surgeon General Koop's First Annual Conference on Family Violence in 1985, I published a companion paper entitled "A Comprehensive Model of Community Organization," that addresses steps to prevent all types of family/stranger violence, including rape. As I stated in that report, "[o]ne group cannot do it alone. One discipline cannot do it alone. One system cannot do it alone. Rather we must have a balanced effort of clinical or micro services and at the same time, we must have the macro or community connections."

Respectfully submitted this 1st day of October, 2008.

Karil Klingbeil, MSW

ER643-669
Order Granting Preliminary Injunction

The Honorable Ronald B. Leighton

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

STORMANS, INCORPORATED doing business as RALPH'S THRIFTW AY; RHONDA MESLER; and MARGO THELEN, Plaintiffs, v. MARY SELECKY, ACTING SECRETARY OF THE WASHINGTON STATE DEPARTMENT OF HEALTH, et al., Defendants.	Case No. C07-5374-RBL **ORDER GRANTING PRELIMINARY INJUNCTION** **September 26, 2008**

THIS MATTER comes before the Court on Plaintiffs' Motion for Preliminary Injunction. Plaintiffs are two pharmacists and one corporate pharmacy. They seek 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" contraceptives, also known as the "morning after" pill.

Plaintiffs' faith informs them that life begins at conception, when an egg from the female is fertilized by the sperm from the male. 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. Plaintiffs believe that it is wrong to terminate that life. They claim a right of conscience to refuse to dispense Plan B, and to instead refer the patient to a nearby pharmacy that will dispense the drug. This practice is known as "refuse and refer."

Defendants are appointed government officials in Washington state who fall into two categories. One group is charged with the promulgation, interpretation and enforcement of the recently adopted regulations, WAC 246-863-095 and 246-869-010. The other group of defendants is responsible for enforcing the Washington Law Against Discrimination, RCW 49.60 et. seq.

The Court has granted a motion to intervene [Dkt. #50] allowing participation by seven individuals: five women who claim to have been affected by the conduct of pharmacists opposed to Plan B contraceptives and two HIV positive individuals who express concerns about access to vital medicines they need to survive.

The Court has reviewed the materials submitted by the parties and participated in extensive oral argument with counsel and for the

following reasons **GRANTS** limited relief as more particularly described in the body of this Order.

FACTUAL BACKGROUND

I. Regulating Authority.

The Washington State Board of Pharmacy (the "Board") regulates the practice of pharmacies and pharmacists in the State of Washington pursuant to RCW 18.64 et. seq. The Board is charged with enforcing all laws placed under its jurisdiction, establishing the qualifications of pharmacists, and promulgating "rules for the dispensing, distribution, wholesaling, and manufacture of drugs and devices and the practice of pharmacy for the protection and promotion of the public health, safety and welfare." RCW 18.64.005. Pharmacies are required to be licensed under RCW 18.64.020. The Board is authorized to take disciplinary action against a pharmacy license per RCW 18.64.165. The Uniform Disciplinary Act provides procedures for disciplining health care providers, including pharmacists, who violate standards of professional conduct. RCW 18.130 et. seq.

II. Existing Laws Regarding Discrimination and Conscience.

Beginning as early as 1957, the people of Washington have been subject to a comprehensive law against discrimination. RCW 49.60 et. seq. In an exercise of the police power for the protection of the public welfare, health, and peace of the people, the legislature recognized and codified a right to be free from discrimination because of race, creed, color, national origin, or sex. RCW 49.60.010 and

.030. This law is known as the Washington Law Against Discrimination (WLAD).

In 1987, the state Legislature adopted the Health Care Access Act. RCW 70.47 et. seq. In 2002, the people, by referendum, passed amendments aimed at further improving the health of low-income children and adults by expanding access to basic health care. RCW 70.47.002. One group targeted to benefit from the act was low-income pregnant women. RCW 70.47.010(2)(c). As a part of the Health Care Access Act, the legislature expressed the recognition "that every individual possesses a fundamental right to exercise their religious beliefs and conscience." RCW 70.47.160(1). The Legislature further acknowledged that "in developing public policy, conflicting religious and moral beliefs must be respected." RCW 70.47.160(1). Accordingly, the Legislature provided that "no individual health care provider, religiously sponsored health carrier, or health care facility may be required by law or contract in any circumstances to participate in the provision of or payment for a specific service if they object to so doing for reason of conscience or religion." RCW 70.47.160(2)(a). No person may be discriminated against in employment or professional privileges because of such objections. RCW 70.47.160(2)(a). The right of conscience, however, is not intended to result in a patient being denied timely access to any service included in the basic health plan. RCW 70.47.160(2)(b).

An identical right of conscience was included within the Insurance Reform Act adopted by the Legislature in 1995. RCW 48.43.065.

III. Development of Regulations.

According to the Final Significant Analysis for Rule Concerning Pharmacists' Professional Responsibilities (WAC 246-863-095) and Pharmacies' Responsibilities (WAC 246-869-010) (Exh. K to Decl. of Kristen Waggoner, Dkt. #11), in 2004, the media began reporting incidents occurring nationwide in which pharmacists refused to dispense prescriptions for moral, religious and personal reasons. Since 2004, complaints were filed with the Board of Pharmacy (Board) concerning some pharmacists refusing to fill prescriptions. In 2005, the Board began to receive calls and emails inquiring into the Board's position on pharmacists refusing to dispense drugs and devices for moral or ethical objections. Board staff concluded that Washington State Pharmacy laws and rules were silent on the issue.

The Washington State Pharmacy Association (WSPA) informed the Board that it had formed an ad hoc committee to develop its position on the issue and requested an opportunity to present the Committee's findings to the Board. WSPA made its presentation to the Board in January of 2006, recommending that pharmacists be allowed to refuse to fill a prescription on religious or moral grounds but that the pharmacist "respect the autonomy of the patient, and not impede the patient's right to seek the service being requested." (Exh. D to Decl. of Kristen Waggoner, Dkt. #11). Consistent with RCW 70.47.160(2)(a) and RCW 48.43.065, the proposed rule would have permitted the "refuse and refer" response to a lawful prescription.

Planned Parenthood and the Northwest Women's Law Center also made presentations to the Board (March 2006), advocating against the right of a pharmacist or pharmacy to "refuse and refer" based on religious objection to Plan B. (Exh. D to Decl. of Lisa Salmi, Dkt. #45). In April 2006, the Board filed a notice to initiate the rulemaking process in order to examine a pharmacist's responsibilities to dispense lawful prescribed drugs or devices. (Exh. K to Decl. of Kristen Waggoner, Dkt. #11). The Board has acknowledged that while issues of access and conscience applied to several types of medications, public attention and comment during the rulemaking process focused on Plan B and other prescription birth control products.[1]

On April 17, 2006, in a letter directed to the Pharmacy Board, the Washington State Human Rights Commission offered its opinion on the subject of the right of conscience and access to Plan B:

> It is the position of the WSHRC that allowing pharmacists to discriminate, based on their personal religious beliefs, against women and others trying to fill lawful prescriptions would be discriminatory, unlawful, and against good public policy and the

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[1] Plan B was available only by prescription from 2003 to late 2006. In December 2006, the U.S. Food and Drug Administration approved Plan B for over-the-counter distribution (stocked behind the counter) for women 18 and older. Plan B remains available to women under 18 by prescription only. No party has suggested that the FDA's decision in any way changes the issues currently before this Court.

> public interest. It is also WSHRC's position that allowing a practice of 'refuse and refer' as a means of addressing this issue, allows and perpetuates discriminatory behavior.

(Exh. J to Decl. of Kristen Waggoner, Dkt. #11). The Commission further opined that the Washington Law Against Discrimination (WLAD) would be violated if the pharmacy/pharmacist (a) refused to stock Plan B, (b) refused to dispense Plan B and instead referred to a nearby pharmacy, or (c) refused to dispense Plan B and instead referred the request to another pharmacist working in the same store on the same shift. The Commission also suggested that the Board of Pharmacy itself would violate the WLAD if it adopted a regulation that included the right of conscience. *Id*.

The Board reviewed Washington laws related to conscience clauses and discrimination. It also referred to regulations adopted in other states. Ultimately, on June 1, 2006, The Board unanimously voted to pursue a draft rule that allowed a pharmacist to refuse to dispense a medication but required that no pharmacy or pharmacist obstruct a patient's effort to obtain lawfully prescribed drugs or devices. (Exh. C to Decl. of Kristen Waggoner).

Reaction to the Board action was immediate. That same day, Governor Gregoire sent a letter to the Chairman of the Pharmacy Board stating her strong opposition to the draft rule. The Governor emphasized that "no one should be denied appropriate prescription drugs based on the personal, religious or moral objection of individual

pharmacists." (Exh. E to Decl. of Kristen Waggoner, Dkt. #11). At a press conference later that week the Governor acknowledged that she could remove the entire Board with the legislature's consent but she would prefer not to take such a drastic step. (Exh. F to Decl. of Kristen Waggoner, Dkt. #11).

On August 28, 2006, Governor Gregoire submitted to the Board an alternative rule that required pharmacies to dispense lawfully prescribed drugs and prevented pharmacists from refusing to dispense a medicine or medical device for religious or moral reasons. (Exh. G to Decl. of Kristen Waggoner, Dkt. #11). The Board voted to reconsider its position on a conscience clause. On April 2, 2007, the Board voted unanimously in favor of adopting the substantive provisions of the rule proposed by the Governor. The regulations adopted by the Board became effective on July 26, 2007. They provide as follows:

> WAC 246-863-095
> Pharmacist's professional responsibilities.
>
> (1) A pharmacist's primary responsibility is to ensure patients receive safe and appropriate medication therapy.
>
> (2) A pharmacist shall not delegate the following professional responsibilities:
>
> (a) Receipt of a verbal prescription other than refill authorization from a prescriber.

(b) Consultation with the patient regarding the prescription, both prior to and after the prescription filling and/or regarding any information contained in a patient medication record system provided that this shall not prohibit pharmacy ancillary personnel from providing to the patient or the patient's health care giver certain information where no professional judgment is required such as dates of refills or prescription price information.

(c) Consultation with the prescriber regarding the patient and the patient's prescription.

(d) Extemporaneous compounding of the prescription, however, bulk compounding from a formula and IV admixture products prepared in accordance with chapter 246-871 WAC may be performed by a pharmacy technician when supervised by a pharmacist.

(e) Interpretation of data in a patient medication record system.

(f) Ultimate responsibility for all aspects of the completed prescription and assumption of the responsibility for the filled prescription, such as: Accuracy of drug, strength, labeling, proper container and other requirements.

(g) Dispense prescriptions to patient with proper patient information as required by WAC 246-869-220.

(h) Signing of the poison register and the Schedule V controlled substance registry book at the time of sale in accordance with RCW 69.38.030 and WAC 246-887-030 and any other item required by law, rule or regulation to be signed or initialed by a pharmacist.

(i) Professional communications with physicians, dentists, nurses and other health care practitioners.

(j) Decision to not dispense lawfully prescribed drugs or devices or to not distribute drugs and devices approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies.

(3) Utilizing personnel to assist the pharmacist.

(a) The responsible pharmacist manager shall retain all professional and personal responsibility for any assisted tasks performed by personnel under his or her responsibility, as shall the pharmacy employing such personnel. The responsible pharmacist manager shall determine the extent to which personnel may be utilized to assist the pharmacist and shall assure

that the pharmacist is fulfilling his or her supervisory and professional responsibilities.

(b) This does not preclude delegation to an intern or extern.

(4) It is considered unprofessional conduct for any person authorized to practice or assist in the practice of pharmacy to engage in any of the following:

(a) Destroy unfilled lawful prescription;

(b) Refuse to return unfilled lawful prescriptions;

(c) Violate a patient's privacy;

(d) Discriminate against patients or their agent in a manner prohibited by state or federal laws; and

(e) Intimidate or harass a patient.

WAC 246-869-010
Pharmacies' responsibilities.

(1) Pharmacies have a duty to deliver lawfully prescribed drugs or devices to patients and to distribute drugs and devices approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies, or provide a therapeutically equivalent drug or device in a timely manner consistent

with reasonable expectations for filling the prescription, except for the following or substantially similar circumstances:

(a) Prescriptions containing an obvious or known error, inadequacies in the instructions, known contraindications, or incompatible prescriptions, or prescriptions requiring action in accordance with WAC 246-875-040.

(b) National or state emergencies or guidelines affecting availability, usage or supplies of drugs or devices;

(c) Lack of specialized equipment or expertise needed to safely produce, store, or dispense drugs or devices, such as certain drug compounding or storage for nuclear medicine;

(d) Potentially fraudulent prescriptions; or

(e) Unavailability of drug or device despite good faith compliance with WAC 246-869-150.

(2) Nothing in this section requires pharmacies to deliver a drug or device without payment of their usual and customary or contracted charge.

(3) If despite good faith compliance with WAC 246-869-150, the lawfully prescribed drug or device is not in

stock, or the prescription cannot be filled pursuant to subsection (1)(a) of this section, the pharmacy shall provide the patient or agent a timely alternative for appropriate therapy which, consistent with customary pharmacy practice, may include obtaining the drug or device. These alternatives include but are not limited to:

(a) Contact the prescriber to address concerns such as those identified in subsection (1)(a) of this section or to obtain authorization to provide a therapeutically equivalent product;

(b) If requested by the patient or their agent, return unfilled lawful prescriptions to the patient or agent; or

(c) If requested by the patient or their agent, communicate or transmit, as permitted by law, the original prescription information to a pharmacy of the patient's choice that will fill the prescription in a timely manner.

(4) Engaging in or permitting any of the following shall constitute grounds for discipline or other enforcement actions:

(a) Destroy unfilled lawful prescription.

(b) Refuse to return unfilled lawful prescriptions.

(c) Violate a patient's privacy.

(d) Discriminate against patients or their agent in a manner prohibited by state or federal laws.

(e) Intimidate or harass a patient.

IV. Agency Interpretation of Regulations.

In a post-adoption letter interpreting the new regulations to Washington's pharmacists and pharmacy owners, the Board acknowledged that the regulations responded to the perceived need to "define standards of patient care and professional conduct when a pharmacist's personal objections conflicted with the patient's access to legally prescribed medications." (Exh. B to Decl. of Rima Alaily, Dkt. #50-4). In resolving the issue, the Board took a pro-patient position. To the pharmacy, no right of conscience was allowed because under the Board's interpretation of the regulations, "the pharmacy business must meet the patient's needs onsite unless one or more of the exceptions described in the rule are present." [2] *Id*. Stated another way, the Board informed the regulated public that "the rule does not allow a pharmacy to refer a patient to another pharmacy to avoid filling the prescription due to moral or ethical objections."

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[2] The exceptions are: "National or state emergencies; potentially fraudulent prescriptions; unavailability of the drug despite a good faith effort to comply with the Board's rule on adequate stock; lack of equipment or expertise to store a particular pharmaceutical; lack of payment."

Id. A narrow right of conscience was allowed to the pharmacist, if the pharmacist worked with another pharmacist on shift who would dispense the medication in place of the conscientious objector. *Id*.

V. Response to the Regulations.

The regulations became effective on July 26, 2007. This lawsuit was filed on the prior day. Plaintiff Rhonda Mesler alleges that she will be fired from her position as pharmacy manager because her employer cannot afford to hire another pharmacist to work with her. Only by hiring a second pharmacist to work side-by-side with Ms. Mesler will her employer be able to comply with 246-869-010.[3] (Decl. of Rhonda Mesler, Dkt. #12). Plaintiff, Margo Thelen, was also informed that her employer could not hire another pharmacist to work with her or remain on call. She was told that her employer could not accommodate her religious beliefs and that "it would not work" for her to remain employed there. In order to find a job where there would be two or more pharmacists on duty, she found employment with a hospital some distance away for less money. (Decl. of Margo Thelen, Dkt. #13).

Prior to the adoption of the regulations, Storman's Stores had been the object of a boycott organized by persons protesting Storman's refusal to stock Plan B. Both the store and the pharmacy

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[3] During the Board meeting of December 14, 2006, Board member Donna Dockter, RPh expressed concern that the then-draft rule was impractical in today's market "where in most situations there is only one pharmacist on staff at a given time." (Exh. O to Decl. of Lisa Salmi, Dkt. #45).

manager were investigated by the Board for allegedly failing to maintain an adequate stock of medicines. (Decl. of Kevin Stormans, Dkt. #14). The Board initiated an additional investigation in response to allegations that Storman's Inc. has violated WAC 246-869-010 by not stocking Plan B. (Def. Amended Notice of New Investigation, Dkt. #84).

VI. Intervenors.

The intervenors are persons concerned about access to lawful medications in Washington. Two intervenors, Judith Billings and Dr. Jeffrey Schouten, are HIV-positive and both have prominent leadership positions in matters of policy affecting the HIV-community. Ms. Billings has been diagnosed with AIDS since 1995. Dr. Schouten is HIV-positive but does not disclose for how long. He treats persons with HIV but does not indicate whether he receives treatment related to HIV. Neither Dr. Schouten nor Ms. Billings claims that he or she has ever been denied access to HIV- or AIDS-related therapies in the State of Washington. They do express the concern that some patient in the future "might face denial or harassment when attempting to fill prescriptions." *See generally*, Declaration of Judith Billings, Dkt. #51 and Declaration of Jeffrey Schouten, M.D., Dkt. #53.

The remaining five intervenors are women of child bearing age who provide personal accounts of their attempts to obtain Plan B and/or express their support for the subject regulations. Rhiannon Andreini needed access to Plan B in late 2005 while visiting her parents in the Edmonds/Mukilteo area. The pharmacist at the Albertson's grocery store

was friendly at first but turned "cold" and "appeared disapproving" when she asked for Plan B. The store did not carry Plan B and the pharmacist suggested she try a nearby Bartell Drug Store. He indicated generally where the store was located but did not provide detailed directions. Ms. Andreini was upset and cut her visit short by two days to return to Bellingham and a pharmacy with which she was familiar. Declaration of Rhiannon Andreini, Dkt. #52.

Molly Harmon presented a prescription for Plan B to a pharmacist at Bartell Drugs in the University Village shopping center in Seattle sometime in 2003. The pharmacist told Ms. Harmon that Plan B was not a form of birth control and that she would provide Ms. Harmon with information about available forms of birth control. Ms. Harmon was extremely upset and asked to speak to the head pharmacist who apologized and filled Ms. Harmon's prescription. Declaration of Molly Harmon, Dkt. #54.

Catherine Mossman has used Plan B on two occasions, once following a sexual assault. In both instances, she chose to obtain Plan B from Planned Parenthood because she has "heard numerous accounts of pharmacists who refuse to fill emergency contraception prescriptions or otherwise act in a hostile or harassing manner to those seeking such prescriptions." Declaration of Catherine Mossman, Dtk, #55.

Emily Schmidt has not used Plan B but has participated in a Planned Parenthood testing program designed to identify pharmacists who were and were not stocking and willing to distribute Plan B. In the Wenatchee area, Ms. Schmidt could

obtain Plan B at two of five pharmacies. At two pharmacies the pharmacist indicated an unwillingness to dispense Plan B. The record does not indicate why the fifth pharmacy did not have Plan B. Declaration of Emily Schmidt, Dkt. #56.

Finally, Tami Garrard has never used Plan B. She, like the others, would like to participate in this litigation "to help ensure that . . . all women in Washington, can get timely access to emergency contraception to prevent an unintended pregnancy without harassment or hostility." Declaration of Tami Garrard, Dkt. #57.

DISCUSSION

I. Preliminary Injunction Standard.

The standard for granting a preliminary injunction balances the plaintiff's likelihood of success on the merits against the hardship to the parties. To prevail on a motion for preliminary injunction, a party must demonstrate either: (1) a likelihood of success on the merits and the possibility of irreparable injury; or (2) that serious questions going to the merits were raised and the balance of hardships tips sharply in the moving party's favor. These alternatives do not represent separate tests but rather represent extremes of a single continuum. The greater the relative hardship to the moving party, the less probability of success must be shown. *Clear Channel Outdoor Inc. v. City of Los Angeles*, 340 F.3d 810, 813 (9th Cir. 2003).

A party seeking preliminary injunctive relief in a First Amendment context can establish irreparable injury sufficient to merit the grant of

relief by demonstrating the existence of a colorable First Amendment claim. *Warsoldier v. Woodford*, 418 F.3d 989 (9th Cir. 2005).

II. Nature of the Claims.

Plaintiffs contend that the enforcement of the subject regulations violates their right to freely exercise their religion as guaranteed under the First Amendment to the United States Constitution. They also assert that the regulations violate the Equal Protection Clause of the Fourteenth Amendment and the Due Process Clause of the Fourteenth Amendment. In addition, plaintiffs allege that the regulations are invalid because they conflict with federal anti-discrimination law and are therefore preempted under the Supremacy Clause of the Constitution.

Those defendants affiliated with the Human Rights Commission argue that, as to them, there is no case or controversy ready for resolution. Citing a lack of ripeness, they ask the Court to deny plaintiffs' motion.

III. Ripeness.

The HRC defendants challenge the timing of plaintiffs' action as to them and assert that no case or controversy exists under the ripeness doctrine. These defendants point out that the HRC has taken no action nor stated any intent to take action against the plaintiffs. They also claim that the HRC has adopted no agency policy or directive that has any force of law. They argue that the April 2006 letter from the Executive Director of the HRC to the Executive Director of the Pharmacy Board did not constitute a threat to prosecute

pharmacists, pharmacies or even the Board, and that even if it was a threat, it could not be actualized until an investigation and conciliation process had occurred. The HRC defendants ask that the motion for preliminary injunction be denied as to them.

Ripeness is peculiarly a question of timing intended to prevent courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements. *New Mexico for Bill Richardson v. Gonzales*, 64 F.3d 1495, 1499 (10th Cir. 1995). Here, the HRC Executive Director wrote a letter which plaintiffs perceive to be a threat to prosecute them, and others like them, for discriminating on the basis of sex. Regarding the threat of prosecution, courts in this circuit look to three factors when determining ripeness: (1) whether plaintiffs have articulated a concrete plan to violate the law in question; (2) whether the prosecuting authorities have communicated a specific threat to initiate proceedings; and (3) the history of past prosecutions or enforcement under the challenged statute. *Thomas v. Anchorage Equal Rights Comm.*, 220 F.3d 1134, 1139 (9th Cir. 2000), *cert. denied*, 531 U.S. 1143 (2001).

Plaintiffs argue that the April 2006 letter was "official" and that its continued presence on the HRC website is intended as a direct threat to pharmacists, and to the pharmacies who employ them, that the anti-discrimination laws of the State of Washington will be enforced against them if they refuse to dispense Plan B to a qualified patient.

The Court is convinced that the controversy before it is much more than a mere abstraction. All plaintiffs have refused to obey the law. By posting

the April 2006 letter on its website the HRC has continued to express its intent to pursue those who violate the WLAD. Significantly, the HRC does not disavow an intention to enforce the WLAD against plaintiffs. The history of the HRC is to aggressively pursue violators of the WLAD. Nothing in the HRC's words or deeds related to this issue suggest they will act differently here. Under these circumstances, the Court is convinced that the matter is ripe for resolution and plaintiffs' action is not premature. See Canatella v. State of Cal., 304 F.3d 843, 852 (9th Cir. 2002) (as amended on denial of rehearing).

Beyond the threat of HRC enforcement, this matter is ripe for the additional reason that enforcement as to individual pharmacists will apparently be accomplished, not by direct agency action but, indirectly, by pressuring pharmacies to either accommodate or terminate objecting pharmacists. Accommodation appears to result only by a pharmacy hiring a second pharmacist, at an estimated cost of $80,000 annually, to work side-by-side with the objecting pharmacist. [4] It is not speculation for the Court to observe that such accommodation presents more than a *de minimis* expense and therefore constitutes an undue hardship on the employer. [5] No employer can be

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[4] According to the "Final Significant Analysis" concerning these regulations, the estimated cost to hire an additional pharmacist is $80,000 annually. (Exh. K, p. 5, to Decl. of Kristen Waggoner, Dkt. #11).

[5] To require more than a *de minimis* cost be incurred by an employer imposes an undue hardship on an employer and relieves that employer from the obligation to accommodate religious practices or beliefs. *TWA v. Hardison*, 432 U.S. 63, 81-84 (1977).

expected to accommodate in this manner. Given the evidence now before this Court, termination is the outcome that any Board member could reasonably have expected when promulgating these regulations. According to Margo Thelen, the regulations have already resulted in her termination. Rhonda Mesler advises the Court that she too will be terminated if these regulations are enforced against her employer. Given the organized effort to pursue objecting pharmacies and pharmacists in this and other states, it is inconceivable to the Court that these regulations would not be enforced against offenders sooner than later. *See Vandersand v. Wal Mart*, 2007 U.S. Dist. LEXIS 55250 (C.D.Ill., 2007), and Decl. of Kevin Stormans, Dkt. #14.

IV. Free Exercise of Religion, Under the First Amendment.

The principle that government may not enact laws that suppress religious belief or practice is so well understood that few violations are recorded in United States Supreme Court opinions. *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 523 (1993). The Free Exercise Clause of the First Amendment provides that "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof . . .." The First Amendment has been made applicable to the states through the Fourteenth Amendment. *See Cantwell v. Connecticut*, 310 U.S. 296, 303 (1940). Religion means all aspects of religious observance and practice, as well as belief, whether or not they are acceptable to others. *Thomas v. Review Bd. of Indiana Employment Security Div.*, 450 U.S. 707, 714 (1981).

State laws intending to discriminate against individuals because of their religious practices and beliefs are subject to strict scrutiny. The state must demonstrate in such cases that the laws serve a compelling state interest and are narrowly tailored to advance that compelling interest. *Lukumi*, 508 U.S. at 533. In contrast, if the law is neutral on the subject of religion and is of general applicability, it need not be justified by a compelling governmental interest even if the law has the incidental effect of burdening a particular practice. *Employment Div. Dept. of Human Resources of Ore. v. Smith*, 494 U.S. 872 (1990). Neutrality and general applicability are interrelated. Failure to satisfy one requirement is a likely indication that the other has not been satisfied. *Lukumi*, 508 U.S. at 531.

A. Neutrality.

The Court will first examine whether the regulations are intended to be neutral as to religion. To determine the object of a law, the Court must first look to the text to see whether the law discriminates against religious practice on its face. A law lacks facial neutrality if it refers to a religious practice without a secular meaning discernable from the language or context. *Lukumi*, 508 U.S. at 533. A review of the subject ordinances reveals no mention of religion or any intention to burden the religious practices of others. The ordinances are facially neutral.

The Court's inquiry does not end with a review of the text of the applicable law. The Free Exercise Clause, like the Establishment Clause, extends beyond facial discrimination. The Clause "forbids subtle departures from neutrality," *Gillette v. United States*, 401 U.S. 437, 452 (1971) and

"covert suppression of particular religious beliefs," *Bowen v. Roy*, 476 U.S. 693, 703 (1986). "The Free Exercise Clause protects against government hostility which is masked, as well as overt." *Lukumi*, 508 U.S. at 534. According to Justice Harlan, "the Court must survey meticulously the circumstances of governmental categories to eliminate, as it were, religious gerrymanders." *Walz v. Tax Comm'n of New York City*, 397 U.S. 664, 696 (1970).

Relevant evidence in the inquiry includes, at a minimum, the historical background of the decision under challenge, the specific series of events leading to the enactment of the subject law(s), and the legislative or administrative history, including contemporaneous statements made by members of the decision-making body. *Arlington Heights v. Metropolitan Housing Development Corp.*, 429 U.S. 252, 267-68 (1977). In addition, the effect of a law in its real operation is strong evidence of its object and purpose. *Lukumi*, 508 U.S. at 535.

Although a law targeting religious beliefs as such is never permissible, *McDaniel v. Paty, supra*, 435 U.S. at 626, *Cantwell v. Connecticut, supra*, 310 U.S. at 303-04, if the object of a law is to infringe upon or restrict practices because of their religious motivations, the law is not neutral, and it is invalid unless it is justified by a compelling interest and is narrowly tailored to advance that interest. *Lukumi*, 508 U.S. at 533.

What then is the object of the regulations that are at the heart of this dispute? Defendants frame the issue in terms of timely access to all medications lawfully prescribed. Plaintiffs see the

regulations in far more nefarious terms. They claim the object of the regulations is to eliminate from the practice of pharmacy, or at least a significant segment of the practice, those pharmacists who, for religious reasons, object to the delivery of lawful medications, specifically Plan B.

Defendants argue that plaintiffs cannot establish a free exercise claim because the challenged regulations are facially neutral and apply generally to all pharmacies, regardless of the religious beliefs of their owners or employees. It is argued that the final regulations represent the Board's best judgment about how to deal with its overriding concerns for the health and safety of all patients who need valid prescriptions filled in a timely fashion. (Def. Selecky et al memo 10:12-15, Dkt. #43). They point to a potential conflict between the interests of pharmacists and those related to the health of the patients. The interest in having prescriptions filled promptly and patients treated fairly are, to defendants, compelling interests that outweigh any alleged harm to plaintiffs. (Def. Selecky et al memo 10:16-22, Dkt. #43).

Defendants further assert that the regulations are not specific to Plan B or any other prescription medication. Defendants argue that pharmacies must ensure the timely delivery of all valid prescriptions to patients and that pharmacists are not required to dispense any medication in violation of their religious beliefs. (Def. Selecky et al memo 7:5-11, Dkt. #43). To the extent adherence to these regulations creates conflicts between a pharmacy and its pharmacist(s), the defendants say such conflicts should be resolved according to the tenets of the

WLAD. If the employer cannot accommodate the objecting pharmacist by hiring another pharmacist to work with him/her, then "at most, . . . the regulations may require a licensed pharmacist to occasionally fill a prescription for a medication whose intended use offends the pharmacist's religious beliefs." (Def. Selecky et al memo 9:17-19, Dkt. #43).

Plaintiffs argue that all relevant evidence touching on the enactment of the regulations makes clear that the regulations are about Plan B and the target of the regulations is any pharmacist or pharmacy who objects to Plan B for religious reasons. Plaintiffs maintain that the very press release announcing the adoption of the rules acknowledged that they "were sparked by complaints that some pharmacists and pharmacies refused to fill prescriptions for emergency contraceptives - also known as morning after pills or Plan B." (Exh. I to Decl. of Kristen Waggoner, Dkt. #11).

Plaintiffs assert that all who participated, formally or informally, in the development of these rules knew the process was about Plan B and the right of conscience.

In a letter evaluating issues relating to the Board's rulemaking effort, the HRC identified, from its perspective, the object of the rulemaking process:

> The WSHRC understands that the Board of Pharmacy (the Board) is currently dealing with issues arising from some pharmacists in the state refusing to fill or desiring to deny

> filling some legal prescriptions for emergency contraception and other prescriptions for women, based on the pharmacists' asserted religious and moral beliefs . . .. As we understand it, the drug at the center of this issue is Plan B, an emergency contraceptive.

(Exh. J to Decl. of Kristen Waggoner, pp. 1-2, 12, Dkt. #11).

The prominent role played by Planned Parenthood and the Northwest Women's Law Center, in both the rulemaking process before the Board and in the Governor's ad hoc effort to develop an alternative approach to the Board's draft rule allowing conscience, offers further proof to the plaintiffs that Plan B and religious objection were the focus of the rulemaking process. (Plaintiffs' Reply Brief 7:17-8:19, Dkt. #66).

Finally, plaintiffs cite the Governor's words and deeds as evidence of the narrow objective of these regulations. The Governor immediately expressed her opposition to any rule that allowed a pharmacist to refuse to fill a prescription based on conscience. She convened a group of stakeholders including the Board of Pharmacy, the University of Washington School of Pharmacy, the Washington State Pharmacy Association, the Department of Health and representatives from Planned Parenthood and the Northwest Women's Law Center to draft an alternative rule eliminating conscience as a basis for refusing to fill a lawful prescription. The Governor also threatened to replace the members of the Board unless they reversed course on this issue. Plaintiffs ask the Court to take a common sense view of this evidence

and conclude that the Governor's focus was on Plan B and her target was pharmacists who oppose that drug on religious grounds.

The evidence thus far presented to the Court strongly suggests that the overriding objective of the subject regulations was, to the degree possible, to eliminate moral and religious objections from the business of dispensing medication. Defendants argue that the objective was to keep pharmacists from imposing their religious or personal views upon the treating public. Defendants deny that there is any affirmative duty imposed upon the pharmacist other than to do what he or she was trained to do. In actual operation, however, the regulations appear designed to impose a Hobson's choice for the majority of pharmacists who object to Plan B: dispense a drug that ends a life as defined by their religious teachings, or leave their present position in the State of Washington. The evolution of these regulations, as currently described to the Court, convinces the Court that these regulations targeted the religious practices of some citizens and are therefore not neutral.

B. General Application.

The Court next considers whether the regulations are applied generally.

> The principle that government, in pursuit of legitimate interests, cannot in a selective manner impose burdens only on conduct motivated by religious belief is essential to the protection of the rights guaranteed by the Free Exercise Clause.

Lukumi, 508 U.S. at 543. The Supreme Court instructs that the essence of the test on general applicability of a law is that "inequality results when a legislature decides that the governmental interests it seeks to advance are worthy of being pursued only against conduct with a religious motivation." *Lukumi*, 508 U.S. at 542-43. Intervenors take this to mean that in evaluating general applicability, courts examine the law's means and the law's ends: if the means fail to match the ends, the statute likely targets religious conduct and is therefore not generally applicable. Applying the test as thus articulated, the Court is persuaded that, when viewed in context, the totality of the evidence supports the conclusion that the subject regulations are not laws of general applicability.

From the very beginning of this issue, it appears that the focus of the debate has been on Plan B and on religious objection to dispensing that drug. All who have participated in the formulation of these regulations have fixed their attention and crafted their response to that issue. Media coverage of the controversy has centered on Plan B. Defendants' efforts to broaden the perspective by articulating a concern for universal or unfettered access to all lawfully prescribed drugs are unconvincing. First, as to Plan B, there has been no evidence presented to the Court that access is a problem. It is available at all but a few licensed pharmacies in Washington state and can be accessed through physicians offices, certain government health centers, hospital emergency rooms, Planned Parenthood and the internet. (Decl. of Kristen Waggoner, para. 3, Dkt. #11). A survey of approximately 135 pharmacies conducted by the Board during the rulemaking process (October

2006) revealed that of the 121 respondents, 93 typically stocked emergency contraceptives while 28 did not. Of those who did not, 18 cited low demand and three relied on an "easy alternative source." Only two pharmacies said they did not stock emergency contraceptives because of religious or personal reasons. (Exh. A to Decl. of Kristen Waggoner, Dkt. #11).

The Court has been presented no evidence establishing that anyone in the State of Washington, including intervenors, has ever failed to obtain Plan B within the 72-hour window of effectiveness because one or more pharmacists/pharmacies refused to fill a lawful prescription for Plan B or refused to stock and/or dispense Plan B as an over-the-counter drug.

In contrast, in a letter to the Governor, the Chief Executive Officer of the Washington State Pharmacy Association touted the wide-spread accessibility of Plan B throughout Washington due, in large part, to the efforts of pharmacists and their innovative, pharmacy-based program which is a national model of collaboration in an effort to improve public health. (Exh. E to Decl. of Kristen Waggoner, Dkt. #11). The Court accepts the letter as some evidence that as of June 5, 2006, the WSPA did not see access to Plan B as a significant issue.

The fact that the Pharmacy Board initially proposed a draft rule permitting a pharmacist/pharmacy to not fill a lawful prescription for reasons of conscience is some further evidence, within the focused debate over Plan B, that the Board did not view access to Plan B as a current problem. At a minimum, to the

Board, the problem was not of such gravity that a health care provider's right of conscience had to be sacrificed.

Expanding the inquiry beyond Plan B, there is some evidence to support defendants' claim that the regulations are about optimal access to all medicines, not just emergency contraceptives. The Governor's various messages on the subject were not limited to Plan B and the "Final Significant Analysis" prepared for these regulations briefly mentions HIV as another condition requiring timely drug therapy. (Exh. K to Decl. of Kristen Waggoner, Dkt. #11). Beyond these limited factors, however, the history of these regulations thus far presented to the Court is directed entirely at Plan B.

As in the case of Plan B, the evidence presented to the Court does not suggest that access to HIV medicines is a problem. Neither of the two intervenors who are either HIV-positive or have AIDS have been refused medications by a pharmacist, for religious reasons or otherwise. (Decl. of Judith Billings, Dkt. #51 and Decl. of Jeffrey Schouten, Dkt. #53). A review of complaints referred to the Board from 1995 to 2007 does not indicate a problem with access to HIV-related medications, or any other medications for that matter. No one has been identified as having been denied access to HIV medicines because a pharmacist refused to dispense them. [6] It is

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[6] The one example where a pharmacist did refuse to dispense hypodermic needles to a young man because of his appearance, seemingly would not run afoul of these regulations which protect a pharmacist's ability to refuse to fill a prescription due to suspected or potential fraud (WAC

certainly plausible that some pharmacist in the State of Washington could, as intervenors fear, deny distribution of needed HIV-medicine because of personal disdain for a homosexual lifestyle. No party to this lawsuit has attempted to defend such conduct as Free Exercise of Religion and in the context of the case before it, this Court will not opine on such a hypothetical situation.

To summarize, the evidence presented to the Court does little to support the argument that expanded access to all medications was the "end" which these regulations were written to achieve. Nevertheless, for purposes of further analysis, the Court will, for the time being, accept defendants broader expression of an end result they aspired to attain. That "end" will be more thoroughly tested against the chosen "means" adopted by the regulators.

The exemptions incorporated into these regulations do not appear designed to materially change the system by which medicines are delivered in Washington state. They excuse a pharmacy from filling a lawful prescription for logistical reasons such as a national or state emergency or the lack of expertise or specialized equipment needed to deal with a particular medicine. They also excuse the pharmacy/pharmacist from filling a lawful prescription whenever, in the exercise of professional judgment, an obvious or known error in the prescription is detected or other inadequacies or contraindications are present. A potentially

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246-869-010(a)(d)). The individual was diabetic and needed the needles for insulin shots.

fraudulent prescription likewise does not have to be filled.

Finally, the regulations exempt pharmacies/pharmacists from filling legal prescriptions where the medicine is not in stock despite good faith compliance with regulations advising pharmacies to maintain an adequate stock of medicines.

These exemptions all reflect legitimate, time-honored reasons for not filling a prescription immediately upon presentation by a patient. Their inclusion within the regulations reflects the Board's intention to continue, as usual, the basic means and methods by which pharmacies and pharmacists stock and dispense drugs in the State of Washington. As for the vast majority of drugs legally available to the public, market conditions will continue to guide the decision whether or not to stock. The means adopted by the Board to accomplish its desired outcome thus does nothing to increase access to lawful prescription medicines generally. Rather, the enforcement mechanism of the new law appears aimed only at a few drugs and the religious people who find them objectionable.

The Court next turns its attention to the conduct the rulemakers determined to be sanctionable under the regulations. Both the Pharmacy regulation and the Pharmacist regulation focus on the same list of five proscribed actions:

> 1) Destroying unfilled lawful prescriptions;

2) Refusing to return lawful prescriptions;

3) Violating a patient's privacy;

4) Discriminating against patients or their agent in a manner prohibited by state or federal laws; and

5) Intimidating or harassing a patient.

Under the Pharmacist's regulation (WAC 246-863-095) such conduct is described as unprofessional and presumably sanctionable under the Uniform Disciplinary Act, RCW 18.130 et. seq. The Pharmacies' regulation prohibits the same activity by threatening "discipline or other enforcement actions." WAC 246¬869-010.

No party now before this Court objects to those provisions which condemn actions described in Sections 1, 2, 3 or 5 above. It is the catch-all use of the anti-discrimination law to prevent "refuse and refer" with respect to Plan B that plaintiffs seek to enjoin. The Court is therefore focused principally on Plan B and those pharmacists and/or pharmacies that refuse to stock or dispense that drug. Currently, the Court has no evidence before it which explains the Board's chosen reliance on state and federal anti¬discrimination laws to define when refusal to dispense is or is not allowed. These laws come with their own exemptions that hint towards at least some potential to further limit the subject regulations' ability to increase access to lawful medicines. For example, the WLAD excludes small employers and religious/sectarian organizations from the definition of "employer," seemingly inoculating such entities from

discrimination claims. *See* RCW 49.60.040. While this definition does not appear to impact entities involved in public accommodation, such as pharmacies, the unexplored nature of the interplay between the WLAD and the instant regulations leads to serious questions about the Board's choice of weapons. The Board clearly chose not to require pharmacies or pharmacists to dispense lawful medications without delay every time they are requested. Instead they chose to invoke the laws against discrimination. At oral argument, questions posed by the Court touching on the obligation of a pharmacy operated by a Catholic hospital to dispense Plan B or other contraceptives went unanswered. The Court's expressed doubts about enforcement action directed at religious hospitals, particularly in light of established statutory protections for such institutions, while unchallenged at this point in the proceeding, at least suggest the new regulations are underinclusive and therefore not generally applicable.

The evidence now before the Court convinces it that the "means" used by the rulemakers do not square with the "end" currently espoused by the defendants. The regulations do not appear to the Court to be of general application. Rather, the regulations appear to target religious practice in a way forbidden by the Constitution. The regulations are neither neutral as to religion nor are they generally applicable. Because the regulations appear to intentionally place a significant burden on the free exercise of religion for those who believe life begins at conception, the regulations must be subjected to strict scrutiny analysis.

C. Strict Scrutiny.

Defendants argue that even if strict scrutiny applies, the regulations are justified by a compelling interest and are narrowly tailored to accomplish their intended purpose. They assert that the Board has a compelling interest in ensuring that all parties are treated equally and respectfully by pharmacies and their employees. (Def. Selecky et al memo 15:5-6, Dkt. #43). They rely on two interests served by the regulations as written: (1) promoting health by ensuring access to Plan B (and other medications) in a timely manner and (2) preventing sex discrimination. (Def. Selecky et al memo, pp. 10, 15-16, Dkt. #43 and Def. Friedt et al memo, p. 11, Dkt. #46).

A law burdening religious practice that is not neutral or not of general application must undergo the most rigorous of scrutiny. *Wisconsin v. Yoder*, 406 U.S. 205, 215 (1972). A law that targets religious conduct for distinctive treatment or advances legitimate governmental interests only against conduct with a religious motivation will survive strict scrutiny only in rare cases. *Lukumi*, 508 U.S. at 546. Although promoting the health, welfare and peace of the people might ordinarily present a compelling state interest for First Amendment analysis, the Court has previously indicated why the regulations do not advance the cause of general access to Plan B and other medicines as advocated by defendants.

The evidence provided by the parties, including the intervenors, convinces the Court that the interests promoted by the regulations have more to do with convenience and heartfelt feelings than with actual access to certain medications.

Patients understandably may not want to drive farther than the closest pharmacy and they do not want to be made to feel bad when they get there. These interests are certainly legitimate but they are not compelling interests of the kind necessary to justify the substantial burden placed on the free exercise of religion. While it is obviously conceivable that a patient in need of Plan B could ultimately be denied access to the drug during its time of effectiveness, that eventuality is just as likely to occur for reasons that are wholly acceptable under the regulations: lack of money, the drug is not in stock, no one has previously requested it, or the store is closed on Sunday. In short, lack of access to Plan B has thus far not been demonstrated, and the concerns that have been expressed about availability are not compelling.

Nor is preventing discrimination on the basis of gender, within the context of this case, a compelling state interest. The United States Supreme Court has recognized that reasonable people disagree over when life begins, and the refusal to participate in an act that one believes terminates a life has nothing to do with gender or gender discrimination. *Bray v. Alexandria Women's Clinic*, 506 U.S. 263, 271-74 (1993). Federal and state law provide a clear right to health care providers to not participate in abortion procedures. *See, e.g.*, 42 U.S.C. §300a - 7(c)(i) and RCW 9.02.150. Washington's legislature has, on separate occasions, conferred upon health care providers, including pharmacists, a fundamental right to not participate in a health care service to which they have a moral or religious objection. Whether or not Plan B acts as an abortifacient or terminates a pregnancy, to those who believe that life begins at conception, the drug is designed to terminate a life.

The Supreme Court's ruling and reasoning in *Bray* applies with equal vitality here. The plaintiffs' objection to Plan B is not about gender, it is about the sanctity of life as defined by their religious teachings.

On the evidence now before it, the Court cannot say that the subject regulations advance a compelling state interest and they are narrowly tailored to accomplish their announced purpose.

The evidence before the Court causes it to conclude that plaintiffs have demonstrated that, as to their constitutional right to free exercise of religion, the criteria for imposition of a preliminary injunction have been met. The facts presented show, to the Court's satisfaction, a likelihood of success on the merits and the possibility of irreparable injury. In reaching this conclusion, the Court has attempted to compare the facts of this case, not just against the platitudes enunciated by established precedent but also to the facts and circumstances of prominent cases providing to this Court both binding and persuasive guidance.

In *Employment Div., Dept. of Human Resources of Oregon v. Smith*, 494 U.S. 872 (1990) the Controlled Substances law at issue was adopted by the Oregon legislature without a thought being given to the religious practices of some who might use hallucinogenic drugs in their ceremonies. The sole purpose of the law was to prevent the illicit use and abuse of mind-altering, addictive drugs while preserving legitimate uses taken under the care of a doctor. The law was applied to all persons who did not have a medical prescription for the drug. The exemption for medical use was wholly consistent with the general purpose of preventing

addiction to drugs. The law was facially neutral, of general application and the legislative history revealed no intent to target religion. That is not this case.

In *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520 (1993), the regulations adopted by the City were intentionally targeted only at the practice of sacrificing animals in a religious ceremony performed by the Santeria church. The laws were not neutral on their face and were certainly not applied generally to similar activities of others, whether secular or religious in nature. Although this case does not present such extensive gerrymandering in order to further the intent to target religious practices, the ultimate objective of the subject regulations may be similar to *Lukumi*. *Smith* and *Lukumi* represent the two extremes when analyzing laws for neutrality or general applicability.

Applying these same precedents, the Third Circuit speaking through then-Circuit Judge Alito explained:

> A law fails the general applicability requirement if it burdens a category of religiously motivated conduct but exempts or does not reach a substantial category of conduct that is not religiously motivated and that undermines the purposes of the law to at least the same degree as the covered conduct that is religiously motivated.

Blackhawk v. Commonwealth of Pennsylvania, 381 F.3d 202 (3rd Cir. 2004). In *Blackhawk*, the Court

was confronted with a Game and Wildlife permit fee that was obviously adopted with no intent to target religious practices. The exemptions to the fee requirement, however, benefitted secular activities but not religious conduct of a similar kind. The Court concluded that the fee requirement was not generally applicable because its exemptions allowed zoos and "nationally recognized circuses" to keep animals in captivity without paying a fee but required a fee from those keeping animals for religious purposes. Strict scrutiny analysis therefore applied.

In the case now before the Court, the extent and impact of exempted conduct allowed by the subject regulations and the WLAD has not been fully developed. Nevertheless, the evidence that has been introduced suggests that secular reasons for delaying or denying access to lawfully prescribed medicines undermine the stated purpose of the law to a degree similar to the plaintiffs' conduct that is religiously motivated.

Following oral argument, Defendant-Intervenors directed the Court's attention to a recent Third Circuit opinion, *Anspach v. City of Philadelphia, Department of Public Health*, 2007 WL 2743446 (CA 3 Pa. Sept. 21, 2007). There, the Court faced issues of Due Process and Free Exercise of Religion arising out of a city health center acceding to the request of a 16-year-old unemancipated daughter to be provided an emergency contraceptive. The district court dismissed the action, and the appellate court affirmed. With respect to plaintiffs' (parents and daughter) claim that their right to free exercise of religion was abridged by the conduct of health center personnel, the Court reiterated the

requirement that, in order to establish a substantial burden on religious expression, plaintiffs must allege state action that is either compulsory or coercive in nature. This statement of law is neither new nor remarkable. Government compulsion either to do or refrain from doing an act forbidden or required by one's religion is the evil prohibited by the Free Exercise Clause. According to the Court, the concept is a simple one: the state may not compel an individual to act contrary to his religious beliefs. *Id.* at *15, citing *Arnold v. Bd. of Educ.*, 880 F.2d 305, 314 (11th Cir. 1989). Since no compulsion or coercion was imposed upon the young woman, there was no violation of the right to freely exercise one's religion.

Here, the situation is much different. By seemingly intentionally creating an immutable conflict between a pharmacy that cannot refuse and a pharmacist that cannot dispense, the regulations impose more than incidental effects having the tendency to coerce individuals into acting contrary to their religious beliefs. At this stage in the proceedings, the evidence suggests that the burden on the religious practices of plaintiffs is intentional not incidental, and substantial not minimal.

Finally, the Court considered a case arising out of the same national controversy reflected in the case at bar. In *Menges v. Blagojevich*, 451 F. Supp. 2d 992 (D.C. Ill, 2006), the District Court was called upon to resolve motions to dismiss brought by defendants state officials against complaints filed by certain state pharmacists and by third-party plaintiff Walgreen Pharmacy. Like the case here, the plaintiffs were pharmacists who had either lost their jobs or were threatened with termination over their refusal to dispense Plan B.

Walgreen's claimed that the regulation requiring a pharmacy to dispense emergency contraceptive upon request without delay forced it to terminate objecting pharmacists who previously were protected by Walgreen's "Referral Pharmacist Policy." The policy allowed Walgreen pharmacists nationwide to decline to fill a prescription based on moral or religious objections as long as the prescription could be filled by another pharmacist or at a nearby pharmacy.

Accepting as true the factual allegations of the Amended Complaint and Third Party Complaint, and drawing all inferences in the light most favorable to the plaintiffs, the Court held that the pharmacists stated a claim for Free Exercise Clause violations as well as Title VII federal preemption. Walgreen's request for declaratory judgment that its policy complied with state law was barred by the Eleventh Amendment.

As in the case at bar, plaintiffs alleged specific expressions of religious animus issued by state officials during the process of enacting the subject laws. Like the Washington regulations, the Illinois law directly compelled the pharmacy, not the pharmacist, to dispense the drug. Unlike the Washington law, however, the Illinois law was directed only at emergency contraceptives, not all lawful prescriptions.

The factual similarities between this case and *Menges* appear to be substantial. Although the Court's decision in that case was compelled by a different standard of review than that which guides this Court, the fact that a Free Exercise violation was stated by the allegations in the *Menges*

Complaint is persuasive authority which is supportive of the Court's conclusion here.

CONCLUSION

On the issue of Free Exercise of Religion alone, the evidence before the Court convinces it that plaintiffs, individual pharmacists, have demonstrated both a likelihood of success on the merits and the possibility of irreparable injury. The Court cannot afford protection to individual pharmacists without including pharmacies within the ambit of the injunctive relief to be afforded. Therefore, the Court **GRANTS** the Plaintiffs' Motion for Preliminary Injunction as follows:

> The defendants are enjoined from enforcing WAC 246-863-095 (4)(d) and WAC 246-869-010 (4)(d) (the anti-discrimination provisions) against any pharmacy which, or pharmacist who, refuses to dispense Plan B but instead immediately refers the patient either to the nearest source of Plan B or to a nearby source for Plan B.

This injunction will remain in place pending trial of this matter or until further proceedings result in a modification or dissolution of this preliminary injunction.

No bond will be required. *See Borbach v. Reno*, 219 F.3d 1087, 1092 (9th Cir. 2000).

The Court has, for the time being, left unresolved the question of whether the corporate plaintiff is a "person" or whether the right of free exercise of religion is a "purely personal"

constitutional guarantee unavailable to corporations. Given the Court's interpretation of the enforcement mechanism built into the subject regulations, it is necessary to extend the injunction to corporate pharmacies as well as to individuals operating pharmacies in order to provide the needed protection for pharmacists. For that reason, it is not necessary for the Court to resolve these questions at this time.

Given the Court's analysis of the facts of this case under the Free Exercise clause, it is not necessary at this time to evaluate plaintiffs' remaining theories: Equal Protection, Due Process or Title VII and preemption. Those theories will be addressed at trial.

As the Court looks forward to trial of the merits several factual and legal issues are of continuing interest.

1. Are there patients who have failed to access Plan B within the 72-hour "window of effectiveness" due to the conduct of Washington pharmacies/pharmacists opposed to Plan B for moral or religious reasons?

2. Did the Board intend that the subject regulations be enforced against religiously-affiliated health care facilities?

3. Should one or more questions of state law be certified to the Washington State Supreme Court to include, for example; a) does the fundamental right of health care providers to refuse to perform services as to which they have a religious objection extend beyond the basic health care and insurance systems, b) does the State

Board of Pharmacy have the power to take away protections previously bestowed by the Legislature upon pharmacists as health care providers, and c) does the statutory right of conscientious objection extend to pharmacies that are one component of a larger "health care facility" such as a hospital? (The parties should confer immediately and inform the Court whether the certification process should be invoked in this case.)

IT IS SO ORDERED.

DATED this 8th day of November, 2007.

/s/
RONALD B. LEIGHTON
UNITED STATES DISTRICT JUDGE

ER779-780
Petition to the Washington Board of Pharmacy Regarding Ensuring Patient Access to Medication

We, the undersigned organizations, urge the Washington State Board of Pharmacy to abandon its decision to amend WAC 248-869-010 and 246-863-095 to allow pharmacies to refuse, for any reason, to serve patients and instead refer them to other pharmacies. The existing rules, that require pharmacies to ensure that patients' lawful medications are dispensed on site and in a timely manner, were adopted after many months of debate and comment from the people of Washington State. They achieve a proper balance between the Board's first priority – protecting patient health and safety – and accommodation of an objecting pharmacist's individual beliefs. Changing the existing rules will serve only to reduce statewide patient access and *increase barriers* to patient's receipt of their medications.

Patients in Washington should be able to obtain the drugs they need on site and in a timely manner. No referral, no matter how polite or well-intentioned, can provide better access than being served at the pharmacy. Referring a patient to another pharmacy is an inferior option in almost all instances, and in many cases will result in preventing a patient from getting the medication she needs or getting it on time. Patients living in rural areas cannot easily get to another pharmacy. Regardless of where they live, many individuals with disabilities, some senior Washingtonians, and many teens do not drive and have limited transportation options. Immigrants, many of whom face significant barriers to obtaining health care,

may not have transferrable insurance, if any at all. Patients with limited English proficiency already struggle to get appropriate instructions in how to use medication since most pharmacies do not use interpreters. For these populations, a referral "a few miles down the toad" means they will not get the medication they need.

People living with HIV and AIDS depend on pharmacies for access to medications critical to their health; and yet people with HIV and AIDS have historically been subjected to discrimination within the health care system and rightly fear that a rule allowing referrals will prevent them from getting timely access to the drugs they need. Women and girls who have suffered sexual assault need immediate access to emergency contraception, and referral may only serve to increase the trauma they've experienced and further delay or deny them access to this critical medication. All women of childbearing age need access to prescription and non-prescription birth control, as unintended pregnancy is a serious health concern.

The Board of Pharmacy has indicated that it intends to enact this rule because there are some instances where referral is needed to better protect patient health and safety. The Board can – and indeed has, in the existing rule – make provision for those limited instances. It is the Board's primary responsibility to protect patient health and safety. Making a rule that allows referrals when such referrals arc not based on a patient's health and safety undermines that responsibility.

Washington patients need access to their time-sensitive medications. Refusals at the pharmacy jeopardize access to care and put

patients at risk. We urge the Board to protect the existing rules that ensure that all patients get the health care they need on site and on time. Three years ago, the Board of Pharmacy adopted rules that sought to protect all the people of Washington. It should not take a step backward and discard those rules.

Signing Organizations:

Advanced Registered Nurse Practitioners United of Washington
American Association of University Women, Washington Chapter
American Civil Liberties Union of Washington
Aurora Medical Services
Cedar River Clinics
Center for Health Training/James Bowman Associates
Center for Multicultural Health
Disability Rights Washington
Equal Rights Washington
FUSE Washington
Governor's Advisory Council on HIV/AIDS
Judy Kimeiman, M.D., Seattle Obstetrics & Gynecology Group
King County Sexual Assault Resource Center
Lambda Legal
Law Students for Reproductive Justice, University of Washington Chapter
League of Women Voters
Legal Voice
Lutheran Public Policy Office of Washington State
Maru Mora Villalpando, Latino Advocacy, LLC
Mt. Baker Planned Parenthood
NARAL Pro-Choice Washington
National Asian Pacific American Women's Forum
National Council of Jewish Women, Seattle Section

National Organization for Women, Washington State Chapter
Northwest Health Law Advocates
Northwest Reproductive justice Collaborative
Older Women's League, Seattle King County
Planned Parenthood Columbia Willamette
Planned Parenthood of Greater Washington and North Idaho
Planned Parenthood of the Great Northwest
Planned Parenthood VOTES Washington
Parents Organizing for Welfare and Economic Rights (POWER)
Real Change
Sahngnoksoo
Sexual Violence Law Center
United Food & Commercial. Workers Local 21
Washington CAN
Washington State Coalition Against Domestic Violence
Washington State Coalition of Sexual Assault Programs
Washington State Labor Council, AFL-CIO
Washington State Nurses Association

ER783-787
Letter in Response to Rules that Ensure Patient Access to Medication

September 21, 2010

Washington State Board of Pharmacy
c/o Doreen Beebe
PO Box 47863
Olympia WA 98504-7863
Fax (360) 236-2901

Sent via email to accesstomeds.wsbopadoh.wa.gov

re: Please Keep the Rules that Ensure Patient Access to Medication

Dear Board of Pharmacy Members:

We, the undersigned organizations concerned about survivors of domestic and sexual violence, write to urge you to keep the existing rules that ensure that a patient will get her prescription at a pharmacy on site and without unnecessary delay.

The organizations Wining this letter work to promote women's health and safety.

Legal Voice is a regional non-profit organization whose mission to advance women's legal rights in the five Northwest states: Alaska, Washington, Oregon, Idaho and Montana. Founded in 1978 as the Northwest Women's Law Center, Legal Voice has been a leading regional advocate for women's rights, including reproductive freedom and the right to live free of domestic and sexual violence. Legal Voice is also co-counsel representing

Defendant-Intervenors in the lawsuit *Stormans v. Selecky*, in which we joined the state of Washington to defend the existing Board of Pharmacy regulation that ensures all patients timely access to lawful medications on site and without discrimination.

The Washington Chapter of the National Organization for Women (NOW) is the state chapter of a national organization founded in 1966 to ensure equality for all women. NOW works to eliminate discrimination and harassment in the workplace, schools, the justice system, and all other sectors of society; secure abortion, birth control and reproductive rights for all women; end all forms of violence against women; eradicate racism, sexism and homophobia; and promote equality and justice in society. Like Legal Voice, NOW has advocated before the Board of Pharmacy since 2005 for rules that promote patient health and safety.

The Washington Coalition of Sexual Assault Programs (WCSAP) is the leading voice of sexual assault victims in Washington State. WCSAP, founded in 1979, is a membership agency comprised of individuals and organizations dedicated to ending sexual assault. The organization's mission is to unite agencies engaged in the elimination of sexual violence through education, advocacy, victim services, and social change. WCSAP also advocated before this body for rules that would ensure access to emergency contraception, a drug that is critical for treating women and girls of childbearing age after a rape.

The Washington Coalition Against Domestic Violence (WSCADV) is a non-profit network of domestic violence programs serving domestic

violence survivors throughout Washington State. For more than 10 years, WSCADV has worked to end domestic violence and ensure safety and justice for survivors. Advocates for survivors of domestic violence understand that women in abusive relationships experience unwanted or coerced sexual assaults, and that even when such intimacy is not coerced, that abusive partners (particularly of young women and adolescent girls) frequently engage in "birth control sabotage" leaving women in these circumstances particularly vulnerable to unintended pregnancy.

The Sexual Violence Law Center (SVLC) is a non-profit organization located in Seattle and serving sexual assault survivors throughout the state of Washington. The mission of the SVLC is to improve the legal response to survivors of sexual violence through education and training, advocacy, legal assistance, consultation and referral services. The Sexual Violence Law Center believes that all systems – the courts, attorneys, law enforcement, shelter programs, advocacy groups, healthcare providers, employers, landlords, schools, and state and local governments – must function in a coordinated fashion to prevent sexual and domestic violence and provide justice to victims of these crimes. Because pharmacies are a crucial point of access to emergency contraception for rape survivors, the SVLC supports the existing rules that ensure onsite and timely access to medications.

Our organizations supported the existing rule because of our concerns for women's health.

Because of our shared concern for women's health, and in particular the health and safety of

survivors of sexual assault and domestic abuse, we joined together in 2002 to ask the Washington State Legislature to require every hospital in the state – regardless of religious affiliation – to counsel sexual assault survivors about emergency contraception, and to provide it to sexual assault survivors upon request.[1] Similarly, when in 2005 we started hearing reports of women refused emergency contraception and regular hormonal birth control at pharmacies, we began advocating with this body for a rule that would ensure timely and non-discriminatory access to these and all other medications.

As you are aware, after a long process, involving more than 20,000 public comments, the Board of Pharmacy ultimately passed a rule that puts patient health and safety first, while accommodating an individual pharmacist to the maximum extent possible. The conclusion this Board reached – that pharmacies must ensure that patient needs are met onsite and in a timely manner – was an appropriate conclusion, confirmed by the Ninth Circuit in *Stormans v. Selecky*.[2]. While that litigation is currently stayed to allow this rulemaking process to go forward, the Ninth Circuit has clearly signaled that the rules are constitutional and will likely be upheld.

<u>The existing rules are necessary to protect patient health and safety.</u>

The existing rules appropriately place the burden on pharmacies to fill their professional and ethical functions – as providers of a community's

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[1] In response, the Legislature passed RCW 70.41.350.

[2] 586 F.3d 1109 (9th Cir. 2009)

pharmaceutical needs whose first duty is to the patient. When pharmacies and pharmacists refuse to fulfill that role for reasons other than professional decisions designed to protect patient safety, people – especially women – are harmed.[3] Access to contraception, in particular, is critical for all women and girls of childbearing age, whose right to decide whether and when to bear children is fundamental.[4] While the exercise of this right is critical for women's equal participation in political, economic, and social life, there are also health consequences associated with an unintended pregnancy. Women with unplanned pregnancies have two to four times the risk of experiencing domestic violence as do women whose pregnancies are planned[5], and are more likely to delay seeking prenatal care. [6] For all women, whether a

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[3] National Health Law Program, Health Care Refusals: *Undermining Quality Care for Women*, available at http://www.healthlaw.orgiimagesistories/Health_Care_Refusals_Undermining_Quality_Care_for_Women.pdf; *see also* National Women's Law Center, *When Health Care Providers Refuse: The Impact on Patients of Providers Religious or Moral Objections to Give Health Care, Information, or Referrals*, available at http://www.nwlc.ore./pdf/apri12009refusalfactsheet.pdf.

[4] *See, e.g., Planned Parenthood v. Casey*. 505 U.S. 833 (1992).

[5] Moore, M., Special Report: *Reproductive Health and Intimate Partner Violence*, Family Planning Perspectives, Volume 31, No. 6, (1999), citing Gazmararian, J. *et al, The relationship between pregnancy intendedness and physical violence in mothers of newborns*, Obstetrics and Gynecology, Vol. 85 No. 6, 1031-1038 (1995).

[6] D'Angeto, D.V. *et al, Differences between mistimed and unwanted pregnancies among women who have live births*, Perspectives on Sexual and Reproductive Health, Vol.

pregnancy is planned or unintended, the risks associated with pregnancy may include high blood pressure, diabetes, or heart, breathing, and kidney problems.[7]

Access to Plan B, the emergency contraceptive, is particularly important for sexual assault survivors and domestic abuse victims. Despite many advances in the law to protect women from sexual assault and intimate partner violence, these remain common crimes, often resulting in death or serious injury. [8] As the Washington State Legislature declared, approximately 38 percent of women in Washington are raped in their lifetimes – a rate 20% higher than the national average. [9] Nationwide, young women and girls, ages 16 to 19, are the most likely to suffer sexual assault. [10] Women and girls who survive domestic or sexual violence may suffer post-

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36 No. 5, 192-197 (2002).

[7] *See, e.g.*, the National Institutes of Health Pregnancy Fact Sheet, available at http//www.nichd.nih.gov/health/topics/pregnancy.cfm. (last visited September 25, 2008).

[8] Tjaden, P. & Thoennes, N., *Extent, Nature and Consequences of Rape Victimization: Findings from the National Violence Against Women Survey* (U.S. Dep't of Justice Jan. 2006) (more than 18 million women in the United States have been raped); *Costs of Intimate Farmer Violence Against Women in the United States*, National Center for Injury Prevention, Atlanta (GA) (2003) (an estimated 1.3 million women are victims of physical assault by an intimate partner each year).

[9] RCW 70.41.350 Findings – 2002 c 116.

[10] *National Crime Victimization Survey: Criminal Victimization*, 2002 (U.S. Dept. of Justice, Washington, DC), August 2003 at 8.

traumatic stress disorder,[11] a mental and physical reaction to a traumatic event or series of events. PTSD and its symptoms can last for many years and have devastating effects on a victim, her family, and her community.[12]

Among the fears a survivor suffers after a rape is the fear that she will contract HIV or become pregnant as a result of the rape.[13] Fortunately, we have the ability to immediately address both of these fears by providing emergency contraception and HIV prophylaxis to everyone who seeks medical care after a rape. Refusals to provide emergency contraception put women and girls at risk of pregnancy and compounds the trauma they suffer.

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[11] *See* Orsillo, S., *National Center for Post Traumatic Stress Disorder Fact Sheet: Sexual Assault Against Females*, United States Department of Veterans Affairs, available at www.ncptsd.va.gov/ncmain/ncdocs/fact_/fs_female_sex_assault.html?opm=1&rr=rr87&srt=d&cchorr=true (last visited September 25, 2008).

[12] *National Center for Post Traumatic Stress Disorder Fact Sheet: What is Post Traumatic Stress Disorder (PTSD)?* United States Department of Veterans Affairs, available at www.ncptsd.va.gov/ncmain/nedocs/fact_skits/fs_wha_is_ptsd.html (last visited September 25, 2008).

[13] Smugar, S., *et al., Informed Consent for Emergency Contraception: Variability in Hospital Care Rape Victims*, American Journal of Public Health, Vol. 90, No. 9 (September 2000) at 1372; see also Osterman, J., *et al., Emergency Interventions for Rape Victims*, Psychiatric Services, Vol. 52, No. 6, 733-740 at 733 (June 2001) (emergency intervention with a rape victim includes providing that person with information to help her address fears about future medical problems, including pregnancy).

Requiring a referral does not alleviate this concern. First, it is obviously meaningless to refer a woman to another pharmacy in a community with only one pharmacy, or when the closest pharmacy is many miles away. Second, requiring a referral ignores the fact that some women requesting Plan B are seeking it under the constraints of an abusive relationship, where their ability to consent to sexual activity, their ability to control reproductive decisions, and their access to doctors, funds and transportation are limited. [14] Women in these circumstances may not be able to follow up on a referral. Further, refusing to dispense Plan B to a woman who has requested it increases that woman's risk of pregnancy, even if there is another pharmacy in her community. This is because timely access to Plan B is critical. The drug is most effective if taken as soon as possible after sexual intercourse or a sexual assault, preferably within the first 24 hours but up to 120 hours after the event. [15] Its efficacy decreases with delay. Accordingly, it is simply bad patient care to deny a woman access to emergency contraception, even if she may be able to obtain it elsewhere later. State policy should not place this burden on women in need of emergency contraception, regardless of their circumstances but it should especially avoid placing any burden on survivors of sexual assault and domestic violence.

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[14] Miller, E., *Editorial: Reproductive Coercion: Connecting the Dots Between Partner Violence and Unintended Pregnancy,* Contraception, Vol. 81, 457-459 (June 2010).

[15] American College of Obstetricians & Gynecologists, *Practice Bulletin: Clinical Management Guidelines for Obstetrician-Gynecologists*, Vol. 69 (December 2005) at 4-5.

A new rule permitting a facilitated referral is not likely to end litigation on this issue.

Any rule that burdens or interferes with access to medications that only women need is subject to challenge under state and federal laws. Women's advocates will not hesitate to bring legal challenges to rules that work a disparate harm on women or interfere with reproductive freedom.

Additionally, our experience – and indeed, public testimony at the first public hearing on this new rulemaking process, held on September 17, 2010 – teaches that not everyone who refuses to dispense certain medications will be satisfied by a rule that requires referral. One need only look to one of our sister states – Idaho – for evidence of this proposition. This year, the Idaho Legislature passed a law that allows any health care provider to refuse to provide, counsel, or refer a patient in need of emergency contraception. [16] So, while a mandated referral may satisfy those pharmacists with objections to Plan B and other medications who are willing to engage in a referral, it will surely not stop potential lawsuits brought by others who believe a mandated referral violates their constitutional rights.

In conclusion, we urge the Board of Pharmacy to leave the existing rules in place. The rules are critical because they ensure that patient health and safety is paramount. A mandated referral is cold comfort for women without access to an alternative provider, or who seek emergency contraception after a sexual assault.

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[16] Idaho Senate Bill No. 1353, available at http://www.legislature.idah.gov/legislation/2010/S1353.pdf

Sincerely,

Lisa Stone
Executive Director

Sara L. Ainsworth
Senior Legal & Legislative Counsel

On behalf of:

Legal Voice
National Organization for Women, Washington Chapter
Washington Coalition of Sexual Assault Programs
Washington State Coalition Against Domestic Violence
Sexual Violence Law Center

ER867
Letter Regarding Consideration of Policy Change

September 28, 2010

Washington State Board of Pharmacy
do Doreen Beebe
PO Box 47863
Olympia WA 98504-7863
Fax (360) 236-2901

To the Board of Pharmacy:

I am writing regarding your consideration of the policy change to allow Washington State pharmacies to refuse to dispense medications because of a pharmacist's personal beliefs,

Several years ago, I went to a Bartell's pharmacy with a prescription from my doctor for Plan B. Upon presenting my prescription to the pharmacist, I received a lecture about my decision to use Plan B. It would have been one thing if the pharmacist had wanted to inform me about potential drug interactions, generic alternatives, or possible side effects. Instead, I had to sit through a questioning of a personal decision that was made in consultation with my physician.

My decision to use Plan B was none of this pharmacist's business beyond verifying that it was safe for me to use given my health history. This pharmacist knew nothing of my reasons for choosing to use Plan B, but I had to listen to this pharmacist's personal, not professional, reasons for why I should not use it. I could go on at length to describe the scenario that caused me to present

myself at this pharmacy to get my Plan B prescription filled, but ultimately that information is none of your business as a board and nor should it be a pharmacist's business either. By allowing pharmacists to refuse to dispense a medication for reasons other than professional reasons, you are allowing a pharmacist to put his beliefs ahead of patient health.

One could argue that I could have gone to a different pharmacy, and indeed I could have. Many other people, however, may not have that luxury. What if I had lived in a rural community with limited access to public transportation and few pharmacies reachable by bus? Given the limited amount of time for the use of Plan B, I could have lost the opportunity to use this medication because of the pharmacist's personal beliefs.

When I go to a pharmacy with a prescription, I expect to be able to avail myself of a pharmacist's professional expertise, not his or her moral guidance. For that, I go to a counselor, priest, or trusted friend or family member.

If pharmacies may refuse medications for any reason, what would prevent a pharmacist from deciding not to dispense antiretroviral drugs to a person with HIV? What if I were a pharmacist who found smoking or drinking to be morally objectionable, could I then refuse to dispense chemotherapy drugs to patients with lung or liver cancer? School teachers who hold personal beliefs that may conflict with a district's mandated curriculum are not allowed to skip over those parts they find objectionable. Police officers are not allowed to choose which laws they enforce based upon their personal beliefs. A paramedic is not

permitted to refuse to treat a person for an injury sustained because of a choice he or she finds to be morally objectionable. If you allow this change, you will have started down a slippery slope.

I urge you to support equal access to all medications for all people.

Molly K. Harmon, Seattle WA

ER899-907
Testimony from September 29, 2010
Washington State Board of Pharmacy Public Meeting

Green: I come to you today as a domestic violence advocate, a sexual assault advocate and a survivor of intimate partner sexual violence. So in other words, I was raped by somebody that I cared and trusted over and over again and it's really hard for me to share actually.

So I woke up one morning to figure out that I had been raped in my sleep and being very, very meticulous about my reproductive health, my choice, I did not want to have a child with this person. This was not my choice. I did not want that. I, it was over a weekend and it took me a long time to be able to get to a phone to make the phone calls to find this prescription. By the time I called and called and called all these different places and was told no over and over again, now mind you I don't live in a rural area, I'm above the poverty level, I don't have very many boundaries at all to getting anything, but I was told no over and over again. I finally got really frustrated, had to wait several days, finally made it into a doctor and I was okay and everything was fine and I did not have a pregnancy, but I was able to get that medicine.

It wasn't safe for me to leave that relationship yet, so I had to stay there and again, a few months later another incident happened. But that time I was so upset by the process and how that had occurred, finding that I really wasn't, I didn't feel honored, I didn't feel like my story mattered. I did tell the pharmacists why I was calling, what I needed and I was just told no. I wasn't told no, you can call this

pharmacy. I wasn't told no, you can find it here. I was just told no. So that time I did not make those phone calls. I did not take that process and I conceived a child and I'm not going to talk about how that ended for me because it's irrelevant. But I really want you to just consider victims' rights in this situation and the fact that referring people is already not happening and I understand that, you know, there's a complaint process, but I just learned that today and how do you expect people to tell you? They don't even know.

Martin: Hi, I'm Dr. Carolyn Martin and I work at I work in downtown Seattle and I think it's important to know what's currently happening to my current patients under the present rules. Back in February a patient came in for a routine annual exam we discussed birth control options, she chose to have an IUD placed. I prescribed her a dose misoprostol, which in small doses helps this procedure go more smoothly and more safely. She went to fill her prescription on the Sunday night prior to the procedure on Sunday afternoon, presented a prescription to her pharmacist who gave her a very strange look and said no, I'll have to check with your physician. She called the physician on call and told this physician that this could be used to cause abortions, that she refused to fill it, that she couldn't fill it legally.

She wouldn't even prescribe this person birth control pills and then went and told the patient the same thing. The patient asked her for a referral, is there any place or anybody in the pharmacy that would fill this for me? The pharmacist said nape, I am the only pharmacist here, there's nobody here who can fill this and I don't know anybody in the area that would fill this for you. The patient then

called my partner who was on call that night. They did find a pharmacy to fill it, but she was mortified. The patient was embarrassed and, you know, really didn't understand what the process was.

This is an important medication. It prevents us from taking people to the operating room. It softens cervix, allows us to endometrial biopsies if they've had cancer, it allows us to do office procedures with minimal pain with minimal intervention. It decreases healthcare costs by allowing us to keep people out of the operating room. It is important for all patients to have access to this or at least to have an opportunity to go to a pharmacy without embarrassing them and get their prescription filled.

Martinez: Thank you for hearing my testimony. My name is Peggy Martinez and I am employed as an assistant technology instructor at the Seattle Lighthouse for the Blind. I myself am blind, but I believe I can speak for many persons with disabilities whether they are blind or deaf or if they use a wheelchair or have developmental disabilities. I'm very independent. I can walk around my neighborhood, do my job, make a living. I use public transportation. I care, take care of my personal needs and I do all of those things fairly I would say well, although I have to say as you can imagine for me to get around and do various errands can be more challenging than it is for a person who can see or who can drive a car because things take a lot more time.

So often public policy decisions are made without considering the impact that they could have on people with disabilities and I'd like to make sure that that doesn't happen here. If the Board of

Pharmacy changes the existing rule and allows pharmacists to refuse services and refer to another pharmacy that could have a devastating impact on me and on other people who have difficulty getting from one place to another place. In my limited time I would just say that folks who learn different routes to navigate definitely would be very challenged if they had to, if they were refused and then time sensitivity could be a very big issue. So I ask you to consider keeping the rules as they are. Thank you.

Female: I'm here on my own behalf, but I've worked at nonprofit organizations my entire professional life on behalf of victims of child abuse, incest, domestic violence and sexual assault and I did so in eastern Washington for the first four years of my career, including in some extremely rural counties. Two things that I wanted to say. The first is that any time you get a professional license that is state sanctioned you make compromises. You agree to submit to certain rules. Now, if a pharmacist said I will not fill a prescription for anyone who's Muslim because I find that unconscionable, we would obviously not find that acceptable, okay? So you wouldn't be allowed to be a pharmacist if that was your conscience and you couldn't sacrifice that. This is no different from that.

The other issues has to do with rural areas and I know because I've lived there and practiced there for quite a while in eastern Washington. I did a little Google Map search while I was sitting in the audience. In Republic, Washington where I've practiced there are two pharmacies as far as I can tell and I can pretty much guarantee you that in Republic, Washington neither of the pharmacists

are gonna wanna prescribe Plan B. Now, if you get refused by those two pharmacies the next closest pharmacy that I could find was in Tonasket I believe it's called, haven't been there. So they've got one pharmacy. That's 45 minutes in one direction. So if then they say no, then, you know, you drive your 45 minutes back and then it's another hour to Kettle Falls in the other direction to find the one other pharmacy there and that's, those are, that's it within an hour radius.

My clients, victims of domestic violence and sexual assault do not have the luxury of getting away for as many hours as they want to seek out prescriptions that their partners would obviously not support. My clients were all indigent and did not have the gas money to travel for hours to try to find the prescription that they need even if doing so was safe for their health. So I really ask you to consider the fact that we're not all privileged enough to live in Seattle, to have the money for a car, for gas money, to have a variety of pharmacies where we can get substitutions.

Nicholson: Thank you. I'm Nancy Nicholson and I'm here to calmly urge the board to keep the current rule. I want to be assured that if I have a legal prescription from my doctor I can get it filled without discrimination or delay. I also stand here for several of my friends whose disabilities require that they use wheelchairs. Unless you use a wheelchair yourself or have a close friend or family member who does, you cannot know the difficulties encountered in traveling from place to place.

If you depend on public transportation it may involve a long wait in cold and rainy conditions. It may mean a bus whose wheelchair lift is broken

and cannot pick you up. Even if you are privileged enough to own your own ramp van, finding accessible parking is often virtually impossible. Having surmounted all of these barriers to arrive at their pharmacy and then be refused service and told to go elsewhere when trying to fill a legal prescription is unconscionable. In keeping with the state's interest in ensuring patient health and safety please retain the current rule. Thank you.

Carlson: My name is Laurie Carlson and my dear friend is the surviving victim in the South Park attack that happened last summer and she would like to be here today, but she would also like to protect her identity, so she asked me to read this for her. To whom it may concern, I am new to my community. I am a pro choice woman who is also personally pro life.

From a very early age I felt that it would be extremely difficult and probably impossible for me to have an abortion should I ever find myself pregnant at a young age. With that said, I have held on dear to the fact that I have that choice. And all the years that I've held this close to me it never dawned on me that I would be confronted with this position through no fault of my own and from the hands of a rapist and murderer.

Last year my partner and I were raped at our own home at knifepoint. My rapist did not use protection. Why would he? He planned to kill us. After watching him kill my partner and almost kill me, I suddenly found myself in a hospital being asked if I wanted to utilize the Plan B pill. While I'm very well aware of the difference between Plan B and an actual aborted pregnancy, it still was a time where I found myself at a moral crossroads.

Based on this long-held belief could I knowingly circumvent a pregnancy? Absolutely. If I had already been pregnant would I have been able to abort my rapist's baby? Most likely, yes. For the sake of the child and my mental health, yes. But the decision and act itself would have been yet another thing I had to endure at the hands of my partner's murderer.

When I heard about this rulemaking process I couldn't help but think to myself that had the pharmacists that night had a personal problem with Plan B and chose not to dispense it I could have become pregnant. The pharmacist would have infringed on my personal belief and what was actually happening in my body. His choice could have aided to my trauma in ways that I'm glad I didn't have to endure. I hope _____ the miracle of life. I make choices based on my beliefs for myself, not for others. I implore you to allow the policy to continue to make choices that are best for our health, physical and mental. Please do not allow our doctors and pharmacists to make them for us.

Stone: Good afternoon. I'm Lisa Stone. I'm the executive director of Legal Voice, but I'm here today to provide you the testimony of Dr. Dale Reisner who has clinical obligations today. Members of the pharmacy board, I'm a perinatologist at Swedish Medical Center in Seattle. I care for the most vulnerable and sick children. I am also the secretary and treasurer for the Washington State Medical Association.

Many physicians have concerns about patients' access to medication. I write today as a physician and as a member of WSMA to offer our support and

working with the pharmacy community to address these concerns. As a physician who cares for women with high risk pregnancies, I understand that women's access to all reproductive healthcare medication is critical. However, it is absolutely clear that this issue affects all medication and all types of refusal. We are especially concerned that refusals at the pharmacy fall most heavily on low income patients, those with disabilities and those with limited English proficiency.

Just last Thursday I discovered that one of my Spanish speaking patients was denied her prescription medication at a pharmacy. The pharmacist told her the dose was wrong and flat out refused to fill the prescription. Rather than calling my office, he just asked her questions about the dose, he turned her away and he kept the prescription. Because English is not her primary language, she was confused and even unsure about what had happened. A whole week went by before I learned of the refusal. I was able to make sure that the patient got her medication. Luckily her pregnancy was not harmed, but the delay in getting her medication put her baby at serious risk.

I hope that the Board of Pharmacy will put aside this current effort to revoke a rule that helps ensure access to medication and instead turns its attention to how to improve such access for patients with language, insurance and other barriers. Thank you for your consideration.

Friedes: _____ Jewish colleague _____ the start of the high holiday. Many of us know every day _____ what it means to have a constance of conscience yet be able to work within our civil society. My name is Joshua Friedes and

I'm the executive director of Equal Rights Washington. It's a lesbian, bisexual transgender civil rights organization.

I understand a lot of the focus today has been on Plan B, but I want to remind people that this proposed measure is extremely broad. It could dramatically impact the lives of transgender people who rely on hormone therapy and, of course, people living with HIV. I am extremely disturbed that we are talking about denying people medications that they need and let me be very clear with what I mean by when I say this. As a gay man, I know the stigmatization and the harm occurs at the moment of denial, which in this case would be referral. Make no mistake about it, those of us who are denied our fundamental basic rights in the society would be hurt by referral. We all know what it means. We are second class, unequal, unworthy and let us also be clear that many of us will not go seek that which we need, essential medication. I implore you to do that which is right and to understand that in a diverse civil society we can accommodate everybody by making sure that when you hand in your script you get the medical treatment that you need.

Johns-Brown: Members of the Board of Pharmacy, I'm Lonnie Johns-Brown. I'm speaking to you on behalf of the Washington State chapter of the National Organization for Women and the Washington State League of Women Voters. And we ask you to continue with the current rule.

I think that you've heard a variety of testimony here today and what's very important to us is that you recognize that what is acceptable in Seattle or Bellingham or Olympia is not necessarily the case

in some of our more rural areas. While it sounds like an easy thing to refer someone to yet another pharmacy, it's not always an easy, an easy thing to accomplish. People who need Plan B or any other time sensitive pharmaceutical or prescription are trying to manage within the parameters of the reality of their lives. They have transportation challenges, they don't always get off work on time. They have multiple barriers that they're trying to overcome. Some of them have, as we just heard recently, physical challenges that make even trying to get across town in Seattle a very difficult and improbable thing for them to accomplish.

So we really urge you to stick with this current rule. Think of the state as a whole. Think of the exceptional barriers, not just the commonality of our lives, those of us that are capable of going across the street and to remember in closing that some folks, many folks have a pharmacy that they are directed to by the varied realities of their insurance plan and that's something we would like you to factor in as well. Thank you.

ER932, 936-938
Washington State Pharmacy Association — Right to Refuse Presentation Summary

WASHINGTON STATE DEPARTMENT OF
HEALTH BOARD OF PHARMACY
CenterPoint Corporate Park
Kent, Washington

CONVENE

Chair Asaad Awan convened the meeting at 11:24 a.m. on January 26, 2006. Board Members present:

Susan Teil-Boyer, RPh
George Roe, RPh
Donna Dockter, RPh
Garry Harris, RPh
Sharron Sellers
Rebecca Hille, Vice-Chair

Staff Members present:

Joyce Roper, Assistant Attorney General
Steven Saxe, Executive Director
Tim Fuller, Pharmacy Consultant
Andy Mecca, Pharmacy Consultant
Grace Cheung, Chief Investigator
Stan Jeppesen, Pharmacist Investigator
Doreen Beebe, Program Manager

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Washington State Pharmacy Association — Right to Refuse

William Fassett, representing the Washington State Pharmacy Association, provided

a summary of the work done last year by the WSPA ad hoc committee tasked with reviewing the Associations' position and providing recommendations on a pharmacist's right to refuse to fill prescriptions. Members of the Committee formed in July 2005 are CJ Kahler, Chair; Merrie Kay Alzola; Marie Bach; Renee Cook; Bill Fassett; Teri Ferreira; Lee Funkhouser; Tim Lynch; Sue Merk; Jim Ramseth; Rod Shafer, and Sepi Soleimanpour.

The Committee considered it important that the pharmacist communicate clearly with the patient the nature and extent of his or her services so that the patient can establish a professional relationship with a pharmacist who is best prepared to meet his or her needs. A patient and pharmacist must enter into a professional relationship and patients should choose pharmacists that meet their needs.

Committee concluded that pharmacist must have options in place to offer patients when the pharmacist is unable to fill an otherwise lawful prescription, e.g., conscientious objections, out of stock, not stocked or other reasons. The pharmacist must do more that just state, "I can't help you".

Some members of the committee did not want to require an individual pharmacist to initiate a referral to another pharmacy on the basis that for some pharmacist the active referral in their mind constitutes a moral connection to something that violates their moral commitment. The committee did agree that the referral is an appropriate option to have.

In the presentation, Mr. Fassett discussed actions for which the committee identified as professionally unacceptable.

- Refusing to identify another pharmacy when asked by the patient for a referral.
- Refusing to transfer a prescription to another pharmacist,
- Destruction of a valid prescription and/or refusal to return a valid prescription to the patient.
- Violation of the patient's privacy.
- Inflicting on the patient an unsolicited lecture regarding the patient's healthcare choices. (not the same as counseling)
- Failure to treat the patient with dignity, or otherwise demeaning the patient

The Committee concluded that the pharmacist must act in accordance with the demands of his or her conscience, based upon an accurate understanding of the medical facts and circumstances, and that "the pharmacist's decision must respect the autonomy of the patient, and not impede the patient's right to seek the service being requested".

The Ad Hoc Committee recommendations were adopted by the WSPA's Board of Directors. These recommendations included recognizing and respecting the professional responsibility of a pharmacist to provide pharmaceutical care for his/her patients and that a pharmacist must act in

accordance with his or her moral, ethical or religious principles. The WSPA supports the establishment of individual systems that protect the patient's ability to obtain legally prescribed and therapeutically appropriate treatment; and the reasonable accommodation of a pharmacist's conscientious objection.

The Committee's recommendations further identifies that a pharmacist has a serious responsibility to always hold the autonomy, dignity, and confidentiality of his/her patients in the highest regard; to appropriately communicate the availability or unavailability of pharmacy services to his/her patients, and the prescribers in the community, to have options in place to communicate to patients when the pharmacist is unable to fill prescription; to diligently develop his/her conscience-guided response to selected pharmaceutical services; and to inform and reach agreement with an employer and the pharmacy's staff as appropriate, concerning his/her anticipated response to identified pharmaceutical care requests.

The Pharmacy Board members recognize that this is a very complex issue and not just about reproductive rights. Some Board members expressed concern with a regulatory body requiring all prescriptions be filled but felt it was appropriate to identify unprofessional conduct as placing additional barriers before patients.

The Board expressed an interest in being able to take disciplinary action for actions the committee found professionally unacceptable. Joyce Roper reminded the Board that its authority to take disciplinary action would be more clear if the

board adopted a rule finding the professionally unacceptable actions to be unprofessional conduct or outside professional standards of practice and the Board could then cite for failure to comply with a board rule defining or establishing standards of patient care or professional conduct or practice {RCW 18.130.180(7)] rather than having to rely on RCW 18.130.180 (4), incompetence, negligence, or malpractice which results in injury to a patient or creates an unreasonable risk that a patient may be harmed because then the state would have to prove harm or unreasonable risk of harm. **MOTION**: Rebecca Hille moved that the Board begin the rule making process. **MOTION CARRIED**.

Steve Saxe reminded the audience that the CR101 form initiated rule making – notice to interested parties and does not contain specific language for rule-making. Normal process can take 12 months or more.

Nancy Sapiro, Northwest Women's Law Center and Kelly Reese of Planned Parenthood request an opportunity to provide comment on this issue and the recommendations by WSPA at a future meeting.

ER979-980
Board of Pharmacy Q&A on Proposed Rules

Department of Health
Board of Pharmacy
Excerpts from Q&A on proposed pharmacist/pharmacies responsibility rules

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What happens if a pharmacy does not want to stock a drug?

Pharmacies are expected to stock all medications in demand by their patients. If they don't have them when customers request them, they must order and stock them. Pharmacies are not expected to stock all medications on the market. This would be prohibitively expensive.

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Why did it take so long to draft these rules?

It takes time to adopt significant rules. The time it took in this case was not out of line with what is common in other rule processes. These rules are important to both patients and the pharmacy profession. The board took great care to listen to both sides of the issue before making a decision on proposing draft rules.

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Were these written specifically to address the Plan B issue?

The Plan B issue was an obvious motivation to clarify responsibilities. But other medicines could also become an issue and the rules were drafted to be broad enough to cover the delivery of all medications.

ER982-994
Final Significant Analysis

Final Significant Analysis for Rule Concerning Pharmacists' Professional Responsibilities, WAC 246-863-095 & Pharmacies' Responsibilities, WAC 246-869-010

The Washington State Board of Pharmacy is adopting amended WAC 246-863-095 and new WAC 246-869-010 to improve state-wide access and reduce barriers for patients seeking U.S. Food and Drug Administration-approved drugs and devices. If a patient is unable to obtain needed medications in a timely manner, the associated medical and social costs can be substantial. For example:

- Each time an HIV patient's infection is effectively treated by timely drug therapy, the patient avoids other medical costs as high as $303,000.[1] If timely treatment does not occur, the patient has increased ability to transmit the HIV virus to others, and may be vulnerable to serious infections.

- The Department of Social and Health Services reports that in Washington, more than 55 percent of births to women receiving state Medicaid care are unintended pregnancies (70 percent for women age 20 to 25), at an annual cost of more than $250 million.[2] Women – particularly those under

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[1] JS Gallant. Moore News Quarterly. Vol. 1(1). December 2000.

[2] 2006. Washington Department of Social and Health Services, *TAKE CHARGE Final Evaluation – First Five Years*

> 18 - who face barriers to obtaining birth control products are at greater risk for unintended or unwanted pregnancy. Unintended or unwanted pregnancies are associated with a variety of poor health outcomes for mothers, infants and children.

The effective treatment of many other diseases and conditions depends on timely access to and administration of prescription drugs and devices. These rules are intended to protect patients' health, safety and welfare, support the Board's Mission and Vision, and help accomplish the goals of the statutes administered by the Board of Pharmacy.

Background:

In 2004 media began to report on incidents occurring nationwide in which pharmacists have refused to dispense prescriptions for moral, religious and personal reasons. In response, many state regulatory boards have enacted laws or regulations, or adopted policies addressing a pharmacist's responsibilities. These laws, regulations and policies vary widely from:

- Requiring pharmacists to dispense all lawful prescribed drugs and devices;
- Allowing pharmacist to refuse for moral or religious objections; to
- Offering protections for consumers but remaining silent on pharmacists' rights to exercise their personal conscience.

July 2001 – June 2006.

Since 2004, complaints have been filed with the Board of Pharmacy (Board) concerning pharmacists' refusal to fill prescriptions. In 2005 the Board began to receive calls and emails inquiring to the Board's position on pharmacists' refusing to dispense drugs and devices for moral or ethical objections. The Board acknowledges that other incidents may go unreported or are reported to entities other than the Department of Health.

Washington State pharmacy laws and rules were silent on this issue. The Board did not have a formal position; however, the Board stressed that public health and safety were primary. The Washington State Pharmacy Association (WSPA) informed the Board that it had formed an ad hoc committee to develop its position statement regarding this issue and asked to present the committee's findings to the Board.

Following a January 2006 presentation by WSPA and a subsequent presentation by Planned Parenthood and other groups, the Board in April 2006 filed notice to initiate the rule making process to examine a pharmacist's responsibilities to dispense lawful prescribed drugs or devices. The Board recognizes this is a very complex issue. But the Board had concerns that requiring all prescriptions to be filled would not adequately ensure public safety, for example: fraudulent prescriptions should not be filled, nor when there are contraindications. The Board did consider it necessary to identify certain conduct as unprofessional as it relates to this issue, for example: placing additional barriers to patients' access to health care.

The Board recognizes that the issues of access to timely drug therapies, and pharmacist's refusal to dispense some medications, apply to several types of medications. But particular public interest and comment during this rule-making process focused on the dispensing and delivery of Plan B, an emergency contraceptive pill, and other prescription birth control products.

Plan B, (levonorgestrel) is taken after unprotected sexual intercourse (or when protection is used but has failed), and must be administered within 72 hours after unprotected intercourse to be most effective. Plan B was available by prescription only from 2003 through late 2006. In December 2006, the U.S. Food and Drug Administration approved Plan B as an over-the-counter (OTC) drug for women age 18 and older, but it must be stocked behind the pharmacy counter and must be requested by the patient. Plan B remains available by prescription only to women under 18. FDA's approval documents said Plan B was proposed for OTC sale because the "prescription requirement presents a barrier to timely access and because delays in treatment reduce efficacy significantly."[3]

Briefly describe the rules.

The Department of Health, Board of Pharmacy is adopting amendments to WAC 246-863-095 *Pharmacist's professional responsibilities, and a new section*, WAC 246-869-010 *Pharmacies'*

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[3] 2006. U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *Application No. 21-045/SO11, Clinical Pharmacology and Biopharmaceraias Review(s).*

responsibilities, to promote patient safety and access to health care by emphasizing the professional responsibilities of pharmacists and pharmacies.

WAC 246-863-095

Amendments to the rule:

1) State that it is a pharmacist's primary responsibility to ensure patients receive safe and appropriate medication therapy.

2) Prohibit a pharmacist from delegating the decision to not dispense a lawful prescribed drug or devices to pharmacy support staff.

3) Provide grounds for discipline when a pharmacist, pharmacy intern, or pharmacy ancillary personnel engages in or permits the following conduct that is unprofessional;

(a) Destroying unfilled lawful prescription.

(b) Refusing to return unfilled lawful prescriptions.

(c) Violating a patient's privacy.

(d) Discriminating against patients or their agent in a manner prohibited by state or federal laws.

(e) Intimidating or harassing a patient.

WAC 246-869-010

This new rule:

1) States that pharmacies have a duty to deliver/distribute lawful prescribed drugs and devices or provide a therapeutically equivalent drug or device to patients in a timely manner. The rule establishes requirements for a pharmacy to assure patients have access to lawfully prescribed and clinically safe medication therapy when a pharmacist cannot dispense.

2) Provides examples of circumstances when it may be appropriate for a pharmacy not to deliver/distribute lawful prescribed drugs, devices, or provide therapeutically equivalent drugs. The list is not inclusive but validates additional circumstances as substantially similar to those listed in the rule. The circumstances listed include: national or state emergencies or guidelines that affect the availability, usage or supply; potentially fraudulent prescriptions; lack of specialized equipment or expertise to safely produce, store or dispense a pharmaceutical; or when a pharmacy is not compensated for its usual and customary or contracted charge.

3) Requires pharmacies to provide patients with a timely alternative to appropriate therapy when the drug is not in stock because it is not customarily purchased or requested by the pharmacy's patients, or the drug is temporarily out-of-stock. A pharmacy may:

- Obtain the drug or device and deliver to the patient;
- Contact the prescriber for alternative drug therapy.
- On patient's request, return the prescription to the patient; or
- On patient's request, transmit the prescription to another pharmacy that will fill.

4) Provides grounds for discipline when a pharmacy engages in or permits the following conduct that is unprofessional:

- Destroying an unfilled lawful prescription.
- Refusing to return an unfilled lawful prescriptions.
- Violating a patient's privacy.
- Discriminating against patients or their agent in a manner prohibited by state or federal laws.
- Intimidating or harassing a patient.

Is a Significant Analysis required for this rule?

Yes. A Significant Analysis (also known as a cost-benefit analysis) is required if a proposed rule meets the definition of a "significant legislative rule" under RCW 34.05.328. Among other

considerations, the Significant Analysis compares the probable qualitative and quantitative costs to the probable qualitative and quantitative benefits of adopting the rule. An analysis is required for new WAC 246-869-010, and Sections (1) and (4) of amended WAC 246-863-095.

Portions of the amended WAC 246-863-095 do not require a significant analysis because they clarify existing language or adopt housekeeping changes.

A. Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

RCW 18.64.005 gives the Board of Pharmacy the authority to adopt rules for the dispensing, distribution, wholesaling and manufacturing of drugs and devices and the practice of pharmacy for the protection and promotion of the public health, safety and welfare. The practice of pharmacy includes, but is not limited to, the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices [RCW 18.64.011 (11)].

RCW18.130.050 grants the Board of Pharmacy the authority to adopt standards of professional conduct or practice.

B. Determine that the rule is needed to achieve these goals and objectives, and analyze alternatives to rulemaking and the consequences of not adopting the rule.

The rules are needed to minimize barriers to health care and to reduce risks for patients' health where there may be an emergent need for a prescribed drug or device, or where timely preventative use is essential to drug efficacy. The people of Washington must know that they can get the medications they need without barriers to health care.

The rules support the Mission and Vision of the Washington State Board of Pharmacy, which includes creating "a climate for patient-focused practice of pharmacy. Pharmacists inform, educate, consult, manage drug therapy and provide products as an integral part of an accessible, quality-based health care system."

The rules meet the goals and objectives of the statute by promoting patient safety and access to health care. The rules assure patients have access to safe and appropriate medication therapy by eliminating barriers that would prevent patients from receiving timely access to their lawful prescribed or therapeutically equivalent drugs and devices.

The rules meet the goals and objectives of the statute by clarifying the expectations for professional conduct and practice for pharmacists and pharmacies when presented with a lawful prescription. In addition, the rules adopt adequate grounds to discipline for failure to comply.

A pharmacy or pharmacist may be disciplined for failing to ensure patients receive safe and appropriate medication therapy in a timely manner. The rules require the pharmacy business to take steps to deliver the drug or device

to the patient. Or, when a medication is not in stock, the pharmacy is required to provide the patient with timely alternatives for appropriate therapy. A pharmacy may not refer a patient to another pharmacy in order to avoid compliance with this rule.

Exceptions:

> A pharmacy may refuse to deliver a prescription when one of the exceptional circumstances in proposed rule WAC 246-869-010 subsection (1)(a) through (e) applies.

A pharmacy or any person authorized to practice or assist in the practice of pharmacy may be disciplined for inappropriate or unprofessional conduct for destroying or refusing to return an unfilled lawful prescription; violating a patient's privacy; and for discriminating, intimidating or harassing a patient.

Also, under RCW 18.64.165, a pharmacy may be subject to discipline for actions that violate "any of the laws of this state or the United States relating to drugs, controlled substances, cosmetics, or nonprescription drugs, or …violate any of the rules and regulations of the Board of Pharmacy…."

The adoption of policies or guidelines could provide an alternative to rule making by establishing similar expectations for pharmacies and pharmacists to improve patients' access to safe and appropriate medication therapy. However, expectations established in a policy or guideline do not provide an enforceable mechanism for noncompliance. And where noncompliance with a

requirement may result in a penalty or sanction, the requirement must be adopted as a rule in the Washington Administrative Code.

C. Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

By adopting the permanent rules, the Board of Pharmacy has determined that the probable benefits of the proposed rules are greater than its probable costs and are needed to protect public health, safety and welfare. Costs of complying with the proposed rules must be balanced against the significant medical and social cost of patients not receiving a time-dependent medication in a timely manner. Access to medication is a critical factor in an individual's health and the efficacy of some medications is directly related to receiving the medication within a specified time.

The following estimates of benefits and costs of the adopted rules, where quantified, are intended to describe the benefit or cost of each instance or unit, and not an aggregate. While it may be possible to estimate the unit cost (price) of the some of these cost-benefit related factors, it is not easy to estimate the quantity and number of these cost-benefit related factors. For example, while the cost of hiring an additional pharmacist is estimated at $80,000, the number of pharmacists (if at all needed) is not easy to estimate with available data. Quantifying the variety of options available to pharmacies and pharmacists to comply with the rules, as well as the variable patient choices, make

such a single aggregate calculation impractical and not useful.

Probable Benefits of the Rule.

Removing barriers and improving state-wide access to FDA-approved drugs under these rules is expected to help patients receive the health benefits of the prescribed drug or device, help patients avoid other health complications, and help patients avoid the costs of treating conditions that may result from inability to access timely prescription drug therapy.

1. Improving state-wide access to prescription birth control products and OTC emergency conception is expected to help women of all child-bearing ages avoid unintended or unwanted pregnancy. If a woman receives emergency contraception pills within 72 hours of intercourse, there is an 89% probability of preventing pregnancy. If barriers exist to accessing emergency contraception, pregnancy is more likely to occur. In 2004, 81,715 children were born in Washington. According to the U.S. Centers for Disease Control and Prevention, 39.7 percent - 32,441 births - likely resulted from unintended pregnancies (excluding miscarriages). Nationwide, unintended pregnancy occurred even though 44.9 percent of women reported using other contraception at the time of intercourse - in Washington this rate is 46.7 percent.[4]

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[4] 2002. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *2002 PRAMS (Pregnancy Risk Assessment Monitoring System) Surveillance Report: Multistate Exhibits Unintended*

Unintended pregnancy is associated with a range of behaviors and conditions that adversely affect the health of women during pregnancy, including delayed entry into prenatal care, inadequate weight gain, cigarette smoking, use of alcohol and misuse of other drugs. Mistimed or unwanted births are associated with adverse outcomes for infants, including prematurity, low birth weight, and smallness for gestational age. Children born as a result of an unintended or unwanted pregnancy may be at greater risk of poor nutrition, reduced emotional development in infants, child abuse, and poor mental health in adulthood.[4]

2. Improving access to prescription birth control and emergency contraception may help patients avoid direct medical costs for an unwanted or unintended pregnancy. Table 1 describes the estimated direct medical costs to patients avoided by successful use of birth control products or emergency contraception.

Pregnancy and Contraceptive Use.

Table 1

Cost Avoided[5]	**Value in 2002 U.S. dollars, National Averages**
Cost of a birth	$ 4,509
Cost of spontaneous abortion	518
Cost of ectopic pregnancy	3,490
Cost of induced abortion	429

A study looking at the cost-effectiveness of Plan B alone indicates that for every dollar spent to purchase the drug may result in $3.24 to $9.30 in pregnancy-related medical costs avoided.[5]

Government costs of unintended or unwanted pregnancy may be avoided as well. According to the state Department of Social and Health Services, 45.9 percent of the births in Washington are paid by state Medicaid assistance, at an annual cost of more than $250 million. DSHS reports that 55 percent of Medicaid-paid births in Washington result from unintended pregnancies.

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[5] 2003. Trussell, James, and Shochet, Tara. Expert Review - Pharmacoeconomics Outcomes Research 3(4), *Cost Effectiveness of emergency contraceptive pills in the public sector in the USA.*

Seventy percent of Medicaid-paid births to women age 20 to 25 are unintended pregnancies.[6]

3. The rule is expected to help assure that women in all areas of the state have access to prescription birth control and timely administration of emergency contraceptives, especially in areas served by few pharmacies or alternative sources such as family planning clinics.

4. Women under 18 needing access to prescription birth control products, either as a preventative or for emergency contraception, will benefit. Since Plan B is available by prescription only to adolescent women, the time interval between intercourse, obtaining the prescription, and obtaining the medication reduces the time window for effective use of the emergency contraception and increases the risk of the drug being administered too late to be effective.

Improving state-wide access to prescription birth control generally is expected to help adolescent women avoid unwanted pregnancy. When teens give birth, their future prospects decline. Teen mothers are less likely to complete high school and post-secondary education, and more likely to live in poverty than other teens.[7]

5. Healthcare providers stress the importance of taking medication as prescribed. For

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[6] 2006. Washington Department of Social and Health Services, *TAKE CHARGE Final Evaluation – First Five Years, July 2001-June 2006*.

[7] 2007. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention website: *Adolescent Reproductive Health: Home*.

example, when a patient has an infection they are instructed to take the entire supply of antibiotics prescribed. Compliance or adherence refers to their ability to take their medications as prescribed. People who comply have better results in combating diseases than those who do not.

For example, human immunodeficiency virus (HIV) medications are highly time sensitive. An HIV patient must regularly take the HIV drugs prescribed to suppress the virus. The consequences of missing as few as three dosages can result in the virus mutating. If the virus mutates, the current drug regimen is no longer effective; requiring new tests to determine what new combination of drugs may be effective. New drugs are usually less effective and more expensive. Given that the mutation is permanent, the ultimate consequence is that the patient's probability of long term survivability can be greatly diminished.

Each time a HIV patient infection is successfully treated by timely drug treatment; there is a medical cost avoidance of $303,000.[1] Healthcare providers caring for HIV patients refer to the "72-hour rule." When a patient misses medication doses, the drug levels in the patient fall and the virus is able to multiply. The "72-hour rule" refers to the time beyond which the virus can mutate and become resistant. If the patient has a gap in taking his or her medication longer than 72 hours, the provider must repeat expensive genotype and phenotype lab tests that cost from $500 to $1,000 each to establish whether treatment failure has occurred.

HIV patients who develop viral resistance must use what is called "salvage therapy." The

medications used in salvage therapy have far greater side effects and one of the drugs must be given by injection at a cost of $1,500 to $1,800 each month. During this time the patient has increased ability to transmit the HIV virus to others. The patient also is immunosuppressed and vulnerable to serious infections.

A similar case can be made for other time-dependent medications or devices such as insulin and diabetic syringes and erectile dysfunction medications.

6. Other Probable Benefits of the Rules:

- Increased pharmacies' and pharmacists' understanding of acceptable practice and behavior.
- Increased pharmacists' understanding of their primary responsibility to ensure patients receive safe and appropriate medication therapy.
- Increased pharmacies' understanding of its duty to deliver lawful prescribed drugs or therapeutically equivalent medication in a timely manner.
- Increased consumer confidence that they will have access to lawful prescribed drugs and devices.
- Increased consumer confidence that they will be treated appropriately without fear of discrimination or harassment

- Increased pharmacies' understanding of the expected outcomes when a pharmacist cannot dispense a prescription that is stocked by the pharmacy.

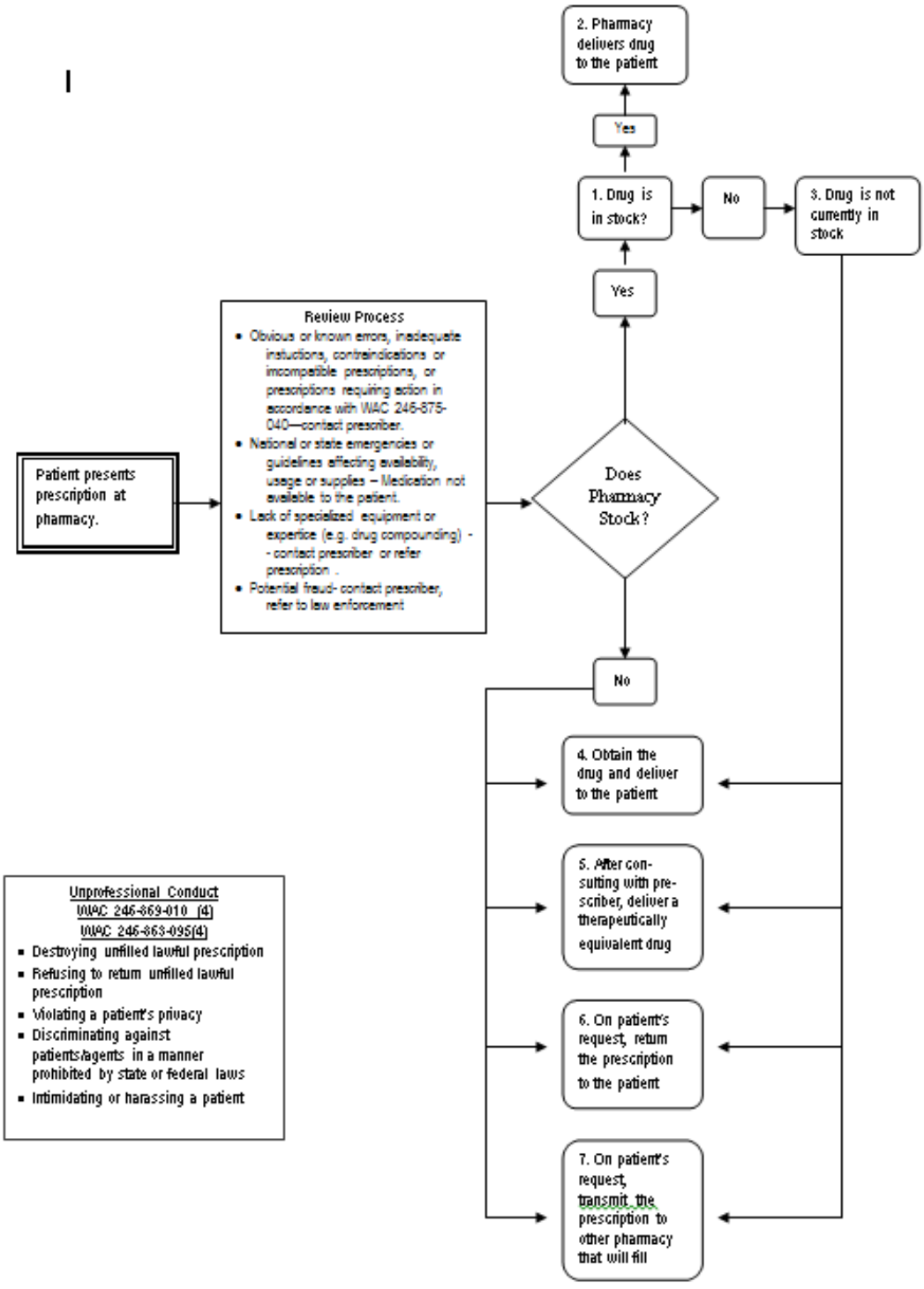
- Increased pharmacies' understanding of the acceptable alternative to providing medication therapy to patients when the medication is out-of-stock.

- Increased likelihood that pharmacies will have procedures in place for when a pharmacist refuses to fill a prescription.

Probable Costs of the Rules

To analyze the probable costs of the proposed rule, we must first look at the processes a pharmacy must follow in order to comply. Many of these steps are considered customary practice in a pharmacy and will not impose additional costs.

Diagram 1


2. Pharmacy delivers drug to the patient
Yes
1. Drug is in stock?
No
3. Drug is not currently in stock
Yes
Review Process
• Obvious or known errors, inadequate instructions, contraindications or incompatible prescriptions, or prescriptions requiring action in accordance with WAC 246-875-040—contact prescriber.
• National or state emergencies or guidelines affecting availability, usage or supplies – Medication not available to the patient.
• Lack of specialized equipment or expertise (e.g. drug compounding) - - contact prescriber or refer prescription .
• Potential fraud- contact prescriber, refer to law enforcement
Patient presents prescription at pharmacy.
Does Pharmacy Stock?
No
4. Obtain the drug and deliver to the patient
5. After consulting with prescriber, deliver a therapeutically equivalent drug
6. On patient's request, return the prescription to the patient
7. On patient's request, transmit the prescription to other pharmacy that will fill
Unprofessional Conduct
WAC 246-869-010 (4)
WAC 246-863-095(4)
▪ Destroying unfilled lawful prescription
▪ Refusing to return unfilled lawful prescription
▪ Violating a patient's privacy
▪ Discriminating against patients/agents in a manner prohibited by state or federal laws
▪ Intimidating or harassing a patient

Upon receiving a prescription from a patient or prescriber, the pharmacist conducts a professional review of the prescription to determine the appropriateness of filling the prescription.

In the first scenario, captured in steps 1 through 3 of Diagram I, the pharmacy normally stocks the requested drug or device.

- In Step 1-2, after a thorough review of the prescription, the pharmacy determines that the drug is in stock and delivers the drug to the patient. COST: There is no additional cost to comply.

- Step 3, the pharmacy normally stocks the drug or device, but the drug is currently out of stock. The pharmacy then applies the options available in WAC 246-869-010(3), described below in steps 4 through 7. COST: There is no additional compliance cost to comply, except as noted in Step 4 below.

In the second scenario, the pharmacy does not stock the prescribed drug or device. The pharmacy's expectations are described in subsection (3) of WAC 246-869-010, and in steps 4 through 7 of Diagram I. In this scenario, the medication/device inventory is established in compliance with WAC 246-869-150.

- Step 4 – The pharmacy obtains the drug and delivers it to the patient. COST: Step 4 may require pharmacy staff time to contact other pharmacies and may require staff to travel to obtain the drug or device for timely administration. Alternatively, pharmacy staff time may be needed to special order and

timely deliver the drug or device, and the pharmacy may need to absorb the cost of express shipping if the special order cannot be combined with other orders.

- Step 5 – After a thorough review of the prescription, the pharmacist contacts the prescriber to address concerns, when appropriate. In this situation, a therapeutically equivalent product is identified and dispensed. COST: No additional cost of compliance.

- Step 6 - By request of the patient or agent, the prescription is returned to the patient. COST: No additional cost for the pharmacy. However, the patient bears the burden of locating a pharmacy that will fill the prescription in a timely manner for effective use.

- Step 7 – By request of the patient or agent, the pharmacy transmits the prescription to a pharmacy of the patient's/agent's choice that will fill the prescription in a timely manner. COST: Staff time may be needed to determine the appropriate pharmacy to transmit to. However, this is not unusual business practice and should present no additional cost of compliance.

Some pharmacies have reported that they would need to hire additional pharmacist staff to comply with Steps 4- 7 if the on-duty pharmacist will not fill a prescription because of his or her personal or religious beliefs. In those cases, the estimated cost would be $80,000 per year for a small community pharmacy, and $14,194 averaged

cost per year for pharmacies that are part of a corporate chain. In a 2006 survey, 112 community pharmacies and nine chain pharmacies (altogether representing 540 of the 1,370 pharmacy outlets in the state) were asked to respond how they might comply if a rule is adopted that required a pharmacist to dispense all lawful prescribed prescriptions. Based on that question:

- Seven community pharmacies indicated they would need to hire staff to comply by hiring one additional pharmacist (although one indicated the need to hire 1.5 additional staff), at the cost stated above of $80,000 per year;

- 76 community pharmacies indicated no additional costs to comply;

- Eight community pharmacies indicated a cost of less than $1,000 to comply, primarily for administrative costs;

- Two chain pharmacies (representing 62 individual pharmacy outlets) indicated they would hire a total of eleven additional pharmacists to comply, at the averaged cost of $14,194 per pharmacy;

- Three chain pharmacies indicated no additional costs to comply;

- Fourteen community pharmacies and four corporate pharmacies did not

indicate any costs, but answered that they would use current staff to comply.

The survey cannot be used to calculate an aggregate cost of the adopted rule statewide, since WAC 246-869-010 as adopted contains several options for pharmacies to comply with the rule. These options could be employed by pharmacies at no or much lower cost. The per-employee cost to hire an additional pharmacist can be estimated. But it is not possible to calculate how many pharmacies - community or chain - would make this choice as a means of remaining in compliance with the rule as opposed to using one of the other available options in WAC 246-869-010(3) to remain in compliance.

It also should be noted that the rule does not explicitly or implicitly require pharmacies to add staff to comply with the rule – this would be an individual business or location decision that may occur if the on-duty pharmacist will not fill a lawful prescription because of a conflict with the pharmacist's beliefs.

For those pharmacies that choose to hire additional staff to comply with the rules, the probable cost of additional staffing would fall more heavily on community pharmacies compared to corporate/chain pharmacies simply because of the availability of additional pharmacists, and because the cost for a small pharmacy would need to be absorbed within that pharmacy's operating profit margin. But most pharmacies responding to the survey said they would be able to comply without hiring additional staff.

Other Possible Costs of the Rule

Costs may be incurred by pharmacies to maintain a representative assortment of drugs in order to meet the pharmaceutical needs of its patients; however, these costs are already present under WAC 246-869-150. Rarely a pharmacy may need to purchase an expensive drug and deliver only part of the quantity purchased. The pharmacy may not be able to return or may not receive a full refund for unused quantities. More commonly, the costs for medications are passed onto the consumer and pharmacies have an array of options to manage medication inventories, such as:

- Returning soon to expire medication inventory to wholesalers/manufacturers.
- More frequent pharmaceutical deliveries – up to 6 days a week – requiring less inventory on hand.
- Pharmacies commonly borrow medications from each other when needed.

Some commenters on the proposed rule stated that some small pharmacies may close as a result of the rule, and that patient access to needed drug therapy would thereby decrease. Some indicated that it would be a business decision related to the cost of hiring additional staff to comply with the rule. Others said that this may occur because some pharmacy owners would close rather than dispense medications that conflict with their beliefs. If a pharmacy closes, its customers may experience a disruption in health care access until they are able to locate an alternate source, such as purchasing from another pharmacy,

ordering medications electronically, or obtaining medications directly from their medical providers. However, the disruption may also be temporary, if it occurs at all. If there is sufficient consumer demand in the area, a pharmacy that is being closed may be purchased and run by a new operator who will comply with these rules, or another pharmacy company may locate in the area to serve that market.

D. Determine, after considering alternative versions of the rule, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.

The Department of Health, Board of Pharmacy staff worked closely with constituents and the public to minimize the burden of this rule. Stakeholder rule writing workshops were held in Tumwater and Yakima. In the course of these and other efforts the rules went through numerous drafts. The following alternative versions of these rules were rejected on the basis that they did not achieve the general goals and specific objectives stated previously:

- A previous draft considered by the Board stated pharmacists shall dispense lawful prescribed drugs or devices on-site. This version of the rule did not take into account specialized pharmacy practices or possible state and federal emergencies which may affect the availability or supply of drugs and devices. In addition, it was thought to impose a disproportionate impact on small independent pharmacies possibly requiring

increase staffing and stocking to comply with the rules.

- Another draft alternative considered by the Board provided options for a pharmacist who cannot dispense a lawful prescription. The rule did not provide adequate protection for patients if a pharmacist denies the patient appropriate prescription drugs based on personal, religious or moral objection. The language did not address the pharmacies' responsibilities. Although this version was least burdensome for pharmacies and pharmacists, it did not achieve the goals and objective of the rule as previously stated.

The adopted rules are consistent with the intent of the goals of the statutes administered by the Board. The rules clearly state a pharmacist's and pharmacy's responsibilities to ensure patients receive safe and appropriate medication therapy.

E. Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

These rules do not require those to whom it applies to take an action that violates requirements of federal or state law.

F. Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

These rules do not impose more stringent performance requirements on private entities than on public entities.

G. Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

These rules do not differ from any applicable federal regulation or statute.

H. Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

There are no other laws applicable to the same activity or subject matter.

ER1018
Excerpt of Trial Testimony of Pharmacy Commission Executive Director Steven Saxe

MR. TOMISSER: Secondly, on the tail end of the question, you are asking this witness to essentially give an opinion on what the Board ultimately would do and that is speculative.

THE COURT: It is speculative. I want his opinion. I want his judgment. How that factors into the decision in the end remains to be seen, but you can ask the question.

A. Would you mind asking it again?

BY MS. WAGGONER:

Q. Assuming with me that a patient of a pharmacy came into the pharmacy and needed to get an expensive drug, and the pharmacy determined that that drug was too expensive based on its particular needs and stocking issues to order the drug. If the pharmacy declined to order that drug, would that be a violation of the rules, in your opinion?

…

ER1024-1025
Excerpt of Trial Testimony of Washington State Pharmacy Association CEO Rod Shafer

[THE COURT] Ladies and gentlemen who are in the audience, I will repeat what I have told the lawyers in prior settings. I am going to create as broad a public record as we can so that this

Court does not have to get involved in this case again.

It has a trajectory up north to the Supreme Court or the Ninth Circuit, and that is why I have enforced liberal rules on the admissibility, and I will apply that to the intervenor defendants and the defendant with the equal liberality that I have adopted. But I want the reviewing court to have all the information that they have on this issue and they don't need to send it back to me to ask another question. So, I just wanted to inform you what the rules are.

Mr. Tomisser?

MR. TOMISSER: Your Honor, you have made that very clear, and would state that the objections from the state are not to irritate the Court. They are simply to maintain our record.

THE COURT: Oh, no, no, no. I am not irritated. Not at all. I want you to keep a record, but I just wanted the audience to know that I have a single purpose here, and it's going to apply -- I mean, there are stories about referrals that are uncorroborated; they are going to be in. That will be part of the grid, that those people have gotten -- as long as members of the Board have considered that in their decision-making process at some point, and if two pharmacists or three pharmacists in the process have gotten information, they had it in their minds in October. So it's coming in. Okay. But please, I take no offense at your objections. I just want those people who have not been here so often as we, that they understand what the ground rules are.

Okay. Court will be in recess.

…

ER1032-1033
Excerpt of Trial Testimony of Pharmacy Commission Executive Director Steven Saxe, Continued

Q. Is that reference in the minutes an accurate summary of what you were hearing from the Board minutes (sic) in terms of their concerns that the issue that they were facing here was about more than just reproductive rights?

A. Yes.

Q. When it says concerned about more than just reproductive rights, is that a reference to being concerned about more than just Plan B?

A. Yes, all of the time-sensitive drugs.

Q. At any time in the discussions about the rules coming up amongst the Board members, input from various stakeholders that happened as these rules were being developed, did you ever hear anything from a Board member that suggested that the Board member was looking to go down this road in the adoption of these rule because of religious animus?

A. No.

Q. What did you find -- what was your sense of what the Board was trying to accomplish in adopting the rules that came into being on April 12, 2007?

A. I think they were trying to weigh the patient safety, patient needs, timely access. I think they were considering some of the pharmacist issues as well.

Q. And they recognized the pharmacist's ability to exercise either a religious or some sort of a personal objection?

A. Yes.

Q. Do you believe that these rules, then, did fairly balance the interests of that pharmacist while maintaining the state's interest in promoting patient access to timely medications?

A. Yes.

…

ER1041
Excerpt of Trial Testimony of Governor's Advisor Christina Hulet

MS. WAGGONER: I would move to admit Exhibit 139.

MR. BOEDER: Objection, relevance.

MR. TOMISSER: State also objects, Your Honor.

THE COURT: Exhibit 139 is admitted.

(Exhibit No. 139 admitted.)

THE COURT: I will explain later. It's not a jury trial, so everything comes in.

…

ER1055-1056
Excerpt of Trial Testimony Pharmacy Commission Consultant Timothy Fuller

Q. [THE COURT] But have they ever discussed, armed with the information that they have -- I guess I kind of reject this complaint-driven, you've got a docile population that they have no complaints, but they go obligingly to some place else and you have another population that's militant. The rule gets enforced for the militant and gets ignored by the docile and you are the regulator. What do you do?

A. It's a little difficult for me to answer that because I am not part of the investigative disciplinary side.

…

ER1057, 1058-1061
Excerpt of Trial Testimony of Intervenor Jeffrey Schouten, M.D.

A. Well, this case was very important to me as a past chair of the Governor's Advisory Council on HIV/AIDS. The council had a strong interest in the Board of Pharmacy rules under discussion in 2006 and early 2007.

As a representative of people living with HIV, we thought it was very important for the interests of people with HIV to be heard on this issue around the Board of Pharmacy rules.

Q. Did you participate in those hearings?

A. Yes, I testified on behalf of the Governor's Advisory Council on HIV/AIDS in the Renton hearings in early 2007.

Q. Do you also have a personal interest in these rules, access to medicine, those issues?

A. Yes, I have been living with HIV since 1988.

…

ER1058-1061

Q. You explained earlier why you testified. Explain for the Court, if you can, exactly what the scope of your testimony was, if you recall.

A. Well, there are several issues around living with HIV/AIDS, a disease that's highly stigmatizing and a great deal of discrimination against people who acquire HIV/AIDS, and at the same time there are critical lifesaving medications and dispensing and continuity of care -- timely dispensing of medications is very important.

Continuity of maintaining exposure -- maintaining a supply of medications is life-important, lifesaving, and missing medications has critical consequences to a person – adverse consequences potentially.

Q. To the best of your recollection, that was the scope of your testimony to the Board of Pharmacy?

A. Well, I think a couple of other issues I raised at that time included a concept called post-exposure prophylaxis, which is a concept where

someone who's been exposed to HIV can take -- actually take Anti-HIV medications afterwards and prevent HIV infection. That's critically dependent on how quickly those medications get started. Within 24 to 48 hours is ideal. After 72 hours, they don't have any effect. So that's one issue where timely access to medications is critically important.

Another issue is issues of people making moral judgments around lifestyles and sexual activity and the desire to have children of people who are HIV-positive, so issues like drugs, erectile dysfunction. We were concerned about people having moral judgments about whether or not people who are HIV-positive should be sexually active or not. So those are the issues that I think I highlighted in my testimony at the time.

Q. Have you ever been personally denied a prescription at a pharmacy?

A. No.

Q. Have you ever treated anyone who's had a prescription denied at a pharmacy?

A. No.

Q. So why is this issue still so important to you?

A. Well, this is still an incredibly stigmatizing disease, even in 2011. The majority of people that are acquiring HIV in this country are people of color and young men who have sex with men. Oftentimes they are kicked out of the house; there's a lot of discrimination against people. People are not engaged in care at the level they

should be. There's a lot of people who should be in care who are not.

So perceptions of discrimination, perceptions of lack of access to care affect people's willingness to come forward and e treated. So that's a really major factor in the treatment of HIV/AIDS these days, is perceptions of access and available care that people don't necessarily seek out care, particularly people who are disenfranchised, and that's the driver of the epidemic in this country today.

Q. So explain what you mean. You are describing a chilling effect if individuals with HIV or AIDS perceive that they could be refused prescriptions; is that right?

A. Yes.

Q. Describe that.

A. Well, there's a lot of reasons why people might perceive that. There is discrimination based on race. There is discrimination based on gender, sexual identity, gender identity, and the moral judgments that people make around behaviors of people who become HIV infected or are exposed to HIV, in the case of post-exposure prophylaxis treatment.

Q. In your current work, is one of the things that you address the consequences of lack of access?

A. Yes, a significant part of what we do is that.

Q. Are there studies that look into the consequences of lack of access?

A. Yes.

Q. What are those?

A. Well, the studies that show that African Americans in this country die earlier of HIV/AIDS, have more life-threatening complications, seek care less often than white people do.

There are also studies that show that only about one in five people with HIV in this country have their virus adequately suppressed on treatment.

The other 80 percent either don't know they are infected or aren't seeking care or aren't sustaining care or don't have access to insurance to cover the cost of the medications.

Q. Now, you wanted to testify today, correct?

A. Yes.

Q. Why? What are your concerns? What are the concerns that you think could result if the Board of Pharmacy rules are ruled unconstitutional?

A. Well, our concern is that if people are given the option of making judgments about who should or shouldn't get medications based on whatever their personal beliefs or biases are, that that could affect people with HIV/AIDS from having access to their medications. And even if they are not actually denied, if that's allowable, that perception influences how people seek care and when people seek care, and that's killing people today in this country, that people aren't coming

forward to be treated. That's my concern in this case.

…

ER1063-1064
Excerpt of Trial Testimony of Pharmacy Commission Investigator James Doll

Q. And is it your testimony that if such a complaint came before the Board, you would expect the Board to find that he violated the rule because he didn't carry that drug that he knew he'd lose money on?

MR. TOMISSER: Objection, Your Honor, speculation on what the Board would rule.

THE COURT: Overruled.

BY MR. O'BAN:

Q. The question is, is it your testimony that if the Board was confronted with such a complaint by a patient who wanted an expensive drug and the pharmacy told the Board, I didn't order it because if I did, I would lose money on it and if I keep having to order these kind of drugs, I will go out of business, what would the Board's response be?

A. Once again, that would be speculation on my part. I can't answer what the Board's decision would be. It would be my job to give that information to the Board for them to make that decision.

…

Q. Mr. Doll, assume with me that a pharmacy has a contractual agreement with its supplier to purchase drugs exclusively from that supplier, okay. That happens, right?

A. Correct.

Q. An existing patient of the pharmacy requests a drug that the supplier does not provide. In order to stock the drug for the patient, the pharmacy would have to violate its contract with the supplier and get the drug from a different supplier. Rather than breaching its contract the pharmacy decides not to stock the drug and refer the patient elsewhere. Is that a violation?

A. Based on the way the rule is written, yes.

Q. They have to violate their contract or they would have to violate the law, right?

A. They would have to find a means of getting the drug for that patient.

Q. Thank you.

…

ER1069
Excerpt of Trial Testimony Petitioner Kevin Stormans

Q. Why did you keep the articles?

A. Well, I keep all articles that are written on the company or the stores just because I think it is interesting history at some point to look back on those, but I really was kind of overwhelmed and

blown away about this whole thing that started happening, and so I just kept the articles that were printed, just like I have with anything else.

Q. Why were you blown away by what was happening?

A. All we did is decide not to carry a product. We made that decision multiple times every single day on what to carry and what not to carry, and it just, you know, was so out of – I guess I never could have dreamed that we'd end up here.

MS. WAGGONER: Your Honor, I move to admit Exhibit 511.

THE COURT: Any objection?

MR. TOMISSER: No objection, Your honor.

MR. GREENE: We object on relevance grounds because we didn't receive the exhibit before today.

THE COURT: 511 is admitted.

(Exhibit No. 511 admitted.)

…

ER1109-1112
Excerpt of Trial Testimony of former Pharmacy Commission Member and Executive Director Susan Teil Boyer

Q. [THE COURT] So can a Catholic Church suppress demand? Can they put a sign up, put a scriptual deal up, and when they tell somebody

that they don't have Plan B, they can go away and find another pharmacy, and that will pass away, there will be no enforcement in that situation even though there's a violation?

A. No, there would be enforcement. It's just like this sign you saw from Walgreens on OxyContin. That's relatively recent. Like I say, we are having conversations with their leadership coming up. Yeah, those are concerns.

Q. Have you contemplated the standoff with the faith-based institutions when you say you have to stock Plan B or you lose your license?

A. I haven't contemplated it, no.

Q. I have contemplated little less -- little more than that for four or five years. I have tried to figure out what you were going to do.

Do you know what the hospital situation in this state is and what percentage of the facilities are in the hands of faith-based institutions?

A. It's significant, yes, I understand.

Q. But you are going to enforce it across the Board, not just taking the low-hanging fruit, Mr. Stormans or anybody, and you are going to enforce it against the pharmacies of the Catholic --

A. Again, the Board operates on a complaint. If a complaint comes in, we will investigate it.

Q. You know, that defies common sense. You know St. Joe's, do they have a population that would have a demand for Plan B?

A. Probably not.

Q. The neighborhood around St. Joe's does not have a need for Plan B?

A. Probably the neighborhood does, but those folks probably don't go there to get Plan B.

Q. So we've got trained patients that will go to their own place until a shopping tour by Planned Parenthood to expose someone, is that right? That's not fundamentally fair. It's got to be enforced against all of them or it's got to be enforced to none of them.

You can put the crucifix on the door of the pharmacy, you can put a sign saying it's wrong or whatever the Pope says in his message, and they just go away, right; they don't have to be vigilant, they don't have to be demanding. They don't have to be militant; they just walk away and go find their Plan B somewhere else, right?

A. Practically speaking, I think the people don't seek Plan B where they assume they can't get it.

Q. My God. My God. So the test marketers, they go to his store and say "do you have Plan B?" And he's honest, he says, "it violates the tenet of my faith and I can't do that." And they will picket him. They will make complaints in triplicate. They will go get him, and he'll be out, and these two women will be out. And nobody will ever complain about the religiously-sponsored care facilities that provide so much of our health care in this state, and that hasn't surfaced in the debate in the Board?

A. It has not, that's right. The Board looked at this deliberately, looked at this in a more broad context, not just Plan B.

Q. The First Amendment implicates the rule in a serious way. That's why we are here. That's the debate. It's not OxyContin. It may be a stupid rule, but I will enforce a stupid rule that's constitutional. It's misguided, maybe. That's okay.

But when you draw a distinction between people of faith and one guy loses his license and another person with the same faith lives in anonymity, supposedly, that's troublesome. That's troublesome.

…

ER1121-1122
Excerpt of Trial Testimony of Pharmacy Commission Member Gary Harris

Q. Is it your understanding that there potentially might be a very wide variety of medications that somebody might have a religious objection to?

A. Certainly. Again, if one were to say homosexuality is a sin, so if you are HIV positive it's your own fault, I am not filling HIV meds. My father was a smoker for 40 years, smoked until he had pretty much no lung function left. I don't have a very favorable opinion of smokers, but I am going to fill inhalers for them. I am going to counsel them to the best of my ability on every med that they get.

Q. Are mood stabilizers, antidepressants, anti-anxiety drugs -- might it be the case that a

member of the Church of Scientology would have religious objection to providing those medications?

A. It could be. I guess if you don't draw a line in the sand, you run the risk of the slippery slope or falling down the hill, and we have exemptions for everything under the sun.

Q. Mr. Harris, let me, just in conclusion ask you, in your years working with this Board on a regular basis, what is your reaction to the allegation in this lawsuit that because the Board of Pharmacy won't carve a religious exception into those rules, that the Board must be comprised of a bunch of religious bigots?

A. Well, I have already given you some of my religious background, if you will, and certainly that's not the case for me. Given that, I am still against a religious carve-out.

…

ER1137
Excerpt of Trial Testimony of Pharmacy Practice Expert Witness Alta Charo

Q. [THE COURT] The Governor has an obligation under the Constitution to faithfully execute the law, and yet the Board of Pharmacy doesn't seem to have thought about the train wreck that's coming.

A. Again, I am not familiar enough to be able to comment.

…

ER1143-1147
Excerpt of Trial Testimony of Intervenor Judith Billings

Q. And have you had personal experience with the challenges of living with HIV/AIDS?

A. I certainly have. I was diagnosed with AIDS in March of 1995.

Q. What role do medications take from your perspective in the treatment for HIV/AIDS?

A. Medications are frankly the lifeline. Without them -- when I was diagnosed, for instance, in 1995, there was one medication available for HIV and AIDS, and it was AZT. When I asked my doctors what my prognosis was, they said "you are diagnosed with AIDS, you have probably 18 to 24 months to live." And at that point -- there had been tremendous advances in the kinds of medications available for HIV and AIDS, and those are the medications that have kept me alive for 17 years. They absolutely are crucial. If I were to stop taking my medications it would not be very long before I would not be on this earth.

Q. And so they are particularly time-sensitive?

A. Very time-sensitive. The thing about HIV, the human immunodeficiency virus, this may sound strange, but it is a very viral virus. It multiplies at the rate of a million virus particles a day if you are not on medication. And it can absolutely consume and overpower the immune system.

Once your immune system is gone, of course, you cannot resist any kinds of infection. And every medication has a half-life, as all medications do. So that if you are more than two hours away from the time of taking your medication, you are in danger of having HIV being able to mutate around the effectiveness of that medication. And you not only lose the effectiveness of that particular medication, but in the six classes of medication that are now available, you may become resistant to an entire class, which means that you can no longer take any of the medications in that class.

Q. So perhaps this is obvious, but does that tend to cause anxiety in HIV/AIDS patients in terms of whether or not they are going to have any glitch in getting medication?

A. It causes huge anxiety if you are not able to get your medication in a timely fashion.

In the last 17 years, I have worked extensively with both the national and local AIDS organizations and so have come in contact with hundreds and hundreds of people who are on HIV/AIDS medication. And I can tell you that the panic you feel, and the panic that is expressed, if you cannot get your medications and you know what the result is going to be -- and I personally had that experience where because of glitches in the mail order service I was using, drugs did not arrive. So I was down to my last pill of a particular medication and could not find a pharmacy that had it, without going to three separate pharmacies to get just enough to get me to the point where the medications were going to be delivered. And that is a horrible feeling because you -- the last thing you need is stress for an immune system that's

damaged anyway. And so it is just -- it's a very hopeless feeling.

Q. In terms of counseling that you've had, communications you've had with other HIV/AIDS sufferers, have you encountered instances where you've been told about refusals or delays in providing those drugs?

A. Certainly delays. And you know, at this point there are people who cannot get medications in states all across the United States. But one of the things that attaches to HIV and AIDS is there has been -- over the period of years, through the years, huge bias and discrimination against people with HIV and AIDS. So there has been a reluctance with many people to -- certainly they won't provide insurance; many people will not hire. Families have excluded members. Pharmacies have been reluctant. There's a whole milieu of bias and discriminatory practices against people with HIV and AIDS.

Q. Is that one of the reasons you became involved in the rule-making process for the Board of Pharmacy?

A. Yes. At the time that the original rule-making took place, I was on the Governor's Advisory Council on HIV/AIDS, and we immediately decided that we wanted to testify before the Board of Pharmacy and make our voices heard in terms of what it would mean to people who were HIV positive if they were refused their medications, and so we put together the testimony. At that time, the chair of the Board was Dr. Jeff Schouten, who I believe this Court has heard from as well.

Q. Yes.

A. And he did the testimony before the Board of Pharmacy at that point, and then when the possibility of reconsideration came up in 2010 I was not able to attend the hearing, but I did submit a letter in support of the rule as originally construed.

…

ER1155-1157
Excerpt of Trial Testimony of Intervenor Molly Harmon

Q. Have you ever experienced a situation in which you were refused medication at a pharmacy?

A. I have never been refused medication, no.

Q. Have you experienced a situation in which you had difficulty accessing medication?

A. I did. It was a number of years ago. I had gone to -- I had gone to the Bartells in the University Village in Seattle, Washington, to fill a prescription for Plan B, at which time a prescription was needed for that medication. My husband and I -- our birth control had failed so, upon talking to my physician, I felt this was our best option.

When I went to Bartells to fill a prescription, I was not denied the medication, but upon approaching the counter to receive my medication, the pharmacist, instead of telling me any side effects the prescription may hold, I was told it wasn't a form of birth control. The situation was, it was pretty upsetting to me because of the emotional

state I was in at the time. And I proceeded to tell the pharmacist that I -- she didn't know my situation at all, and I could have had a traumatic experience the night before, possibly being raped or something terrible, and I didn't feel it was her place to be placing judgment upon a decision myself and my doctor had made.

So at that time I did ask to speak to her supervising pharmacist. He did come out and I explained to him the situation, and what was said. And he agreed with me that what she had said was not appropriate, and that he would be providing her with additional training.

Q. What was the first pharmacist's demeanor during this encounter?

A. She was pleasant enough. She wasn't -- I guess to me was a little cold because that was the first thing out of her mouth was a statement of "this is not a form of birth control," rather than giving me any side effect that may occur from this legal prescription that I was trying to obtain. Q. And when she asked you whether you knew there were other forms of birth control, how did that make you feel?

A. I was angry. I was upset. I was really taken back, because she really had no idea what my situation was. I kind of -- my first thought was, you know, I could have been raped the night before and, you know, a statement like that would have been just even so much more troubling to me if I was a woman in that situation. Thankfully I wasn't, but it was upsetting.

Q. Did you want to have to explain to the pharmacist what your situation was?

A. No, not at all. First off, it was none of her business; this was a decision I made with my doctor and my husband. You know in that pharmacy, there's no privacy. There's just a couple chairs behind the counter. And it's just about two feet, so there's no wall to create any kind of privacy. So this whole conversation was being heard by the couple people behind me, so that was also just a little obnoxious to me that these people can hear my business.

Q. So the encounter wasn't private, as you perceived it?

A. No, no, by no measure.

Q. What did you do -- did you receive the medication from the manager?

A. I did.

Q. And you purchased it and left?

A. I did.

Q. What did you do right after this?

A. I called my husband. And then following that, I returned to work, and then my husband and I spoke about it further and he was really upset and angry about it. And we did the one thing that kind of came to mind. We felt we needed to file some kind of complaint with someone.

…

ER1165, 1195, 1198-1199, 1207-1208
Excerpts of Trial Testimony of former Pharmacy Commission Executive Director Lisa Hodgson

Q. As you watched the rules in this case be developed, did you ever get any kind of a sense that the rules were being gerrymandered in some way such that they would only apply to people with religious objections to Plan B?

A. No.

Q. Did you ever see any indication that the focus of the Board was actually broader and applicable to all types of medications?

A. Yes.

Q. Can you describe why you have that impression?

A. We heard about people that were not getting access to their diabetic syringes, their insulin, their diabetic syringes, concerns from HIV patients that they may not be getting access to lawful medications. So I believe it was broader to make sure that it was all medications; access to all medications.

Q. And those anecdotes or examples of those situations, those were presented to the Board in public hearings?

A. In public hearings and in written form.

…

ER1195

Q. You were asked a few questions about the reasons in your view for the Board initiating rule-making in 2005, I believe you said; do you recall that?

A. Yes.

Q. And that's the rule-making that led to the enactment of the pharmacy and pharmacist rules?

A. Yes.

Q. I believe your testimony was that you perceive the Board was concerned about patient access and safety and also clarifying the responsibilities of pharmacies and pharmacists; is that right?

A. Correct.

Q. Was there other conduct the Board was concerned with?

A. The Board had heard instances where pharmacists were ripping up and destroying prescriptions, and they wanted to put something in place that made sure that that didn't happen.

Q. I take it that the reasons for the Board commencing the rule-making and issuing the rules was not that the Board had received an overwhelming number of complaints related to this issue; is that right?

A. That's correct.

…

ER1198-1199

Q. Now, at the time the rules were adopted, you understood that the purpose of the rules, from the Board's perspective, was to improve patient access to important time-sensitive medication and to eliminate perceived barrier to that access, correct?

A. Correct.

Q. It's your testimony that you believe the rules achieve those goals?

A. Yes, I do.

Q. It's also your opinion, and I believe you just said that the Board was concerned about certain conduct of pharmacists, correct?

A. Correct.

Q. And this is unprofessional conduct, right?

A. In the Board's eyes it would be unprofessional conduct.

Q. In your view the, rules also address and clarify that conduct, correct?

A. Correct.

Q. In terms of the benefits of the rules in your opinion, you agree and you believe that the rules improve patient access, correct?

A. Correct.

Q. And you believe that they address unprofessional conduct?

A. Yes.

Q. And you believe that they clarify the professional responsibilities of pharmacies and pharmacists?

A. Yes.

…

ER1207-1208

Q. And was it common for Board members also to attend those public hearings?

A. It was.

Q. And it's your belief that all that information was considered by the Board as part of this process?

A. Yes, and our staff did summarize the information that was received.

Q. And so to your knowledge, is it accurate that there was information presented to the Board during the rule-making, both about specific refusal stories but also about general access concerns by a number of constituents?

A. Yes.

Q. And this included concerns related to access for insulin syringes?

A. Yes.

Q. And it included concerns about access to HIV/AIDS medication?

A. Yes.

Q. And included concerns about access to antibiotic prescriptions?

A. Yes.

Q. And it also included access concerns to other drugs, including prenatal vitamins, oral contraceptives, erectile dysfunction medication and Plan B, correct?

A. Yes.

Q. You testified earlier, in your view, the rules were never about Plan B; is that correct?

A. That's correct.

Q. And that's your understanding of the Board's view as well, correct?

A. Correct.

…

ER1214-1217, 1219-1226
Excerpts of Trial Testimony of Witness
Katherine McLean, M.D.

Q. Have you ever had a situation in which a patient of yours was refused medication?

A. I had a patient who I consulted regarding -- during an emergency room visit in the middle of the night at the University of Washington. She had come in with spotting and knew that she had -- that she was pregnant but had not yet initiated care with an OB-GYN at that time. She received an ultrasound, and she was diagnosed with a pregnancy where the fetus had died, and she was approximately eight weeks along, given her last menstrual period dating at that point.

So I went to the emergency room and counseled the patient on her options at that point. We came to the decision together that, rather than proceeding with a surgical procedure to help complete the miscarriage, that she would prefer to use a medication call Misoprostol in order to help complete that miscarriage at home. Misoprostol initiates uterine contractions and helps the body to pass the pregnancy in a more natural way.

It would be what would normally happen if the body had recognized a miscarriage had occurred; that would be the natural process the body would go through anyway. She really wanted to avoid surgery, so she went with the medication route. So I wrote her a prescription for that medication, and she lives in a small town.

She ended up re-presenting to the emergency room about 48 hours later with bleeding. And at that point she told me that she had attempted to fill the prescription at her local pharmacy and she had been told that the only pharmacist that was on that day, that participated in abortions, was on a break

and that she would have to wait in order to get that medication.

And this was quite upsetting to my patient, because she was going through a very traumatic miscarriage experience of a pregnancy that was highly desired. And she felt like she was being labeled as having an abortion in the pharmacy, with a line of five other people standing behind her in a small town where everybody knows everybody, so she left without getting her prescription filled.

When she re-presented to the emergency department at the University of Washington she was bleeding and required a surgical procedure to complete the miscarriage at that time.

Q. When your patient told you this story, did she relate to you the experience in the pharmacy was upsetting to her?

A. Oh, absolutely. She was already upset due to the miscarriage, and the experience was really quite traumatic for her. She was really afraid that people in the small town would think that she had an abortion, that she would be labeled as such, that people had overheard. It was altogether very, very traumatic on top of the already difficult experience.

Q. So how did she react when the pharmacist on duty told her?

A. She told me she started to cry and she turned around and left.

Q. In your medical opinion, what are the chances if your patient had received the

Misoprostol prescription that she could have avoided having surgery?

MR. O'BAN: Object to form.

THE COURT: Overruled.

BY MS. BENNETT:

Q. You may answer.

A. So there are numerous studies looking at the effectiveness of using Misoprostol to complete miscarriage, and the effectiveness depends on the dose. But given the dose that I prescribed, most studies agree that the chance of success is somewhere in the range of about 80 percent. So there's an 80 percent chance that if she received the medication, she could have avoided a surgical procedure, based on that evidence.

Q. And it was important to her to avoid surgery?

A. Yes, for a number of reasons. I think that a lot of patients find the idea of having surgery to be intimidating, and I think she was a little bit frightened. Despite the fact that it is a safe procedure, I think that she was nervous. And I think a lot of patients are also concerned about cost. Obviously having a surgical procedure is a lot more expensive than receiving medication.

…

ER1219-1226

Q. Was this patient upset by the refusal to receive her medication?

A. I think she was really upset. I think -- she told me that she was angry and upset. And I think it's really difficult for patients when they are having a medically traumatic experience already. She knew she was pregnant. She really wanted to be pregnant, had started to bond with the pregnancy. And she was very, very sad when she learned she was miscarrying. So she was already in a pretty fragile state. And it's difficult to make decisions in that state, to start with. Did she want to have surgery, did she want to have medication to deal with the situation? I spent a really long time talking with her, and it was difficult to come to the right decision, but we felt we had gotten there, and that was a significant process that we went through together.

And I think that once we had a plan in place, she felt more comfortable. That had helped ease some of her anxiety about the situation. And then to feel like she couldn't have the plan carried out as we had decided, I think was really difficult.

Q. So is it your perception that this refusal compounded what was already a difficult situation?

A. Absolutely.

Q. Did you recommend this patient receive any mental health care after this experience?

A. Yes. So she was sent to followup in our outpatient clinic at the University of Washington

where we have a social worker who routinely works in the women's health care center. And we had discussed her seeing a social worker during her follow-up visit just to talk about how she was feeling and how she was dealing with the whole process.

Q. I think you might have alluded to this earlier, but I want to be clear. Did you get the sense that the patient's encounter at the pharmacy with the pharmacist was a private encounter?

A. No. One of the main things the patient seemed upset about was the fact that there were a bunch of other people behind her in line, and she was in a small town where lots of people know each other, and she was very nervous about the fact that she thought this had all been overheard by all those people standing in line. Now whether or not that was true, I don't know. But it did sound like it was quite close quarters, where she seemed to really feel as though they were really easily able to hear what was said.

Q. In your professional opinion and as a physician, did this pharmacist violate her own ethical obligations to your patient when she refused this medication?

A. I think so because I really think that we as health care providers should put our personal beliefs aside and put our patients first. I believe our most important job is to serve our patients, and I don't think that my patient was well served by that encounter.

somewhere in the range of 24 to 72 hours later to give a dose of Misoprostol. And typically that's

dosed vaginally, although you can also dose it orally and buccally.

Q. In your experience with medical abortions, have you ever seen Misoprostol prescribed by itself with the purpose of inducing an abortion without also being prescribed Mifepristone?

A. I have not. It's really not the standard of care, at least not at the University of Washington, largely because the evidence shows that the combination of the two medications is more effective than using Misoprostol alone in that situation.

Q. Are you aware that pharmacists under the FDA rules are not allowed to dispense Mifepristone?

A. Yes.

Q. Did you testify about this refusal incident at the Board of Pharmacy in 2010?

A. Yes.

Q. What was the substance of your testimony?

A. Essentially just what I relayed today about my patient situation and the fact that she was told she would have to wait to get Misoprostol and that she felt as though other people had overheard the conversation, where it had been insinuated she was having an abortion, and that traumatic experience is what I testified regarding.

Q. When you testified in September 2010, you had just completed your residency; is that correct?

A. I completed it at the end of June.

Q. So is it fair to say that you were, and are, busy?

A. Yes.

Q. I am just wondering, why was it important for you to drive down, wait in a room and testify about this experience; why was that important to you?

A. I really thought that her experience was one that no other patient should ever have to repeat. That patient should be able to get the care that they and their doctor come to an informed decision about together, and they should be able to get that care without delay and without humiliation. I really felt like the situation that she had to go through was really horrific, and I didn't want that to happen to anybody else.

Q. Did you discuss your testimony with the patient before you testified?

A. I did. I called her on the phone.

Q. And what was her reaction about your testimony?

A. She said that it was fine for me to testify, but I asked her if she wanted to make a formal complaint regarding what had happened, and she said that she was really afraid that it would come

out that she was making this complaint, and that people in town would be reenforced that she had an abortion, and she was really worried about that. So I told her that I respected her privacy, and then asked if it was okay if I testified, obviously not using her name. And she said "yes, obviously I don't want this to happen to other people," and she agreed with me when I said that. She said "I agree, I just need my privacy." And I said fine.

Q. So she wasn't willing to come forward?

A. No, she was not, and I have to say I understood. She said something to the effect of "I have already been through too much regarding this," and I thought "yes, you have, I understand that."

Q. When you were an OB-GYN resident, did you treat patients for miscarriages?

A. Quite frequently, unfortunately.

Q. Could you give a rough estimate of the number of women you might have treated?

A. Really, it's too many to count. I would say probably 100 over the course of four years; quite frequently.

Q. Could you provide some general observations of what women experience going through miscarriage, what their emotional state is?

A. The majority of my patients are terribly sad when they miscarry, and some of them are really surprised by their own reaction because they think to themselves, miscarriage is really common,

I have many friends who have been through it. Most the time they are early in pregnancy, so they are surprised by the intensity of their emotion. But I do think it is a traumatic and sad experience. People grieve the loss of that early pregnancy. They feel like it's a shock to the system, something unexpected.

Q. Are you aware of patients who had other problems accessing other medications because of personal beliefs of pharmacists?

A. I have talked to colleagues who have had patients who have been refused Plan B, and I have also talked to colleagues who have mentioned patients having -- well, not having trouble getting the medication, but getting hassled by pharmacists regarding HIV medications.

Q. Could you explain a little more about the HIV medications?

MR. O'BAN: Your Honor, I just need to object. We are going beyond the reason given for this witness to come, and she's now going to testify about second, third-hand incidences.

THE COURT: Overruled. Go ahead.

BY MS. BENNETT:

A. So I was speaking with a colleague who was working in a clinic at the University of Washington that specializes in giving HIV care to pregnant women, and she mentioned one of her patients -- and this doesn't even make any medical sense whatsoever -- a patient had been told, like, I don't want to give you your HIV medications

because of your lifestyle, and indicated that they were afraid that they were homosexual, which really does not make any sense at all because this was a it is a traumatic and sad experience. People grieve the loss of that early pregnancy. They feel like it's a shock to the system, something unexpected.

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because of your lifestyle, and indicated that they were afraid that they were homosexual, which really does not make any sense at all because this was a pregnant female patient. And, I mean, the chance that she had HIV through a homosexual relation is almost nil. It doesn't even make any medical sense, but the poor patient had been harassed because of that.

Q. Because the pharmacist thought she might be homosexual?

A. Right, that was the insinuation.

…

ER1236-1241
Excerpt of Trial Testimony of Intervenor Rhiannon Andreini

Q. Changing gears, have you also had a personal experience in which you've been refused medication by a pharmacy?

A. Yes.

Q. Describe that.

A. So it was Thanksgiving, several years ago, six years ago now, and I had a completely consensual, yet totally unexpected, experience with someone I had been close to for a very long time. I wasn't that proud of myself for my lack of planning. And the morning after, I was driving home to a home that was my parents -- I grew up in Bellevue. And my parents had recently moved to Mukilteo, and I was visiting for the holidays, for Thanksgiving from college. And I had never been to

their new home. It was my second night there. And I went to the Albertson. That was just -- I make a left and I am almost to my parents house, and I happened to be right there. I walk into the pharmacy. I am nervous, actually. I mean there's a lot of shame I was feeling about the situation in general. And I walk up to the counter and I ask for Plan B, knowing -- because I serve as an educator -- that I don't need a prescription for this, that I can ask for it.

And he said "Plan B?" And was, you know -- I felt as though his judgment was palpable. And he said "Oh, I can't give that to you, we don't carry that here," and kind of waved this way and said "There's a Bartells that might give you that."

And I felt his disdain, and I felt judged, and I was quite appalled actually, and couldn't even argue. I was frozen and walked out.

I went home. I mean, yeah, I was trying to figure out what to do, knowing I had 72 hours. Didn't feel -- I felt frozen and embarrassed, and ended up driving first thing, gosh, it was very early in the morning, back to Bellingham the next day where I knew I would be able to receive medication from the pharmacy, in a fairly progressive town, and one that I referred students to go to myself.

Q. Did you know where the Bartells was?

A. No clue. I had never -- the Mukilteo Speedway is this really wide, fast road. I didn't even feel comfortable catching the left. I was still figuring out my bearings. And more than that, I felt so embarrassed. I didn't feel like -- I mean I wanted to go home and cry, which is essentially what I did

for the rest of the evening. Yeah, I don't know, even knowing that this happened.

Q. Did the pharmacist offer to call the other pharmacy for you?

A. Nope. He didn't ask me if I had ever been in before. He didn't ask me if my insurance card was on file. Didn't ask my name, what I needed. He just looked -- I felt judged, and he just kind of waved, said "that way."

Q. Now, do you know why you were refused in that pharmacy?

A. No idea, but I mean, I just got a degree in counseling, I feel as though I am a fairly -- one can tell when something -- when one is being judged. I feel like there was some kind of objection that could have been religious, I don't know, it could have been moral. But it definitely wasn't a "we don't have that in today."

Q. Did you think that the pharmacist was helpful in his interaction with you?

A. No, not at all.

Q. To the extent you can -- and you've done this a little bit -- but if you can describe sort of your perception of the pharmacist's demeanor during this interaction.

A. He was very -- he was just -- I am trying to think of the best handful of adjectives, stern, I feel, as though I felt -- I felt very small. He was dismissive and cold, and he seemed completely, completely not concerned with my well-being.

Am I allowed to talk about things I heard this morning?

Q. You better not.

A. Okay.

Q. Just for the record, you attended trial this morning?

A. Yes.

Q. And you listened to Mr. Harris's testimony?

A. Yes. I was going to talk about dignity.

Q. I assume from your description that you had access to a car to return to Bellingham; is that correct?

A. Absolutely, yes, I had a car. I was privileged enough to have the means to get there. And yet the psychological impact was so -- I am someone who is trained to guide people to know what to do in these situations, and yet -- I had my own means of doing that. I even had a phone to figure out. I could have Googled the next pharmacy and kept going. But I just felt shut down, I am not even going to try, I am going to go back somewhere safe. And I was able to do that. I had a car. I had the time. I wasn't working. I could drive an hour and a half back to Bellingham. I could do that early. I had friends to be there when I got there.

Q. And I presume that you also had the financial means to purchase Plan B if you had been able to?

A. Absolutely.

Q. Why didn't you simply go to Bartells in Mukilteo?

A. You know, I have thought about this a lot myself. Mostly I felt just -- I felt like I didn't know my surroundings. I felt like I was tired, and I felt like I had been shamed enough. I felt like I was beating myself up. I didn't want to deal with another rejection. I wasn't convinced -- whatever he gave me was no kind of referral. I was not convinced at all that the Bartells would have had it stocked. And I didn't feel like I wanted -- I didn't feel tough enough to go get another no and a hand wave and judgment from a middle-aged man at the moment. No, I just didn't feel like that was something I wanted to do.

Q. You had been an educator on this exact topic, correct?

A. Yeah.

Q. Did your reaction surprise you?

A. Oh, absolutely. In fact, in recounting this all to my friends, that was like the fundamental bottom line, was I cannot believe that I reacted this way. Thinking about all the women that I have worked with, even now talking about it today, thinking about all the women that I have worked with and how I was in the best possible position to know what to do.

And I also, you know, talked -- I still talk regularly about the stigma around sex or the silence around gender violence or the leaps and bounds women

often have to make for health care. And I feel like I still froze, like I couldn't snap myself, couldn't rally my ownself to go. And I had all the material and time and monetary means.

Q. Now, in addition to your personal experience, have you worked with women in any of your employment or volunteer experience that have also been refused prescriptions at pharmacies?

A. No, but I have heard stories. I had conversations with women -- a few residents at one of the nonprofits I worked with who have heard stories or know, who won't go; they won't go to a pharmacy.

…

ER1252-1253
Excerpt of Trial Testimony of Pharmacy Commission Member Gary Harris, Continued

MS. WAGGONER: I move to admit Exhibit 540.

MR. BOEDER: Objection, Your Honor. There is no foundation that this was ever presented to the Board of Pharmacy. There is no foundation whatever. It was not identified as a trial exhibit and this is the first time that we have seen it. I think it should be excluded.

MR. O'BAN: Your Honor, I would also ask the Court to consider that Ms. Waggoner has elicited questions and answers from the witness and I think it's his testimony, if anything, that should stand. This document is --

THE COURT: Oh, I --

MR. O'BAN: --- at least a couple of a dozen pages and I don't think we need to admit the whole thing.

THE COURT: There would be some folks at the end of the trial, the Court of Appeals or the Supreme Court may find something in this. I will admit it, but it's not temporally related.

ER1321-1322
Excerpt of Trial Testimony of Petitioner Margo Thelen

Q. But the three times that I was referring to, and perhaps I introduced the confusion in my question, I had understood you to have testified in deposition that you had referred a woman three times when you were at Safeway?

A. I referred -- I recall referring twice at Safeway.

Q. Twice?

A. Uh-huh.

Q. Let me ask you the same questions and maybe the answers are the same with respect to those Safeway referrals.

A. Uh-huh.

Q. Did you ask in either or both of those instances how long it had been since the patient had unprotected sex?

A. I didn't. I just said the one gal volunteered.

Q. So, did you ask either of them whether they had transportation to get the alternative location to which you were referring them?

A. I did not.

Q. Did you check to see if Plan B was available there?

A. I volunteered to call, yes, and I called on both of those.

Q. You did?

A. Uh-huh -- well, I volunteered to call for Ms. Gigler; she didn't want me to. The other one I did call and checked and made sure they had it.

Q. In the other one, did you basically ask the patient whether it was okay to call, or how did that work out?

A. I don't recall exactly how that worked, but I know I volunteered to call.

…

ER1326-1329
Excerpt of Trial Testimony of Petitioner Rhonda Mesler

Q. When you were deposed in 2008, you testified that you've never been personally asked by a woman for Plan B; is that correct?

A. Correct.

Q. Do you understand that Plan B has a limited period of time in which it's effective?

A. Yes.

Q. And what is that period of time?

A. 72 hours.

Q. Is Plan B more effective the earlier a woman takes it after unprotected sex?

A. I believe that's what the literature says, yes.

Q. You testified that, I guess a week and a half ago, that it was your practice to refer someone requesting Plan B to another pharmacy; is that correct?

A. Yes.

Q. When you are making this referral to another pharmacy, do you ask the woman or the person requesting the drug if they have transportation?

A. No.

Q. When you are making these referrals, do you ask the patient how long it's been since she's had unprotected sex?

A. That wouldn't be an appropriate question for a technician to ask the patient. But if a person offered that information, then I would deal with that with her, but nobody's ever done that.

Q. But you don't inquire how long it's been?

A. No, I don't. Like I say, I haven't personally been asked.

…

Q. When you, or technicians you work with, have made referrals for Plan B in the past, has the patient been told why you would not fill the prescription?

A. No, I don't believe so. They are told that it's not in stock and they are told a list of places they can get it, and then we offer to call those places for them.

Q. When you are working with technicians, speaking with them about dispensing Plan B, what do you tell them to do if they receive a request for Plan B?

A. Just what I just said. They are told to notify the patient that that's not a product we have in stock and there is a list of nearby pharmacies that have it. They are told the names of those pharmacies, and they are asked if they would like us to call ahead and make sure that the pharmacy has it in stock.

Q. You testified in your deposition that you had made a referral while you were working at Fred Meyer; do you recall that?

A. Uh-huh.

Q. And you also testified that you did not call the pharmacy recommended to see if that pharmacy would be willing to fill the prescription for Plan B; is that correct?

A. Yes, that was the time in the middle 1990s, I believe, quite a while ago.

Q. You also testified that there was another pharmacy refusal, a refusal for Plan B in 2007; do you recall that?

A. Not specifically, no.

Q. Is it correct as a general matter that you don't -- you will not usually know in the end whether the woman who requests Plan B eventually receives it?

A. No.

…

ER1336
Excerpts from Plaintiffs' Reply in Support of Stipulation and Agreed Order to Stay Trial

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON AT TACOMA

STORMANS, INCORPORATED, et al., Plaintiffs, MARY SELECKY, Secretary of the Washington State Department of Health, et al., v. Defendants, and JUDITH BILLINGS, et al. Defendant-Intervenors.	NO. C07-5374 RBL PLAINTIFFS' REPLY IN SUPPORT OF STIPULATION AND AGREED ORDER TO STAY TRIAL

LAW AND ARGUMENT

1. Intervenors Have The Right To Be Heard, But Their Agreement Is Not Necessary For The Stipulation

Intervenors argue, without citation to authority, that the Court should not "sanction" the facts set forth in the stipulation because they did not agree to them. First, Plaintiffs do not contend Intervenors are bound by the stipulations. Intervenors are free to challenge their accuracy if they can.

…

ER1349-1352
Excerpt of Deposition Testimony of Petitioner Margo Thelen

Q. You say that to refer is your practice now. What is involved when you refer?

A. I -- if the patient asks to, us to call a pharmacy, we will do that. Otherwise we mention the pharmacies that we are aware of that stock it and dispense it.

Q. If the patient asks you to call, do you call to make sure that they have Plan B in stock and they'll dispense it?

A. Certainly.

Q. Do you ever inquire of the patient as to whether she has transportation?

A. No, I've not asked that.

Q. Do you ever inquire of the patient how many hours it has been since she had sexual intercourse?

A. I've not asked that.

Q. Do you follow-up with the other pharmacy to ensure that the person got the medication?

A. I have not done that.

Q. You mentioned that you also received one OTC request for Plan B while you were working at Safeway. Can you tell me about that?

A. Yes. The person requested it, and I said that I would not be able to dispense it and asked if I could call our pharmacy that's half a mile away for her. She said she -- I can't remember exactly what her response was. The technician who was working with me is comfortable dispensing it, and the woman said -- I don't remember how the conversation exactly went, but my tech ended up selling it to the customer. She didn't have any desire for counsel. If she had, I would have, I would have requested that she go to the other pharmacy, but the tech, she said she did not, and the tech sold it to her.

Q. When did this take place?

A. I don't know. Sometime during my employment there. I don't recall.

Q. Did you tell her about the mechanism of

A. Um-hum.

Q. Or something to that effect?

A. Um-hum.

Q. What do you recall that she said after you told her that?

A. She said, I didn't know that. Thank you for telling me.

Q. At some point in your conversation with this woman did you tell her that you would not dispense Plan B, and that you would have to refer her somewhere else?

A. Yes.

Q. When did you tell her that in the course of this conversation?

A. I don't know.

Q. Do you recall whether it was before or after you told her that one effect of the medication could possibly be the taking of a life?

MR. O'BAN: Objection, mischaracterizes her testimony.

A. I didn't say that, what you just said, taking of a life. I didn't say that to her.

Q. You said the implantation of life, can prevent the implantation of life?

A. Implantation. I told her first thing that I couldn't -- it was a medication that I was -- I don't 2 know how I worded it, that I wouldn't be able to fill 3 it for her, fill the prescription for her.

Q. You don't recall if that was before or after?

A. It was probably before. Typically that's what I, if I ever talk to anybody, I mean, that's my recollection.

Q. Do you remember if you actually ended up giving her a specific referral to another pharmacy, or had she decided at the end of your conversation that she was not going to get the medication?

A. I don't recall. The technician was on the phone getting, calling another pharmacy, and was relaying that to the patient, and I was in on that -- I mean, we were all there standing together, and then she left, and I don't know what she did. I mean, she left.

Q. How long after that was it that you heard from your manager that there had been some sort of a complaint about that interaction?

A. I don't know. It was a little while later.

Q. A little while like --

A. I'm thinking like days. I don't recall.

…

Excerpt of Transcript of Trial Court's Oral Decision Before the Honorable Ronald B. Leighton United States District Court Judge

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

STORMANS, INCORPORATED doing business as RALPH'S THRIFTWAY; RHONDA MESLER; and MARGO THELEN, Plaintiffs, v. MARY SELECKY, Acting Secretary of the Washington State Department of Health, et al, Defendants.	Docket No. C07-5374RBL **CA No. 12-35221** **CA No. 12-35223** **CA No. 12-35224** **Tacoma, Washington** **February 22, 2012** **VOLUME 13**

TRANSCRIPT OF TRIAL
COURT'S ORAL DECISION
BEFORE THE HONORABLE RONALD B. LEIGHTON
UNITED STATES DISTRICT COURT JUDGE

…

THE COURT: All right. A number of people and groups have made a substantial investment of time, energy, and though into this issue before the Court. It seems so intuitive to so many that any lawful medicine should be dispensed on demand from any pharmacy. Sometimes the analysis stops there, but the calculus breaks down in the details.

There are other interests, however, vital interests of paramount concern to the Court. The devotion to the rule of law. Daniel Webster said of the rule of law, "Justice is the greatest interest of man on earth. It is the ligament which holds civilized beings and civilized nations together.["]

In that light, in my judgment, this case is a simple decision to make. But unlike the occasion of delivering the opinion in don't ask, don't tell, an issue that was understood well by the public, a short decision was appropriate. Here, a lengthy, scholarly decision aimed at a skeptical appellate court is necessary. Your patience will be tried for about one hour and fifteen minutes.

…