No. 15-862

In The Supreme Court Of The United States

STORMANS, INC., DBA RALPH'S THRIFTWAY, ET AL.,
PETITIONERS,

v.

JOHN WIESMAN, SECRETARY OF THE WASHINGTON STATE DEPARTMENT OF HEALTH, ET AL.,
RESPONDENTS,

AND

JUDITH BILLINGS, ET AL.,
RESPONDENT-INTERVENORS.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

WASHINGTON STATE RESPONDENTS' BRIEF IN OPPOSITION

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QUESTION PRESENTED

In 2007, the Washington State Board of Pharmacy adopted two rule changes. The amended rules protect the right of religious *pharmacists* to decline to fill prescriptions contrary to their beliefs, Wash. Admin. Code § 246-863-095, but require *pharmacies* to ensure timely delivery of needed medicines to their patients, *id.* § 246-869-010.

The district court found that the rules as written are clearly constitutional. But it found that the Board had enforced the rules in an unconstitutional manner. It made this finding even though no pharmacist or pharmacy had ever been disciplined for violating the rules. Despite this lack of enforcement, the district court also found that the rules had been selectively enforced *in favor of* Catholic-run pharmacies, and that this was evidence of religious animus. The court of appeals unanimously reversed, with no judge even requesting a response to the petition for rehearing en banc.

The question presented is:

> Whether administrative rules that are neutral and generally applicable, that allow individual pharmacists to assert religiously-motivated objections while requiring pharmacies to meet the pharmaceutical needs of their patients, and that have never been enforced against any religious objector, violate the Free Exercise Clause.

PARTIES

Petitioners are Stormans, Inc. (doing business as Ralph's Thriftway), Rhonda Mesler, and Margo Thelen.

Respondents are John Wiesman, Secretary of the Washington State Department of Health; 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, and *Kristina Logsdon, Members of the Washington Pharmacy Quality Assurance Commission; *Mark Brenman, former Executive Director of the Washington Human Rights Commission; and Martin Mueller, Assistant Secretary of the Washington State Department of Health, Health Services Quality Assurance.

Intervenor-Respondents are Judith Billings, Rhiannon Andreini, Jeffrey Schouten, Molly Harmon, Catherine Rosman, and Tami Garrard.

*These persons no longer hold the positions identified. In addition, Mr. Brenman was dismissed from the case in 2009. Pet. App. 292a-95a, 332a; ER 1290 (Dkt. 376).

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INTRODUCTION

Little in the petition for certiorari is accurate. Nothing in it warrants this Court's review.

In 2007, Washington's Board of Pharmacy unanimously adopted two rule changes to ensure patients prompt access to needed medications. Pet. App. 11a-14a, 23a. Under the rules, *pharmacists* may refuse to fill prescriptions for religious or moral reasons, but *pharmacies* must ensure that patients promptly receive prescribed medicines. Pet. App. 22a-23a. The court of appeals correctly held that the rules are neutral and generally applicable. Its decision created no split of authority. Petitioners' contrary arguments rely on omissions and distortions as to the facts and the law. The Court should not be fooled.

On the facts, Petitioners assert that the rules "target religious conduct." Pet. i. But they never mention that the rules "specifically *protect* religiously motivated conduct" by "creat[ing] a right of refusal for pharmacists . . . who have religious, moral, philosophical, or personal objections to the delivery of particular prescription drugs." Pet. App. 22a-23a. In fact, Petitioners *never even cite* one of the rules they ask the Court to invalidate, Wash. Admin. Code § 246-863-095, presumably hoping the Court will overlook this element of the rules.

Petitioners ask the Court to believe the rules "have been enforced only against religious conduct." Pet. i. In reality, the 2007 rules have not been enforced against *anyone*. No one—religious or otherwise—has been disciplined for violating either rule. Pet. App. 225a. And the Board dismissed every

single complaint filed against Petitioners under the rules. Pet. App. 15a; Resp. App. 74a; ER 1739-43. Indeed, the primary evidence of "selective enforcement" the district court cited was the Board's supposed refusal to enforce the rules against Catholic-run pharmacies. Pet. App. 95a-105a. How such non-enforcement against Catholics could show targeting of religion is unclear.

On the law, Petitioners start by implicitly conceding that they cannot meet the standards for certiorari, instead asking the Court to summarily reverse. They claim the Ninth Circuit's decision is "truly radical," "absurd," and "patently inconsistent with" this Court's decisions. Pet. 39, 38, 19. Yet not a single judge of the Ninth Circuit even called for a response to Petitioners' request for rehearing en banc. The reality is that two different Ninth Circuit panels have now reviewed these rules, first on appeal of a preliminary injunction, and second in the merits appeal. Both panels carefully applied this Court's precedent and unanimously concluded that the rules are neutral and generally applicable. Petitioners fervently disagree with those conclusions, but their fervor is no basis for summary reversal.

Petitioners next claim that the Ninth Circuit rejected a rule announced in *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520 (1993), that "a law is not generally applicable when it exempts nonreligious conduct that undermines the government's interests 'in a similar or greater degree than [religious conduct] does.'" Pet. 23 (alteration in Petition) (quoting 508 U.S. at 543-44). But the Ninth Circuit quoted and applied that very holding. Pet. App. 29a-30a & n.7. The Ninth Circuit did not reject

the controlling legal test; it applied that test and found that the rules' exemptions did not undermine the government's interests in the same way that a religious exemption would. Pet. App. 30a-31a.

Petitioners also contend that the rules as written allow the Pharmacy Board too much discretion and that the Ninth Circuit deviated from other circuits as to the relevance of "individualized exemptions" allowed by such discretion. Pet. 29-32. But the Ninth Circuit approvingly cited decisions of those other circuits in evaluating Petitioners' claims of "individualized exemptions." Pet. App. 35a-37a. It simply rejected Petitioners' view that the rules allowed impermissible discretion. *Id.*

Petitioners likewise claim that the decision below "conflicts with the Third Circuit on . . . whether even a facially neutral and generally applicable rule is subject to strict scrutiny due to selective enforcement." Pet. 32. But the Ninth Circuit never disagreed with the Third Circuit or any other about the relevance of selective enforcement; rather, it found "no evidence of selective enforcement." Pet. App. 40a.

Petitioners' last legal claim is that the Ninth Circuit split from the Seventh and Eighth Circuits by refusing to consider "a law's historical background to show a lack of neutrality." Pet. 35. That is false. The Ninth Circuit noted that *Lukumi* left an open question as to whether courts should consider legislative history, but it held that the answer to that question made no difference here because "[e]ven if we should analyze that history, it does not reveal improper intent." Pet. App. 27a. Again, Petitioners

disagree with the Ninth Circuit's application of the law to the facts, not its statement of the law.

Finally, Petitioners' assertion that this case "is a clean vehicle to resolve critical questions of free exercise law" is untenable. Pet. 38. Every one of Petitioners' legal claims turns on factual claims rejected by the court of appeals. Petitioners' primary legal argument is that the rules' exemptions are improper. But both the district court and Ninth Circuit held that the rules' written exemptions are unproblematic. *Stormans, Inc. v. Selecky*, 524 F. Supp. 2d 1245, 1262 (W.D. Wash. 2007); Pet. App. 30a-31a, 315a-317a. The only dispute is whether the rules contain "unwritten exemptions," as the district court found, a finding the Ninth Circuit rejected as clear error. Pet. App. 31a-32a. Similarly, Petitioners press a selective enforcement claim, but *no one* has ever been disciplined for violating the rules, and the Ninth Circuit found "no evidence of selective enforcement" by the Board. Pet. App. 40a. Moreover, Petitioners' primary objection to the rules—potentially having to dispense the emergency contraceptive Plan B—has evaporated, as it is now available over the counter and thus no longer covered by the rules at issue.

In short, Petitioners seek nothing more than fact-bound error correction where there is no error. The Court should deny review.

OPINIONS BELOW

In addition to the opinions Petitioners cite, the relevant opinions below include: (1) the Ninth Circuit's order denying rehearing en banc (unreported), reproduced at Pet. App. 261a-62a; and

(2) the Ninth Circuit's opinion reversing the district court's order preliminarily enjoining enforcement of the challenged rules, reported at *Stormans, Inc. v. Selecky*, 586 F.3d 1109 (9th Cir. 2009), and reproduced at Pet. App. 263a-332a.

JURISDICTION

The Petition correctly describes this Court's jurisdiction.

STATUTES OR OTHER PROVISIONS INVOLVED

Petitioners cite two Washington administrative rules as "relevant" here. Pet. 5 (citing Wash. Admin. Code §§ 246-869-010 and -150(1)). But the district court also invalidated a third rule, Wash. Admin. Code § 246-863-095, which is set forth at Pet. App. 348a-50a.

STATEMENT OF THE CASE

A. Development and Adoption of the Challenged Rules

Like every other State, Washington heavily regulates the practice of pharmacy. For decades, the Legislature has directed the Washington State Board of Pharmacy to adopt rules "for the protection and promotion of the public health, safety, and welfare." Wash. Rev. Code § 18.64.005(7).[1] By law, only the Board itself—not Board staff or individual Board

[1] In 2013, the Board was renamed the "Pharmacy Quality Assurance Commission" and expanded from seven members to fifteen. 2013 Wash. Sess. Laws page no. 141 (Reg. Sess., ch. 19, § 3). Because at all times pertinent here it was called the "Board," we use that term.

members—may adopt rules or impose professional discipline. *See* Wash. Rev. Code §§ 18.64.005, .160, .165; 18.64A.030, .050; 18.130.040(2)(b)(viii), .050.

In 2005, Board staff informed the Board about accounts of pharmacists confiscating or destroying lawful prescriptions or refusing to dispense medicine for non-clinical reasons; staff reported receiving inquiries from pharmacists and the public about whether such conduct was permissible in Washington. Resp. App. 1a, 18a, 55a. The Board determined that its rules were unclear as to whether a pharmacist could refuse to dispense medicine to a patient. *Id.* 19a, 55a. The Washington State Pharmacy Association, a voluntary professional association, offered to prepare a report to assist the Board. *Id.* 19a.

At the Board's meeting in January 2006, the Pharmacy Association submitted its report. It recommended that individual pharmacists should have discretion to refuse to dispense medicine, but listed specific acts (such as refusing to return an unfilled prescription) that should be considered "unprofessional conduct" and could lead to disciplinary action. Resp. App. 4a-6a. The Association acknowledged a tension between "the professional responsibility of a pharmacist to provide pharmaceutical care for his/her patients" and respecting a pharmacist's "moral, ethical or religious principles." *Id.* 5a-6a.

After receiving the report, the Board collectively observed that "this is a very complex issue and not just about reproductive rights," and it voted to initiate rulemaking to address

it. Resp. App. 6a-7a. Under Washington law, rulemaking is a multi-step process that requires public participation, preparation of various explanatory documents, and publication of proposed rule language before final adoption. Wash. Rev. Code §§ 34.05.310-.395. A vote to begin rulemaking starts the process but is not a commitment to adopt a rule. *Id.* § 34.05.310.

The decision to begin rule-making attracted substantial attention. Representatives of Northwest Women's Law Center and Planned Parenthood asked for and were given an opportunity to respond to the Pharmacy Association's report. Resp. App. 8a. At the next Board meeting, in March 2006, they advocated for a rule under which "[p]harmacies can accommodate the religious refusal of [a] pharmacist" while ensuring that "the patient's care is not disrupted or delayed in any way." *Id.* 12a.

Over the next sixteen months, the Board conducted numerous public hearings and work sessions, prepared multiple drafts of possible rules, and received and considered some 21,000 comments. Pet. App. 268a. While many commenters focused on access to Plan B, the Board heard testimony about individuals who, for nonclinical reasons, had been refused a wide variety of prescription medicines and devices, such as HIV medications, syringes (for insulin), prenatal vitamins, and contraceptives. Pet. App. 269a; Resp. App. 61a, 65a. Throughout the rulemaking, the Board maintained a consistent focus on ensuring timely access to all medicines—not just Plan B—as evidenced by every rulemaking document

the Board produced. *See, e.g.*, Resp. App. 6a, 19a, 23a, 40a, 44a-45a; *see also id.* 47a-48a, 59a, 62a-63a, 76a-77a; 84a.

By June 2006, the Board had prepared several drafts without reaching agreement on language to be published for public comment. Pet. App. 272a n.4. One unresolved issue was whether pharmacists should be allowed to refuse to fill prescriptions if they referred patients to another pharmacy. While some pharmacists supported such a rule, other pharmacists testified in opposition, saying that even being required to tell a patient where to obtain certain medications would violate their beliefs. Resp. App. 4a-5a. Meanwhile, some commenters, including the State Human Rights Commission, opposed any refusal to fill a prescription, even if there was another pharmacist available at the same pharmacy to fill it. Pet. App. 374a-99a.

Washington Governor Christine Gregoire advocated for a compromise approach. She emphasized that "[t]his issue goes far beyond women's access to contraception" and urged the Board to focus on "protecting the health of Washington residents[.]" Resp. App. 2a. She suggested that *pharmacies* should be required to fill lawful prescriptions but also able to "accommodate . . . the individual rights of conscience of their employees." *Id.* To help the Board reach agreement, she convened a working group that included Board members as well as representatives of the Washington State Pharmacy Association, the Department of Health, the Northwest Women's Law Center, and Planned Parenthood. Pet. App. 272a n.4; SER 1085, 1114. As the district court found, the

Governor's involvement was "well within" her role under State law, was "part of the normal political process, and does not taint the rulemaking processes undertaken by the Board." Pet. App. 138a.

In August 2006, the Governor's staff presented a negotiated draft rule to the Board that allowed individual pharmacists' refusals for religious or moral reasons, placing the responsibility on the pharmacy as a business to ensure that patients receive the lawfully prescribed medicines they need. SER 1114. Over the next nine months, the Board revised the draft several times, held additional public hearings, received further comments, and prepared the required rulemaking analysis. On April 12, 2007, the Board unanimously voted to adopt the two rule changes. Resp. App. 13a-14a. They took effect on July 26, 2007. Pet. App. 274a.

B. The Challenged Rules Accommodate Individual Pharmacists' Beliefs While Requiring Pharmacies to Ensure Patients' Timely Access to Medicine

The changes the Board adopted are codified in two rules.

The Pharmacist Responsibility Rule applies to individual *pharmacists* and was codified as an amendment to Wash. Admin. Code § 246-863-095. Pet. App. 348a-50a. Under that rule, "[i]t is considered unprofessional conduct" for a pharmacist to "(a) Destroy unfilled lawful prescription[s]; (b) Refuse to return unfilled lawful prescriptions; (c) Violate a patient's privacy; (d) Discriminate against patients . . . in a manner prohibited by state or federal laws; and (e) Intimidate or harass a

patient." Wash. Admin. Code § 246-863-095(4). As the court of appeals explained:

> "[T]he parties agree that the foregoing rule does *not* require an individual pharmacist to dispense medication if the pharmacist has a religious, moral, philosophical, or personal objection to delivery. A pharmacy may 'accommodate' an objecting pharmacist in any way the pharmacy deems suitable, including having another pharmacist available in person or by telephone." Pet. App. 12a (citations omitted).

The second rule, known as the Delivery Rule, applies to *pharmacies* and is codified at Wash. Admin. Code § 246-869-010. Pet. App. 344a-46a. It requires pharmacies to "deliver lawfully prescribed drugs or devices to patients . . . or provide a therapeutically equivalent drug or device in a timely manner consistent with reasonable expectations for filling the prescription[.]" Wash. Admin. Code § 246--869-010(1). Like the pharmacist rule, the Delivery Rule prohibits pharmacies from destroying or refusing to return an unfilled lawful prescription; violating a patient's privacy; or unlawfully discriminating against, intimidating, or harassing a patient. *Id.* § 246-869-010(4). Unlike the pharmacist rule, the Delivery Rule does not allow a pharmacy to refuse to deliver a drug or device to a patient because its owner objects to delivery on religious, moral, or other personal grounds.

The Delivery Rule provides limited exceptions from its delivery requirement. In particular, pharmacies need not fill a prescription where doing

so would threaten patient safety, such as obvious medication errors, contra-indicated prescriptions, fraudulent prescriptions, or where the pharmacy lacks specialized equipment needed to safely dispense the drug. *Id.* § 246-869-010(1)(a), (c), (d). Pharmacies also need not fill prescriptions where the patient is unable to pay, or where an emergency limits availability of a drug. *Id.* § 246-869-010(1)(b), (2). Finally, the rule provides an exception where a pharmacy, despite its best efforts, runs out of a drug it normally stocks; in that circumstance, referral to another pharmacy is permitted. *Id.* § 246-869--010(1)(e), (3).

Exception (1)(e) is explicitly premised on "good faith compliance with" Wash. Admin. Code § 246-869-150, the "Stocking Rule." Pet. App. 347a. That rule was adopted in 1967 and has remained virtually unchanged since. Pet. App. 11a-12a. The rule does not require a pharmacy to stock every prescription drug; rather, it provides that a pharmacy "must maintain at all times a representative assortment of drugs in order to meet the pharmaceutical needs of its patients." Wash. Admin. Code § 246-869-150(1).

In sum, the combined effect of the rules is that an individual *pharmacist*, based on his or her beliefs, may refuse to dispense a medicine to a patient. Where that occurs, the *pharmacy* has a duty to find a way to timely deliver the medicine to the patient.

In adopting this compromise approach, the Board was clear and consistent in articulating its goals: first, to accommodate individual pharmacists' beliefs while fulfilling its mission of ensuring that

patients timely receive needed medicines; and second, to ensure timely access to all medications (not just emergency contraceptives). Pet. App. 272a-74a; Resp. App. 14a-15a.

For example, as to the first goal, the Board's Final Significant Analysis specifically acknowledged that the rules allow a pharmacist to refuse to fill a prescription because of his or her beliefs. Resp. App. 31a. The Board explained how its rules provide several options for pharmacies to fill a prescription where a pharmacist expresses personal objections. Resp. App. 31a-33a, 37a-40a, 44a-45a. And while these options would have some costs to pharmacies, the Board explained that those costs had to be balanced against the substantial medical and social costs of being "unable to obtain needed medications in a timely manner." *Id.* 17a; ER 995.

As to the second goal, the Board's Final Significant Analysis explained that the purpose of the two rules was "to improve state-wide access and reduce barriers for patients seeking U.S. Food and Drug Administration-approved drugs and devices." Resp. App. 17a. The Board acknowledged that much of the public interest and comment had focused on Plan B. *Id.* 19a. But the Board again made clear that its concern was broader: "[t]he people of Washington must know that they can get the medications they need without barriers to health care." *Id.* 23a. The Board specifically described the probable benefits of the rules as related to medicines necessary to treat a wide range of diseases, including HIV and diabetes. *Id.* 25a-27a.

C. The Board's Enforcement of Its Rules

The Board enforces its rules largely by responding to public complaints. Resp. App. 66a-73a, 76a. While the Board does conduct biannual inspections of pharmacies, it has never enforced the Stocking or Delivery Rules in that manner. Pet. App. 37a, 177a-79a.

As the Board was considering and adopting the 2007 rules, a group of local residents staged protests against Ralph's Pharmacy, filing with the Board twenty-four complaints against Ralph's alleging failure to stock or deliver Plan B. ER 1739-43. The Board considered the complaints in its normal process and dismissed twenty-one of them for procedural reasons, all before the district court's injunction. Pet. App. 15a; Resp. App. 74a. The Board suspended processing the remaining three complaints in response to the injunction and a subsequent stipulation, ER 639-40, 1739-43, and they remained suspended until the Ninth Circuit's merits decision in July 2015. After the Ninth Circuit's decision, and thus not in the record, the Board dismissed the three remaining complaints without any enforcement action.[2]

Ralph's was not alone in facing complaints. Members of the public filed complaints against a number of pharmacies for failure to deliver a wide range of drugs; the majority involved drugs other

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[2] *See* Letters from Paige L. Fury, Wash. State Dep't of Health, to Daisy Ouye (Aug. 25, 2015), Diana Arens (Aug. 25, 2015), and Sarah E. Adams (Aug. 25, 2015) (letters on file with counsel).

than Plan B. Pet. App. 179a-80a. The Board opened investigations into refusals by a number of pharmacies. ER 744-47. But if the pharmacy stated that it was temporarily out of the requested drug and would order more (and thus was in compliance with the Delivery Rule), the investigation was closed. *See* Resp. App. 78a-80a.

Two facts are indisputable on this record. First, the Board has taken no disciplinary action against any religious objector for violating the rules. *See, e.g.*, Pet. App. 225a ("[I]n the four years since the Delivery Rule went into effect, no pharmacy has ever been cited for violating it."); Pet. App. 118a. Second, the Board has closed every complaint filed against Petitioner Stormans under the rules without taking enforcement action. Pet. App. 15a.

D. *Stormans I*: Preliminary Injunction and the Ninth Circuit's Reversal

Petitioners filed a complaint challenging the Pharmacist Responsibility Rule and the Delivery Rule on July 25, 2007, the day before the rules were to take effect. Pet. App. 14a, 274a; ER 705-23. Petitioners never mentioned the Stocking Rule in any of their three complaints, even when the district court permitted them to amend their complaint a second time four years into this litigation. ER 705-23, 686-704, 520-39, 1298 (Dkt. 470).

On November 8, 2007, the district court granted Petitioners' motion for a preliminary injunction. 524 F. Supp. 2d 1245. The court granted the injunction despite finding that: (1) "A review of the [regulations] reveals no mention of religion or any intention to burden the religious practices of

others," 524 F. Supp. 2d at 1257; (2) the rules' exemptions "all reflect legitimate, time-honored reasons for not filling a prescription immediately upon presentation by a patient," *id.* at 1262; and (3) "there is some evidence to support defendants' claim that the regulations are about optimal access to all medicines, not just emergency contraceptives," *id.* at 1261. Notwithstanding these findings, the court held that the rules had been adopted to "target religious practice" and therefore were not neutral or generally applicable. *Id.* at 1263.

The court of appeals unanimously reversed. The Ninth Circuit held that the rules are neutral because they "do not suppress, target, or single out the practice of any religion because of religious content." Pet. App. 306a. "[T]he object of the rules was to ensure safe and timely patient access to lawful and lawfully prescribed medications." Pet. App. 306a-07a. The court explained that the rules serve that object by requiring delivery of all lawfully prescribed medications, except when "one of several narrow exemptions permits refusal. . . . [A]side from the exemptions, any refusal to dispense a medication violates the rules, and this is so regardless of whether the refusal is motivated by religion, morals, conscience, ethics, discriminatory prejudices, or personal distaste for a patient." Pet. App. 307a. The court held the rules are generally applicable because they are not underinclusive: "all pharmacies have a 'duty to deliver' all medications 'in a timely manner.' Neither regulation . . . applies to refusals only for religious reasons." Pet. App. 315a. And observing that the rules "do not prohibit individual pharmacists from refusing to dispense a

medication for religious reasons," Pet. App. 320a, the court held "the rules do not selectively impose an undue obligation on conduct motivated by religious belief"; rather, they "actually provide for religious accommodation—an individual pharmacist can decide whether to dispense a particular medication based on his religious beliefs and a particular pharmacy may continue to employ that pharmacist by making appropriate accommodations." Pet. App. 321a.

E. The 2010 Rulemaking

In June 2010, after prevailing in the Ninth Circuit, the Board commenced a new rulemaking process as part of a discussion of "changes occurring in the practice of pharmacy." ER 748. The Board made clear that the rulemaking process was not limited to any single option but was intended to consider whether to "allow additional or alternative procedures that would improve access to medications when patients need them." ER 752, 896. One possible alternative under consideration was a "facilitated referral" option for pharmacies, which Petitioners supported. Because including that option could moot the litigation, the State Defendants and the Plaintiffs stipulated to delay trial. ER 552-58.

Over the next five months, the Board again conducted public hearings and received over 5,000 comments. ER 871; *see* ER 754-880, 893-910. By a 4-1 margin, commenters opposed changing the rules. ER 871, 1090-91. In particular, commenters highlighted the physical and psychological barriers that a referral rule would pose for those with limited mobility (including the disabled and seniors), for

victims of sexual assault, and for patients needing time-sensitive medication. ER 779-80, 783-87, 899, 901-07. In December 2010, the Board voted to leave the Rules unchanged. ER 882-83.

The district court then lifted the stay of the proceedings and set trial. ER 544-45.

F. Trial and the Ninth Circuit's Reversal

During the preliminary injunction proceeding, both the district court and the court of appeals found the two challenged rules to be facially neutral. 524 F. Supp. 2d at 1257; Pet. App. 305a. Thus, at trial, Petitioners sought to prove that the rules had been enforced in an unconstitutional manner. But the rules had not been enforced against anyone prior to trial. *See, e.g.*, Pet. App. 225a.

Petitioners' solution to this challenge was to ask witnesses at trial—including many who had never been members of the Board—endless hypothetical questions about how the Board would interpret the rules in the future. *See*, *e.g.*, ER 1063-64 (asking non-Board member "if the Board was confronted with such a complaint . . . what would the Board's response be?"), 1550-51 (stating "in this scenario, you are the Board," after non-Board member said the Board must decide a violation), 1022-23 (asking former CEO of pharmacists' association about his understanding of the rules). Despite repeated objections, the district court allowed this approach. *See*, *e.g.*, ER 1018 ("It is speculative. . . . [B]ut you can ask the question."). Indeed, the district court itself asked witnesses who were not on the Board how the Board might apply the rules. *See*, *e.g.*, ER 1043 (asking former adviser

to the Governor how the rules would apply to a pharmacy at a Catholic-run hospital).

None of these witnesses could authoritatively answer how the Board might respond to hypothetical scenarios. As Board Chair Gary Harris explained, "only the Board of Pharmacy when they take a vote can make a decision," Resp. App. 81a, and "on a hypothetical case, I don't think we can possibly know what might happen until we actually have that case in front of us," Resp. App. 81a-82a. *See* Resp. App. 52a (same), 83a (same).

Unsurprisingly, these hypotheticals elicited speculative and inconsistent predictions about how the Board might address particular situations, sometimes from the same witness. *Compare* ER 1045 (Board staffer Timothy Fuller speculating that the rules might allow pharmacies to decline to stock expensive drugs) *with* Resp. App. 48a (Fuller acknowledging that "the Board of Pharmacy had actually concluded [in its Final Significant Analysis] that a pharmacy may very well be required to stock an expensive drug," and that "the official documents . . . control how the rules actually operate").

Ultimately, Petitioners prepared proposed findings of fact and conclusions of law that relied extensively on such hypothetical testimony, and the district court adopted them almost verbatim. *Compare* ER 156-273 (Petitioners' proposed findings and conclusions) *with* Pet. App. 112a-258a (district court's findings and conclusions). Speculative responses to hypotheticals thus became "Findings of Fact," even where contradicted by direct evidence. *See, e.g.*, Pet. App. 163a (citing Fuller's testimony

that pharmacies can decline to stock expensive drugs, despite the Board having provided official written guidance saying exactly the opposite, *see, e.g.*, Resp. App. 33a-34a, 38a); *see also id.* 42a ("Pharmacies are expected to stock all medications needed by their patients.").

Another unusual feature of the trial was that the district court proposed for Petitioners a theory they had not advanced themselves: that the Board was selectively enforcing the rules by declining to punish Catholic-run pharmacies that did not stock emergency contraceptives. *See* ER 315-421 (Plaintiffs' Trial Brief). In the district court's own words, it had a "single-minded focus on the Catholic facilities." ER 1248; *see also* ER 1079-80, 1151-53. The court emphasized its "one-track mind" about this issue, ER 1073, by extensively questioning witnesses about the rules' impact on Catholic-run pharmacies. ER 1029, 1034-38, 1042-43, 1073-74, 1106-12, 1136-39, 1149-50, 1243-48. The Board had never received a complaint about a Catholic-owned pharmacy violating the rules, Resp. App. 74a-75a, but several Board witnesses testified that any such complaint would be treated just like any other complaint. *See, e.g.*, *id.* 83a; ER 1109-10; SER 391. Nonetheless, the district court held that the Board was selectively enforcing the rules by not taking action against Catholic facilities. Pet. App. 95a-105a.

A different panel of the Ninth Circuit unanimously reversed the district court again.

The court of appeals first held that the rules are neutral. Pet. App. 21a-28a. The court found that, unlike the laws in *Lukumi*, the rules here do not

target religion. Pet. App. 22a. Indeed, "the rules specifically *protect* religiously motivated conduct" of pharmacists by allowing them to decline to fill prescriptions based on their beliefs. *Id.* As to pharmacies, the court found the rules neutral because they apply to all drugs and all reasons for refusal, except for very limited and necessary exemptions (e.g., for patient safety). *Id.* 23a. The court also reviewed the rules' legislative history and concluded that "the district court clearly erred in finding discriminatory intent." *Id.* 28a.

As to general applicability, the court began by assessing whether the rules were "substantially underinclusive." Applying *Lukumi*, it asked whether the rules applied solely to "'conduct motivated by religious belief'" while exempting "comparable secular conduct that would similarly threaten the government's interest[.]" Pet. App. 28a-29a (quoting *Lukumi*, 508 U.S. at 545). Like the district court, the court of appeals found that none of the exemptions written in the rules undermined the government's interest in the same way that a religious exemption would. *Id.* 31a. The court then rejected as clearly erroneous the district court's factual finding that the rules contained many "unwritten exemptions." *Id.* 31a-32a. The court acknowledged that pharmacies had sometimes in the past refused to fill prescriptions for other reasons, but it found that the district court "clearly erred by concluding that the [Board] permitted those practices or exempted them from enforcement" where there was no evidence that the Board had received a complaint about such practices or decided that they were permissible. *Id.* 31a-32a.

Next, the court of appeals rejected Petitioners' claim that the rules impermissibly contained "individualized exemptions." *Id.* 32a-37a. The court explained that, under uniform case law from other circuits, "[t]he mere existence of an exemption that affords some minimal government discretion does not destroy a law's general applicability." *Id.* 35a-36a (citing cases).

Finally, the court carefully reviewed the record and rejected the district court's finding of selective enforcement. The court found that the Board had investigated alleged violations of the rules "only when a consumer files a complaint of a violation," and "[t]he record does not show that the [Board] has made religiously based distinctions in its complaint-driven enforcement of the rules." Pet. App. 38a. In short, Petitioners "provide[d] no evidence of selective enforcement." *Id.* 40a.

Petitioners moved for rehearing/rehearing en banc. The Ninth Circuit denied the motion, with no judge requesting a vote on rehearing and no judge dissenting. *Id.* 261a-62a.

REASONS FOR DENYING THE PETITION

A. There Is No Basis for Summary Reversal

Apparently aware that the decision below creates no real conflict with other circuits, Petitioners lead with a request for summary reversal, portraying the decision as "absurd," "truly radical," and "patently inconsistent with *Lukumi*." Pet. 39, 38, 19. Their argument collapses under the slightest scrutiny.

To begin, if it is truly "absurd" to find these rules neutral and generally applicable, why have two separate panels of appellate judges, of divergent ideological backgrounds, found them so? Why did not a single one of the twenty-eight active judges of the Ninth Circuit even request a response to Petitioners' motion for rehearing en banc?

Petitioners' substantive arguments fare no better than their hyperbole. Their central point is that this case is indistinguishable from *Lukumi* and the Ninth Circuit refused to apply *Lukumi*. Not true.

Far from flouting *Lukumi*, the court of appeals explicitly applied *Lukumi* to the record evidence. The court carefully examined the rules' text, Pet. App. 22a-23a, 25a, the Board's statements regarding the rules, *id.* 23a-24a, the rulemaking history, Pet. App. 27a-28a, and the actual effect of the rules in light of each of Petitioners' theories, *id.* 30a-40a. The court explicitly contrasted these rules with the ordinances in *Lukumi*, concluding that "[u]nlike the ordinances at issue in *Lukumi*, the rules here operate neutrally" because they *protect* religiously motivated conduct by pharmacists, apply to all pharmacists and pharmacies (not just religious practitioners), apply to all medicines (not just emergency contraceptives), and affirmatively support the articulated goal of removing barriers to timely access to medicines. *Id.* 22a-26a. In finding the rules generally applicable, the court again contrasted the rules here with the ordinances in *Lukumi*, concluding that unlike the ordinances there, the rules here did not allow secular conduct that endangers the government interest "in a similar or

greater degree" than a religious exemption would. Pet. App. 29a-30a & n.7.

Petitioners nonetheless contend that the Ninth Circuit deviated from *Lukumi* because the exemptions here are indistinguishable from those in *Lukumi*. Pet. 20. But in *Lukumi*, this Court found that the text of the exemptions made the ordinances apply solely to "the religious exercise of Santeria church members." 508 U.S. at 535. Here, by contrast, even the district court found that the rules as written "pass constitutional muster," Pet. App. 80a, and that the rules' few written "exemptions all reflect legitimate, time-honored reasons for not filling a prescription immediately upon presentation by a patient." 524 F. Supp. 2d at 1262. Yet the district court found the rules invalid based on alleged "unwritten exemptions." Pet. App. 89a, 198a-218a. The Ninth Circuit correctly found that the district "court clearly erred by concluding that the [Board] permitted those practices or exempted them from enforcement," because there was no evidence that the Board would actually create the "unwritten exemptions" the district court hypothesized. *Id.* 32a.

Ironically, Petitioners also complain that the Ninth Circuit supposedly ignored the principle that "*Lukumi* requires the court to consider 'the effect of a law in its real operation'—not speculate about the future." Pet. 21 (quoting *Lukumi*, 508 U.S. at 535). But it is Petitioners who rely on speculation about the rules rather than real evidence. To give one of countless possible examples, Petitioners contend (and the district court adopted their contention) that the rules created an unwritten exemption allowing

pharmacies to decline to stock expensive drugs, Pet. App. 163a, but the Board's written guidance makes very clear that it will allow no such exemption. *See*, *e.g.*, Resp. App. 33a-34a, 38a. Similarly, Petitioners repeatedly contend that "the Regulations have never applied to any secular conduct," *see, e.g.*, Pet. 21, but as explained above, the evidence presented at trial showed that the Stocking Rule had never been enforced against a religious objector, that the new Delivery Rule and amendments to the Pharmacist Responsibility Rule had never been enforced at all, and that the amended Pharmacist Responsibility Rule in fact protects individual pharmacists' religious objections. In short, the Ninth Circuit did examine the rules' real effect; it is Petitioners who rely on speculation.

B. The Ninth Circuit's Decision Creates No Conflict With Other Circuits

1. The Ninth Circuit correctly identified and applied the controlling rule from *Lukumi* in assessing the relevance of exemptions

Petitioners correctly cite the holding from *Lukumi* that a law is not generally applicable when it "exempts nonreligious conduct that undermines the government's interests 'in a similar or greater degree than [religious conduct]'" it prohibits. Pet. 23 (alteration in Petition) (quoting 508 U.S. at 543-44). They also correctly observe that other circuits have applied that holding to find Free Exercise violations. Pet. 23-24. But they are wrong when they assert that the Ninth Circuit ignored that rule or created a conflict with any other circuit.

The Ninth Circuit applied exactly the same test Petitioners cite—that a law is not generally applicable if it "pursues the government's interest 'only against conduct motivated by religious belief' but fails to include in its prohibitions substantial, comparable secular conduct that would similarly threaten the government's interest[.]" Pet. App. 29a (quoting *Lukumi*, 508 U.S. at 545). The Ninth Circuit simply found no evidence that the rules affected only religiously motivated conduct or permitted secular conduct that would threaten the government's interest in ensuring timely access to medicines in the same way as the religious exemption Petitioners advocate. Pet. App. 30a-32a. A difference in outcome because of a difference in evidence does not produce a circuit split. And the Ninth Circuit's description of the evidence was correct.

The Delivery Rule contains a small number of narrow exceptions, allowing pharmacies to decline to fill prescriptions where: (1) filling the prescription would threaten patient safety (e.g., medication errors, contra-indicated prescriptions, or where the pharmacy lacks specialized equipment needed to safely dispense the drug); (2) the patient is unable or unwilling to pay; (3) an emergency limits availability of a drug; or (4) the pharmacy, despite its best efforts, runs out of a drug it normally stocks. Wash. Admin. Code § 246-869-010(1), (2). Even the district court recognized that these exceptions are all "legitimate, time-honored reasons for not filling a prescription." Pet. App. 316a (quoting 524 F. Supp. 2d at 1262). In *Stormans I*, the Ninth Circuit called them "necessary," "narrow," and not subject to "serious question," and concluded that they "increase

access to medications by making it possible for pharmacies to comply with the rules, further patient safety, and maintain their business." Pet. App. 273a, 307a, 315a-17a. Reviewing the exceptions a second time after trial, a different panel of the Ninth Circuit reached the same conclusion. *Id.* 30a-31a. By contrast, allowing a pharmacy owner to refuse to stock a medicine, regardless of the reason, does not enhance safety or increase access to medicine. The purpose of the exemption Petitioners advocate is not to assist patients.

The Ninth Circuit also examined the so-called "unwritten exemptions" the district court found and held that the district court clearly erred in finding that the Board treated them as exemptions. Pet. App. 31a-32a. The court of appeals noted that while these practices might have occurred in the past, there was no evidence the Board would permit them under the new rules if ever presented with a complaint about such conduct. "The [Board] has never issued an official interpretation of the rules suggesting that those practices are permitted." *Id.* 32a. "Trial testimony shows that, if complaints were filed about those practices, the [Board] would follow its normal procedure in deciding whether to investigate and to initiate an enforcement action." *Id.* Indeed, witnesses familiar with the Board's enforcement processes testified consistently that if complaints were filed in the hypothetical scenarios Petitioners repeatedly posed, those complaints would be subject to the normal investigation process and, if the facts warranted, the initiation of an enforcement action. *See*, *e.g.*, ER 1016, 1047, 1062,

1118-19, 1258, 1430, 1485, 1541, 1550; SER 15, 22, 28-29, 103, 703.

Thus, the Ninth Circuit recognized and applied the legal principle this Court announced in *Lukumi*—the same principle cited in the cases Petitioners contend create a circuit split. Pet. 23-24 (citing *Fraternal Order of Police Newark Lodge 12 v. City of Newark*, 170 F.3d 359 (3d Cir. 1999); *Ward v. Polite*, 667 F.3d 727 (6th Cir. 2012); *Midrash Sephardi, Inc. v. Town of Surfside*, 366 F.3d 1214 (11th Cir. 2004); *Mitchell Cty. v. Zimmerman*, 810 N.W.2d 1 (Iowa 2012)). The difference between this case and those is the evidence, not the legal rule. Indeed, one of those cases, *Mitchell County*, explicitly cited the rules at issue here as an example where the exemptions do *not* undermine the general applicability of the rules. 810 N.W.2d at 14-15 (citing *Stormans I*, 586 F.3d at 1115-17).

The bottom line is that Petitioners' dispute is not with the legal rule the Ninth Circuit applied, but rather with its application of that rule to the evidence. There is no circuit conflict.

2. The Ninth Circuit created no circuit split as to the relevance of "individualized exemptions"

Petitioners also contend that the decision below conflicts with other circuits as to the relevance of "individualized exemptions" to a law. Their argument mischaracterizes this Court's decision in *Lukumi*, the decisions of the other circuits they cite, and the decisions below.

Petitioners claim that *Lukumi* requires strict scrutiny whenever "a law gives the government discretion to grant case-by-case exemptions based on the reasons for the relevant conduct." Pet. 29 (internal quotation marks omitted). Not true. If that were the rule, every zoning system in America would be subject to strict scrutiny. Instead, *Lukumi* says, "in circumstances in which individualized exemptions from a general requirement are available, the government 'may not refuse to extend that system to cases of "religious hardship" without compelling reason.'" 508 U.S. at 537 (quoting *Emp't Div., Dep't of Human Res. of Oregon v. Smith*, 494 U.S. 872, 884 (1990)). Thus, strict scrutiny applies not to every system involving discretion, but rather where the law allows government to exercise discretion in favor of secular conduct but not religious conduct, or where the government does so in practice.

That was the situation in each of the cases Petitioners cite from other circuits. For example, in *Blackhawk v. Pennsylvania*, 381 F.3d 202 (3d Cir. 2004), the problem with the law was not the availability of individualized exemptions per se, but rather that the law "create[d] a regime of discretionary, individualized exemptions under which Blackhawk might qualify *if his conduct were not religiously motivated*." *Id.* at 210 (emphasis added). In other words, the law allowed the State to exercise discretion in granting exemptions only as to secular conduct. The Third Circuit confirmed this understanding of *Blackhawk*—and that Petitioners' reading is incorrect—in *Lighthouse Institute for Evangelism, Inc. v. City of Long Branch*, 510 F.3d

253 (3d Cir. 2007): "In *Blackhawk*, it was not the mere existence of an exemption procedure that gave us pause but rather the fact that the Commonwealth could not coherently explain what, other than the religious *motivation* of Blackhawk's conduct, justified the unavailability of an exemption." *Id.* at 276.

Similarly, in *Axson-Flynn v. Johnson*, 356 F.3d 1277 (10th Cir. 2004), a university professor exempted a Jewish acting student from an improvisational exercise on Yom Kippur, but refused to exempt a Mormon student from certain acting exercises requiring her to use profane language. *Id.* at 1298-99. The court's concern was not merely that the University exercised discretion in deciding which requirements were mandatory, but rather that the record suggested the University had applied its policy in a discriminatory way. *Id.* The Tenth Circuit confirmed this understanding in *Grace United Methodist Church v. City of Cheyenne*, 451 F.3d 643 (10th Cir. 2006). There, the court noted that federal courts routinely find laws "neutral and generally applicable notwithstanding that they may have individualized procedures for obtaining special use permits or variances." *Id.* at 651 (internal quotation marks omitted). As the court put it:

> "[T]he Sixth, Seventh, Eighth, and Eleventh Circuits have rejected a *per se* approach and instead apply a fact-specific inquiry to determine whether the regulation at issue was motivated by discriminatory animus, or whether the facts support an argument that the challenged rule is applied in a discriminatory fashion that disadvantages religious groups or organizations." *Id.*

Petitioners' citation to *Ward v. Polite*, 667 F.3d 727 (6th Cir. 2012), is no more supportive of their argument. There, the University had an anti-discrimination policy that *permitted* "values-based referrals," but it nonetheless prohibited a religiously-objecting graduate counseling student from referring a homosexual student to a different counselor. *Id.* at 739. In the court's words: "What poses a problem is not the adoption of an anti-discrimination policy; it is the implementation of the policy, permitting secular exemptions but not religious ones and failing to apply the policy in an even-handed, much less a faith-neutral, manner[.]" *Id.*

Nothing in the Ninth Circuit's ruling deviates from these decisions. In fact, the Ninth Circuit cited decisions from these circuits in explaining that "[t]he mere existence of an exemption that affords some minimal government discretion does not destroy a law's general applicability." Pet. App. 35a (citing *Grace United*, 451 F.3d at 651). Rather, "'[w]hat makes a system of individualized exemptions suspicious is the possibility that certain violations may be condoned when they occur for secular reasons but not when they occur for religious reasons.'" Pet. App. 36a (quoting *Lighthouse Inst.*, 510 F.3d at 276). The Ninth Circuit found no evidence that the Board took such an approach here, or that the rules would allow unfettered discretion in the first place.

The Ninth Circuit examined the Delivery Rule language the district court characterized as allowing discrimination against religion and rejected that characterization as erroneous. Pet. App. 34a-35a. The rule had never been enforced against a religious objector and had never been interpreted by the

Board in a way that would "allow exemptions except for religious reasons." *Id.* 35a. The court found the exemptions "are tied directly to limited, particularized, business-related, objective criteria," and "do not create a regime of unfettered discretion that would permit discriminatory treatment of religion or religiously motivated conduct." *Id.* 36a-37a. But the Ninth Circuit explicitly left open the possibility of an as-applied challenge in the future should the Board adopt a new interpretation of the rules that penalizes religious conduct while permitting similarly harmful secular conduct. *Id.* 37a n.8.

In short, the Ninth Circuit created no conflict with other circuits in its analysis of Petitioners' "individualized exemptions" argument.

3. The Ninth Circuit did not disagree with the Third Circuit about the relevance of selective enforcement, it simply found no evidence of selective enforcement

Petitioners contend the Ninth Circuit's decision here "conflicts with the Third Circuit on the question of whether even a facially neutral and generally applicable rule is subject to strict scrutiny due to selective enforcement." Pet. 32. But the Ninth Circuit did not disagree with the Third Circuit or any other circuit about the relevance of selective enforcement; it simply found "no evidence of selective enforcement" by the Board. Pet. App. 40a.

The rules here were never *enforced* against Petitioners at all, much less *selectively* enforced. As explained above, the evidence showed that no

religious objector has ever been disciplined for violating the Delivery Rule, the Pharmacist Responsibility Rule, or the Stocking Rule. The threshold element of a selective enforcement claim—that the plaintiff was treated differently than a similarly situated person—cannot be established where there has been no enforcement against the plaintiff.

Petitioners point to the complaints filed by consumers against Ralph's Pharmacy as evidence of "enforcement" by the Board, Pet. 32-34, but they fail to mention that the Board quickly dismissed virtually all of those complaints. Pet. App. 15a; Resp. App. 74a, 87a-88a; ER 1739-43. On the remaining complaints, the Board took no action because of the district court's injunction and subsequent stay, ER 639-40, 1739-43, but it promptly dismissed even those complaints following the Ninth Circuit's ruling. Petitioners thus lack even the most basic element of a selective enforcement claim.

Even if the receipt and subsequent closure of a citizen complaint without any disciplinary action against Ralph's Pharmacy could qualify as "enforcement," there is no evidence the Board ever received a complaint about any similarly situated pharmacy. The court of appeals explained that three complaints filed against other pharmacies are not comparable because those pharmacies simply experienced a temporary shortage of a drug they normally stock. Pet. App. 39a n.11. "By contrast, [Stormans] refuse[s] to stock Plan B and *ella* at all times." *Id.*

Petitioners also contend that the Board's reliance on consumer complaints was a pretext to allow discrimination. Pet. 34-35. But the Ninth Circuit explicitly rejected that argument, noting that the Board "has utilized the complaint-driven system to enforce the Stocking Rule since its enactment in 1967, decades before" the issues in this case arose. Pet. App. 40a; *see also* Wash. Rev. Code §§ 18.130.050, .080 (providing for enforcement in response to complaints). The court also noted this Court's holding that using a complaint-driven system is not inherently suspect. Pet. App. 39a-40a (citing *Wayte v. United States*, 470 U.S. 598, 607-08 (1985)).

The district court postulated a second selective enforcement theory never advanced by Petitioners: that the Board was targeting Petitioners for enforcement but exempting Catholic-owned pharmacies. Although the Board had never received a complaint against a Catholic-owned pharmacy for violating the Delivery Rule, Resp. App. 74a-75a, and although several witnesses testified that a Catholic-owned pharmacy would be treated just like other pharmacies if it were the subject of a complaint, *see*, *e.g.*, *id.* 80a, ER 1109-10, SER 391, the district court nevertheless insisted that if a complaint were filed against a Catholic pharmacy, the Board would not enforce its rules. Pet. App. 27a; *see also* ER 1034-38, 1042-43, 1073, 1106-12, 1136-39, 1149-53, 1243-48. The district court was so fixed in its belief that Catholic pharmacies received special treatment that it used this supposed special treatment as its justification for concluding that the rules had no rational basis. Pet. App. 109a.

The Ninth Circuit properly rejected this theory of selective enforcement as well. The record shows no evidence that the Board has ever received a complaint against any Catholic-affiliated pharmacy. Pet. App. 38a. It contains nothing showing that the Board made any religious distinctions in its complaint-driven enforcement of the rules or that it responded differently to complaints about Catholic-affiliated pharmacies than it did to complaints about Ralph's. *Id.*

In short, like this Court and every other circuit, the Ninth Circuit recognized that evidence of selective enforcement can show that a law is not generally applicable. But the Ninth Circuit found "no evidence of selective enforcement" here. *Id.* 40a. There is no conflict.

4. The Ninth Circuit did not refuse to consider legislative history, it simply found that the legislative history of the challenged rules showed no discriminatory intent

Petitioners claim that the Ninth Circuit split from the Seventh and Eighth Circuits by refusing to consider evidence of "a law's historical background to show a lack of neutrality." Pet. 35. That is false.

The Ninth Circuit acknowledged that *Lukumi* left an open question as to whether courts should consider legislative history, but it held that the answer to that question made no difference here. "Even if we should analyze that history, it does not reveal improper intent." Pet. App. 27a. "To the extent that the record reveals anything about the [Board]'s motivation in adopting the rules, it shows that the

[Board] approached the problem from the point of view of ensuring patients' timely access to prescription medications." *Id.* Thus, "the district court clearly erred in finding discriminatory intent." *Id.* 28a.

Nothing in the Ninth Circuit's opinion creates a disagreement among the circuits about the relevance of legislative history in analyzing neutrality. Petitioners' real disagreement is with the Ninth Circuit's analysis of the facts, not its interpretation of the law.

C. This Case Is a Poor Vehicle For Resolving Questions About the Free Exercise Clause

Petitioners claim that this case is "a clean vehicle to resolve critical questions of free exercise law" that they say are presented, specifically as to the relevance of (1) exemptions, (2) selective enforcement, and (3) legislative history. Pet. 38. In reality, this case presents none of those issues cleanly.

As to exemptions, the fundamental problem with this case is that the Court would have to resolve an underlying factual dispute about what exemptions the rules actually contain before it could assess whether they are proper. Both the district court and the Ninth Circuit found that the Rules' written exemptions are constitutional. Pet. App. 30a-31a, 80a, 306a-07a, 315a-17a. Petitioners never contest those holdings, instead implicitly asking this Court to decide whether the rules contain improper "unwritten exemptions," as the district court found. But that is essentially a factual question

that this Court should be loath to tackle, especially because, as noted above, the district court adopted Petitioners' proposed findings of fact verbatim and repeatedly disregarded the Board's official statements in favor of speculative and contradictory testimony.

As to selective enforcement, it is hard to imagine a worse vehicle to address the proper standard for a selective enforcement claim than a case where the rules at issue have never been enforced. But that is what the Court would face here.

As to the legislative history, again the Court would not be resolving a legal dispute about whether to consider such history, but rather deciding as a factual matter what the legislative history shows. The Ninth Circuit carefully analyzed that history, finding that "it does not reveal improper intent" and that "the district court clearly erred in finding discriminatory intent." Pet. App. 27a, 28a. Petitioners ask this Court to ignore that holding and look to the record, but the record contradicts what Petitioners claim. For example, Petitioners focus much of their legislative history argument on alleged interference by the Governor in the Rules' development, Pet. 8-11, 36-37, but the district court explicitly held that the Governor's involvement was "well within" her role under State law, was "part of the normal political process, and does not taint the rulemaking processes undertaken by the Board." Pet. App. 138a.

In addition to these problems with assessing Petitioners' specific questions presented, this case

also presents broader vehicle problems. Three are most noteworthy.

First, many of Petitioners' arguments—such as their "individualized exemptions" theory and their selective enforcement claim—rely on alleged flaws or vagueness in the Stocking Rule. *See, e.g.*, Pet. 30-31. But Petitioners never challenged the Stocking Rule in any of their three amended complaints. They thus ask this Court to review and invalidate a State regulation they never properly challenged.

Second, Petitioners' primary objection to these rules at trial was that they might be required to dispense the emergency contraceptive Plan B. Their objections to dispensing Plan B were the focus of the trial testimony and the district court's holding. But as Petitioners acknowledge, Pet. 7 n.2, the most common form of Plan B is now available over the counter, and thus is no longer covered by the rules at issue, Wash. Admin. Code § 246-869-010 (covering "lawfully prescribed drugs" and drugs approved by the FDA for "restricted distribution by pharmacies"). While the case may not technically be moot, there is no evidence in the record suggesting how often—if ever—any Petitioner might be asked to dispense a different drug to which he or she might object. Thus, the Court cannot be sure that the rules will have any meaningful impact on Petitioners.

Third, the Board included the Rules at issue here in a notice of rulemaking to address ongoing changes in the practice of pharmacy. Wash. St. Reg. 14-22-048 (Oct. 30, 2014). Though the process is in the early stages, it is possible that the Board could modify the Rules in a way that would impact

Petitioners' claim. For this reason, too, the Court cannot be sure that the Rules will have any meaningful impact on Petitioners.

In short, nothing about this case makes it a good vehicle to address the proper interpretation of the Free Exercise Clause.

CONCLUSION

Petitioners' arguments misrepresent the facts and the law. The Court should deny review.

RESPECTFULLY SUBMITTED.

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APPENDIX

Appendix

ER 1726-32 (Trial Exhibit 20) Minutes of Board of Pharmacy Meeting, August 10, 2005 (excerpt at ER 1730-31).

Pharmacist Responsibility to Fill Prescriptions

Steve Saxe informed the Board that the office has received telephone calls from both the public and profession regarding pharmacists ability to refuse to dispense emergency contraceptives for reasons of conscience. Currently there are no rules requiring a pharmacist to fill prescriptions if they choose to do so for reasons that do not violate the laws prohibiting discrimination. When we get calls from pharmacists who do not wish to dispense for reasons of conscience, Board staff suggest the patient be directed to another colleague or pharmacy. **ACTION:** Ms. Sellers requested staff research the possibility of adding the 1-800NOT2LATE number to the Board and/or Department's website so the consumer could obtain the necessary information in a timely manner. **ACTION:** Susan Boyer moved to continue, with current message crafted by Steven Saxe and refine based on the Board's discussion today. **MOTION CARRIED.**

SER 941 (Trial Exhibit 41), Letter to Board of Pharmacy from Governor Christine Gregoire, January 18, 2006.

Dr. Asaad Awan, Chair
Board of Pharmacy
Box 359885
Seattle, WA 98104

Dear Dr. Awan:

It has come to my attention that the Washington State Board of Pharmacy (Board) is evaluating state policy regarding pharmacists who refuse to sell lawfully prescribed products and services. No one should be denied appropriate prescription drugs based on the personal, religious, or moral objection of individual pharmacists. I urge the Board to continue to honor our state's long history of protecting the health of Washington residents, regardless of such personal objections.

This issue goes far beyond women's access to contraception, but appeals to the right of all patients to have their prescription filled without judgment or discrimination. Pharmacists have an important and clear job in our health care system to dispense drugs deemed appropriate by doctors and their patients. It is, in my view, inappropriate for pharmacies or pharmacists to interfere with this established patient-doctor relationship by granting or denying prescriptions based on their personal objections.

Many pharmacies now have policies that accommodate the medical needs of customers and the individual rights of conscience of their employees. I support policies that recognize that pharmacies bear

the ultimate responsibility for filling prescriptions and, if necessary; have staff readily available to serve the patient, if another pharmacist has personal objections.

I appreciate the role of the Washington State Board of Pharmacy in deliberating on this issue and urge that the rights of patients remains central in its review.

Sincerely,

Christine O. Gregoire

Governor

cc: Members of the Board of Pharmacy (BOP)
Steven Saxe, Executive Director, BOP
Mary Selecky, Secretary, Department of Health
Christina Hulet, Executive Health Policy Advisor

ER 932-45 (Trial Exhibit 37) Minutes of Board of Pharmacy Meeting, January 26, 2006 (excerpt at ER 936-38).

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 Rarnseth; 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 [a] 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 than 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. The 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 identif[y] 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 [a] 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 . . . **MOTION:** Rebecca Hille moved that the Board begin the rule making process. **MOTION CARRIED.**

Steve Saxe reminded the audience that the CR 101 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.

ER 946-54 (Trial Exhibit 45) Minutes of Board of Pharmacy Meeting, March 10, 2006 (excerpt at ER 951-53).

Northwest Women's Law Center & Planned Parenthood

Steven Saxe reminded the Board that representatives from Northwest Women's Law Center and Planned Parenthood requested in January to present to the Board their views following the Washington State Pharmacy Association's presentation on a Pharmacist's "Conscience Clause." Mr. Saxe went on to say that this is just one step in the rules process. The rule making process initiated by the Board in January will consist of stakeholder meetings held in various locations throughout the state and are scheduled to begin this spring. The Board will then determine whether rules are needed. If rules are necessary, draft language will be written and additional public comment received. This is a very open process.

Washington has been a leader – first in the country where pharmacists with a collaborative agreement can prescribe and dispense emergency contraception. Washington has the longest running pharmacist emergency contraception training program. Training is available for pharmacist[s] through the American Pharmacy Association and the Washington Pharmacy Association (WSPA) and included as part of the curriculum for pharmacy students.

Steven Saxe reiterated that the Board staff advises pharmacists to be proactive by working with their employers and colleagues to ensure patients receive timely and convenient patient care.

The following is a summary of the presentation made to the Board by Nancy Sapiro, representing the NW Women's Law Center; Roberta Riley and Amy Luftig representing Planned Parenthood Presentation.

The presenters provided a brief overview of the legal landscape in Washington and why they feel that pharmacist[s] have a greater responsibility to their patients under Washington law than the position reported in the WSPA's position presented at the January meeting. Ms. Sapiro stated that while they think that WSPA's proposal is viable in some respects they feel it is an inadequate response to the issue of pharmacist's refusals in this state.

They acknowledged that the vast majority of pharmacists in this state take their ethical and legal responsibility very seriously and that they are committed to protect the patients' safety and timely access to needed medications. They went on to say, pharmacists in this state are refusing to fill prescriptions and particularly refusing to fill prescriptions for birth control. In so doing they are creating a significant new threat to women's reproductive healthcare. The impact of these refusals is not simply minor inconveniences[;] they pose significant barriers to necessary health care for women. These negative impacts are greatest for those with limited access to alternative pharmacies.

Reasons to fill legally prescribed medications:

- Professional standards of conduct[.]
- National Pharmacist Codes of Ethics – requires pharmacist to avoid actions that

compromise the dedication to the best interest of their patients.

- Washington laws
  - Duty to fill – pharmacy practice[.]
  - RCW 9.02.100 Reproductive Privacy Act – that an individual had a fundamental right to choose birth control and that the state can not discriminate in a way that inhibits an individual's ability to exercise that right.
  - 1978 US Supreme Court noted that laws can not interfere with religious belief/opinions, the constitution protects these individual beliefs; however, laws may regulate our actions.

Reasons not to fill legally prescribed medications:

- Professional judgment
  - Forgery
  - Contraindications

Amy Luftig highlighted trends in the nation[] and gave four examples from Washington State of pharmacist[s] refusing to fill prescriptions for antibiotics, syringes, prenatal vitamins and ECP citing religious or implying other biases. Ms. Luftig stated that these examples pose a direct health risk to the client and are not limited to emergency contraception.

National Trends

- Other states and pharmacy boards summarily reject pharmacists' right to refuse in favor of patient protection[.]
- Wyoming and Nevada Boards of Pharmacy adopted a proposal that pharmacists can refuse only on the basis of unlawful prescription or contraindications.
- North Carolina Board released a policy stating it is unacceptable for pharmacist[s] to impose their moral or ethical beliefs on their patients the[y] serve.
- Governor Jim Doyle of Wisconsin stated regarding a similar bill proposal – it is hard enough for many people to get the healthcare they need.

They acknowledged that the WSPA's position paper recognizes the foremost responsibility of a pharmacist is to provide pharmaceutical care to their patients. They strongly disagreed that in those instances when a pharmacist's personal beliefs conflict[] with their professional responsibilities the pharmacist[] has the right to refuse to fill. A referral is not a minor inconvenience for many women who live in towns with only one pharmacy or have to go to another town or across town. This is especially compelling when you think of emergency contraception where the efficacy of the drug is decreasing.

Ms. Sapiro, Ms. Luftig and Ms. Riley urged the Board to follow their colleagues in other states and reach the same conclusion. They asked the Board to

move forward with a policy that will protect the health of all Washington residents to ensure that no one is denied safe and legal prescriptions in this state because of an individual's personal beliefs. Without imposing an undo burden on the employer, the employer should attempt to accommodate the employee. Pharmacies can accommodat[e] the religious refusal of [a] pharmacist while protecting a patient's rights if and only if the patient's care is not disrupted or delayed in any way.

Comments from the Audience

There were approximately eighty persons in attendance. Twenty-one individuals provided their input on the issue and their perspective of the presentation by the NW Women's Law Center and Planned Parenthood. Eighteen supported a "conscientious clause", three opposed. Speakers included representation from healthcare practitioners, lawyers, political affiliations, pro-choice activist groups, religious affiliations, pharmacy students and concerned citizens.

* * *

ER 955-64 (Trial Exhibit 258) Minutes of Board of Pharmacy Meeting, April 12, 2007 (excerpt at ER 956-57).

RULES HEARING DELIBERATIONS

The Board continued its deliberation regarding the proposed rules for Pharmacist's Professional Responsibilities WAC 246-863-095 and Pharmacies' Responsibilities[] WAC 246-869-010. The Board did not take public comments or answer questions from the audience during this agenda item.

Lisa Salmi provided background on the Board's activity to date regarding the proposed rules. She stated that the Board heard testimony from 91 stakeholders and the public at the rules hearing on March 29, 2007. Of the testimony, 46 supported the rules as written and 45 opposed. The intent of the proposed rules is to promote patient safety and access to health care by emphasizing pharmacist and pharmacies responsibilities. On March 30, the Board met and discussed the testimony and supporting documents. The Board directed staff to make changes to the Small Business Economic Impact Statement (SBEIS) and Significant Analysis (SA). Rebecca Hille read the vision and mission statements of the Board. The Board confirmed receipt and review of the revised SBEIS and SA. The Board confirmed receipt and review of all materials from the rules hearings. Board members Gary Harris and Vandana Slatter, who were not present during the hearing or deliberation on March 30, confirmed that they have reviewed all materials and have no questions at this time.

Tim Fuller summarized the changes made to the SBEIS, a[s] directed by the Board. Mr. Fuller's presentation was followed by Andy Fernando's summary of changes to the Significant Analysis. Changes requested by the Board consisted of clarifying the explanation of potential costs and benefits in both documents.

Gary Harris confirmed, as stated in the SA, that "the rules are needed to minimize barriers to health care and to reduce risks for a patient's health when there may be an emergent need for a prescribed drug or device or a timely preventative use is essential to drug efficacy."

Madame Chair Hille asked if there is a consensus among the Board that the changes and information contained in .the SBEIS and SA meet the direction of the Board. All agreed.

Following the approval of the SBEIS and the SA the Board was asked to discuss the proposed rule language.

Dan Connolly expressed the challenges and thoughtful work that went into crafting these rules, and acknowledges that it is difficult to craft rules that would satisfy all parties. He went on to state that the Board represents the people of the state of Washington and is charged with protecting their health and safety and ensure access to health care. The proposed rules will meet this requirement. George Roe concurred.

Vandana Slatter stated that this is a very complex issue and wished to acknowledge the compassion and

commitment of the citizens of Washington in their active participation/interest in their health care.

Susan Teil Boyer acknowledges that it has been a difficult process, but also felt the proposed rules were well crafted and protecting patients is what the Board does. Ms. Teil-Boyer stated that the first line of WAC 246-869-095 is the key statement "a pharmacist's primary responsibility is to ensure patients receive safe and appropriate medication therapy." She stated that pharmacists will need to adjust to this rule.

Gary Harris stated that the Board members have read a tremendous amount of information and stakeholder input over the past sixteen months related to these rules. Mr. Harris declared that the Board has made a good effort to draft the best rule it can.

Mr. Harris also stated that it is not the intent of the Board or the rule to expect every pharmacy to stock every drug, in every strength, for every medical condition. There are many options available in this new rule that would allow a pharmacist to provide service to patients.

Rosemarie Duffy also acknowledged how challenging this process was and commended the Board for its professionalism and staff for their work.

ACTION: Gary Harris moved that the Board accept WAC 246-863-095 Pharmacist's Professional Responsibilities as it is currently amended. George Roe second. **MOTION CARRIED 6-0.**

ACTION: George Roe moved that the Board accept WAC 246-869-010 Pharmacies Responsibilities. Vandana Slatter second. **MOTION CARRIED 6-0.**

The adopted rules will become effective 31 days after filing with the Code Reviser's office. The anticipated effective date is mid-June and all interested parties will be notified.

ER 982-94 (Trial Exhibit A-12) Final Significant Analysis for Rule Concerning Pharmacists' Professional Responsibilities, WAC 246-863-095 & Pharmacies' Responsibilities (April 12, 2007) (excerpts).

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 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.

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.

* * *

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' 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.

* * *

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)].

RCW 18.130.050 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 (l)(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. . . ."

* * *

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. . . .

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. . . .

* * *

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. Seventy percent of Medicaid-paid births to women age 20 to 25 are unintended pregnancies.[5]

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.

* * *

5. Healthcare providers stress the importance of taking medication as prescribed. For 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.[7] 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.

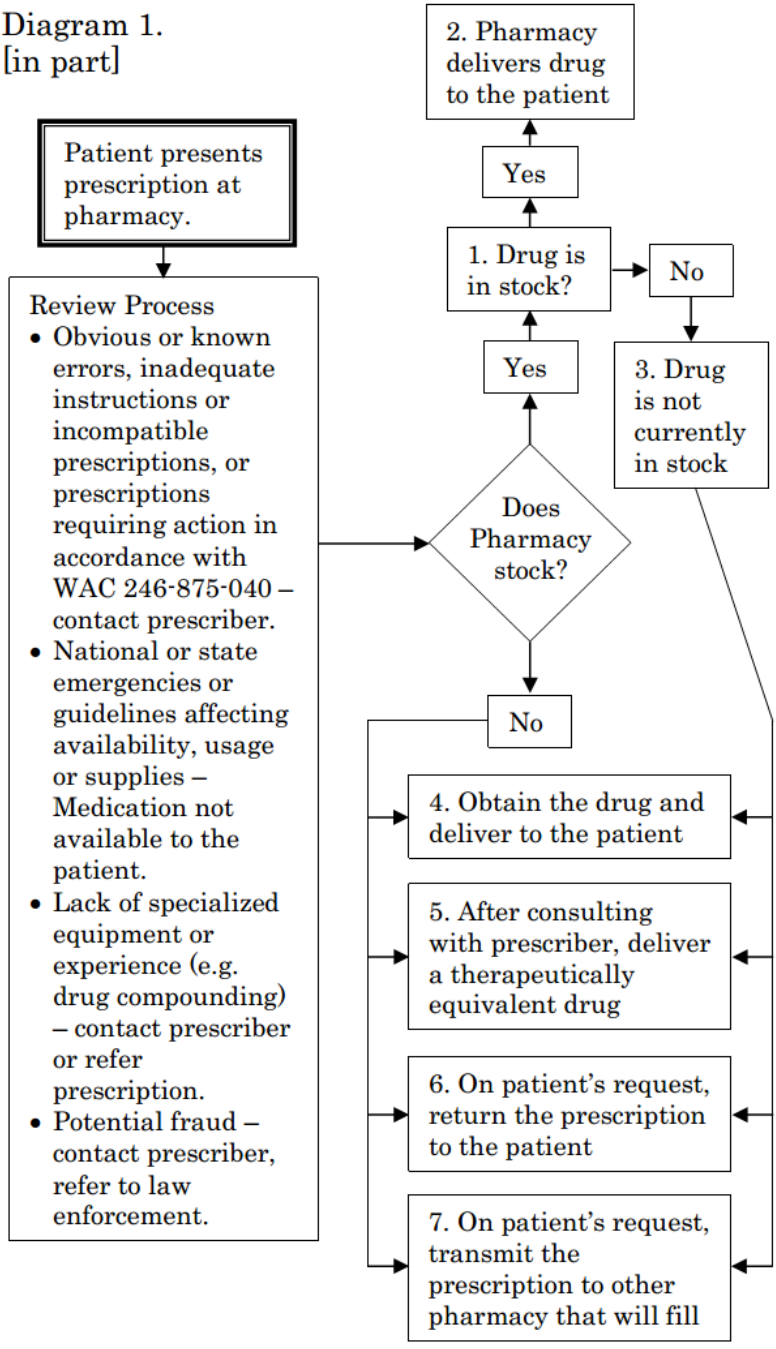
HIV patients who develop viral resistance must use what is called "salvage therapy." The medications used in salvage therapy have far greater side effects and one of the drugs must be given by injection at a cost of $1,500 to $1,800 each month. During this time the patient has increased ability to transmit 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.

Diagram 1.
[in part]



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 1, 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 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 1. 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.

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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 July 2001 – June 2006.*

[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 Pregnancy and Contraceptive Use.*

[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.*

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

ER 730-38 (Trial Exhibit A-12) Concise Explanatory Statement for WAC 246-863-095 Pharmacist's Professional Responsibilities and WAC 246-869-010 Pharmacies' Responsibilities (June 25, 2007) (excerpts).

Comment: The Significant Analysis states that if a pharmacy has an objecting pharmacist and the pharmacy only employs one pharmacist per shift the pharmacy has no choice but to hire additional staff. This is not the intent or scope of the rule.

Response: The rules do not tell pharmacies what steps they must take to comply with the rule. Businesses are given the discretion to make their own business decisions on how to comply. Other methods to comply may not necessarily be as costly.

The Board noted that there are other ways to deliver the medication to the patient in a timely manner – some are described in WAC 246-869-010(3). In the survey, only 13% of the pharmacies stated they would need to hire additional staff.

* * *

Comment: The SA indicates the pharmacy will not face discipline if it refers to another pharmacy. The rule as drafted imposes a duty upon pharmacies to deliver.

Response: If the pharmacy does not have the medications in stock, the patient may request the pharmacy to transmit the prescription information to another pharmacy that will fill the prescription. Under WAC 246-869-150(1), pharmacies are required to maintain at al1 times a representative assortment of drugs in order to meet the

pharmaceutical needs of its patients. Pharmacies would not be considered to be in compliance if their policy/procedure and/or practice is to refer patients to another pharmacy when dealing with prescriptions for which the pharmacy/pharmacist has a personal objection.

Comment: The statement "costs for medications are passed on to the consumer and pharmacies have an array of options to manage medication inventories" overlooks dispensing only part of the containers of unusually expensive drugs, no reimbursement for partial containers, and pharmacies only receive a discounted price for returning soon to expire medications.

Response: It is the current practice for pharmacies to work with patients and healthcare providers to provide patient care. Sometimes pharmacies work together, especially if part of a chain, to deliver these unusually expensive drugs in a more cost-effective manner, while ensuring that patients have access to necessary care. Pharmacies should be proactive. Pharmacies have a number of options to avoid unused product cost.

* * *

Comment:

- Need a clause that would protect the pharmacist who has conscientious objection from retaliation by the Board.
- Add a right to refuse clause with guidelines to ensure access.

Response: These rules allow an employer to accommodate an individual pharmacist's personal

beliefs, so long as the business assures timely access to prescribed medications and devices for patients. The Board recommended no changes to the rules based on these comments.

* * *

Comment:

- The rules will result in closing pharmacies or pharmacist that will not be employed or forced to quit because of their religious beliefs.
- Look for solutions that address access without violating the principles of an individual's conscience.
- Pharmacists must be given a choice: 1) have their license taken away for not serving the public or 2) prominently post a sign informing the public that (s)he intends to withhold services based on personal theocratic interpretation.

Response: The rules give pharmacies several options for complying if a pharmacist will not fill a prescription. The rules do not imply nor require that pharmacists lose his or her job because of religious beliefs. These rules allow an employer to accommodate an individual pharmacist's beliefs, while assuring that patients timely receive medications or devices prescribed.

Comment: Constitutional right to freedom of religion[.]

Response: The rules do not affect a person's freedom of religion. The rules allow an employer to accommodate an individual pharmacist's beliefs, so

long as the business assures timely access to prescribed medications and devices for patients.

Comment: Access to contraceptives is not a moral or religious issue but a health care issue. Access is a real issue.

Response: The Board finds that the rules are broad and speaks to the access of a variety of drugs and devices.

Comment: Add language allowing for business decisions – example a pharmacy's decision not to provide a product or service is often simply a business decision – staff time best spent.

Response: *This* concern is addressed in the rule. WAC 246-869-010 (l)(c). Consistent with the rules' purpose of access to necessary health care, pharmacies must timely provide prescribed medications and devices, except under circumstances in the rules.

Comment: The pharmacy has an obligation to find another pharmacy that will fill the prescription in a timely manner.

Response: The Board agreed with this statement; however, this is at the patient's request.

Comment: The proposed rule is a win/win situation – It allows a pharmacy to accommodate a pharmacist's religion.

Response: Agreed.

* * *

The rules are written to require pharmacies to deliver appropriate medication therapy; however,

many opponents to the rules have concerns that they do not allow an individual pharmacist to opt out of dispensing medications for which they have a personal objection. The rules do not override the individual pharmacists' moral or religious beliefs; however the rules do impose a duty on the business to ensure timely access to lawful prescribed medications and devices. The rules do not prohibit an employer from accommodating a pharmacist's personal objections.

Additionally, concerns were expressed that the rules restrict the pharmacy's business practice from making business decisions; however, the rules require a specific outcome without directing the means by which the business is to accomplish that outcome, leaving the means to the discretion of the business.

SER 979 (Trial Exhibit 433) Board of Pharmacy: Pharmacists' and Pharmacies' Professional Responsibilities – Questions and Answers (undated).

What has fundamentally changed?

These new rules spell out what pharmacists and pharmacies must do to take care of the patient's medication needs. If they fail to do so, the Board now has the authority to take disciplinary action.

If I walk into a pharmacy with a prescription, will I walk out with the drugs?

You or any patient should expect: to get your medications needs met at the pharmacy. If the pharmacy is out of stock, you can ask the pharmacist to refer you to another pharmacy that has the medication in stock. Pharmacies are expected to stock all medications needed by their patients.

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.

What is the stocking rule?

The stocking rule states that a pharmacy must maintain a representative assortment of drugs to meet the needs of patients. In practice, that means they are expected to stock all medications to meet the needs of their patients. If they don't have them

when customers request them, they must order and stock them.

What should I do if a pharmacist won't fill my prescription?

You can ask the pharmacist to refer you to a pharmacy that will fill your prescription and you can expect that they will do so. You can also make a complaint with the Department of Health.

What is the penalty for a pharmacy that does not follow the new rules?

The Board looks at each complaint on an individual basis. The Board has the ability to suspend or revoke the license of the pharmacy.

SER 1247-49 (Trial Exhibit 436) Board of Pharmacy: guidance provided to pharmacists and Pharmacy owners (July 2007) (excerpts).

The Board of Pharmacy recently adopted rules concerning the professional responsibilities of a pharmacist and a pharmacy. We are sending you this document 1o help you understand these important rules and assist you in complying with the rules. These rules will be in effect on July 26, 2007.

Purpose: The Board adopted these rules to promote patient safety by assuring that patients have access to lawful, appropriate medications without delay. The rules clearly state the responsibilities of pharmacists and pharmacies in dispensing and delivering medications. The rules also identify options the pharmacist and pharmacy have when a drug is not in stock.

* * *

Question: Do these rules require pharmacists to dispense all prescriptions regardless of the pharmacist's moral or ethical objection?

Answer: A pharmacist's primary responsibility under the rule is to ensure patients receive safe and appropriate medication therapy. The rule does not mandate that individual pharmacists dispense all prescriptions regardless of the pharmacist's personal objection.

Question: Do these rules require pharmacies to deliver all prescriptions?

Answer: The pharmacies' responsibilities rule states it is the responsibility of the pharmacy to deliver all lawful prescriptions in a timely manner. It is the

pharmacy's responsibility to assure that patients have access to lawfully prescribed and clinically safe drugs. The pharmacy business must take steps to deliver the drug or device to the patient.

Businesses are given the discretion to make their own decisions on how they will comply with the rule as long as the pharmacy is in compliance with the rules and state and federal law.

Question: If a pharmacy does not have a pharmacist on staff that is willing to dispense a prescription, can the pharmacy refer the patient to another pharmacy that will fill the prescription?

Answer: If the patient requests that the prescription be transferred to another pharmacy, then the prescription may be transferred. This must be at the patient's request. A pharmacy cannot avoid filling prescriptions by referring to another pharmacy. This rule expects pharmacies to meet the pharmaceutical needs of their patients.

Question: Does this rule require that my pharmacy stock Plan B? I am a compounding pharmacy and do not carry any standard commercial drugs. I have never been presented with a prescription for emergency contraception.

Answer: These rules do not discuss stocking requirements. The rule does provide options for a pharmacy that is temporarily out of stock or has been presented with a prescription that is not customarily needed by its patients. WAC 246-869-150, referenced in the rule, describes a pharmacy's responsibility to maintain an adequate stock of drugs to meet the needs of their patients. The Board does

not expect pharmacies to stock all medications on the market. However, as required by WAC 246-869-150, a pharmacy is expected to meet the pharmaceutical needs of their patients.

* * *

Question: Can I refuse service to a customer who is difficult to deal with?

Answer: The Board expects that pharmacists and pharmacies provide good patient care. The pharmacist may want to talk with the patient about transferring the patient's prescription records to another pharmacy that can meet the needs of the patient. This must be done with the patient's consent.

ER 1032-33 Testimony of Steven Saxe, former Executive Director, Board of Pharmacy.

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.

ER 1046, 1050-54 Testimony of Timothy Fuller, former Pharmacy Consultant, Board of Pharmacy.

Q. Is the significant legislative analysis the official statement of the department as to how the rules work?

A. Yes.

Q. And similarly there's a small business economic impact statement that has to be done; is that correct?

A. That's correct.

Q. And that's the evaluation – economic evaluation of the department as to potential economic impact of the rule; is that correct?

A. That's correct.

Q. So as you are examined in these cases, Mr. Fuller, if your opinion is different than what the official documents are published by the state, isn't it the official documents that would control how the rules actually operate?

A. Yes.

* * *

Q. You recall from the significant legislative analysis that the Board of Pharmacy had actually concluded that a pharmacy may very well be required to stock an expensive drug even if they couldn't recoup their cost; is that correct?

A. That's correct.

Q. And that is the official interpretation of the Board's rules coming from that analysis; is that correct?

A. That's correct.

Q. You also mentioned a question about a situation possibly with a pharmacy being asked to do simple compounding and not wanting to do it because it was too burdensome and sending the patient away to somewhere else to have that done; do you recall that?

A. Yes.

Q. Is it possible that that is in fact happening in the community?

A. Yes.

Q. Has the Board, to your knowledge, ever received a complaint from a patient that their pharmacy was refusing to deliver a simple compound?

A. No.

* * *

Q. Mr. O'Ban asked you about access; do you remember that?

A. Yes.

Q. And he read from your deposition in 2008 and suggested that there wasn't an access problem in Washington, correct?

A. Yes.

Q. You were also deposed two months ago in 2011, correct?

A. Yes.

Q. And in fact it's your testimony that there is an access problem to pharmacy services in many locations in Washington, correct?

A. Correct.

Q. In fact, you are aware of locations in Washington that are rural and aren't near any pharmacies?

A. That's correct.

Q. There's also locations where there's great distances between pharmacies, correct?

A. That's correct.

Q. And you mentioned this earlier, but there's locations where the distance between pharmacies could be 70 or 80 miles?

A. That's correct.

Q. And in those locations, if a patient walks into a pharmacy and is refused, and they need to get the medicine that day, they could be looking at a 160-mile round-trip drive to get the medicine; is that correct?

A. That's correct.

Q. So at least three hours, roughly?

A. Yes.

Q. And that assumes they have a vehicle?

A. Yes.

Q. So there are rural locations where access to timely medicine, when it's needed, creates an issue, correct?

A. That's correct.

Q. You were also asked a number of questions about – a number of hypotheticals and questions about how the rules would be interpreted?

A. Correct.

Q. The Board responds to complaints, right?

A. That's correct.

Q. And the Board issues officials position statements of what rules mean, correct?

A. Yes.

* * *

Q. And it's the Board's authority, I guess, to pass the rules and to interpret the rules and to enforce discipline, right?

A. That's correct.

Q. If there was any question about the interpretation of the rules, or if any of these hypotheticals that you've been asked came up in real life, if it was a tough question, that would go to the Board, wouldn't it?

A. Yes.

Q. And the Board could collectively consider the issue?

A. Yes.

Q. And the Board could get legal counsel?

A. Absolutely.

Q. And the Board would make a reasoned decision, in your view?

A. Yes.

Q. I guess with those caveats, it's your understanding that the rules treated all drugs the same, right?

A. Yes.

Q. And it's your understanding that the rules treat all referrals, whether it's personal, moral, or religious, that seems to be the phrase we use, but for whatever reason the referral occurs, the rules treat all those the same, right?

A. Yes.

Q. Is it your understanding that the rules place the duty to dispense on the pharmacy?

A. Correct.

Q. And that's both the text of the rules make that allocation and the operation of the rules make that allocation, right?

A. Yes.

Q. It's the pharmacy's duty?

A. Yes.

Q. And the rules specifically say – or the guidance of the rules specifically state that a pharmacist can't be disciplined if they exercise a personal objection, correct?

A. Yes.

Q. It's the pharmacy's obligation to see that the patient gets the medicine?

A. Yes.

Q. And that's consistent with the Board's vision and mission statement, right?

A. Yes.

Q. The Board's vision and mission statement both specifically reference patient safety and patient access?

A. That's correct.

Q. They put the patient needs first?

A. Yes.

Q. When the rules were adopted, you understood their purpose to be so that patients had access to timely important medication, right?

A. That's correct.

Q. And it is your understanding that the rules that were in fact passed, achieved these goals, right?

A. Yes.

Q. And they ensure that patients receive access to the medicine they need, right?

A. Yes.

* * *

ER 1081-84 Testimony of Susan Teil-Boyer, former member, Board of Pharmacy.

Q. . . . I want to turn your attention back to the 2004-2005 timeframe and ask you, what sort of information was coming to the attention of the Board at that prior time that caused this to be something that the Board wanted to look into?

A. There were several instances that were reported to the Board, both in the state and externally out in other states, in the media and to the Board at Board meetings about patients being denied and refused.

Q. So when these reports started to come in, are you aware, did the Board and Board staff take a look at Washington law to see whether or not there's guidance to the profession on whether or not this is permissible or impermissible for the pharmacy to simply turn the patient away even though the medication is on the shelf?

A. Yes, the staff looked at that, yes.

Q. At that time, was there clarity in Washington law about whether or not this is going to be an acceptable standard of practice or not?

A. No, there was no clarity.

* * *

Q. Is it your understanding that part of the regulatory charge of the Board for the citizens of this state is to set standards of practice in the rules for pharmacies?

A. Absolutely.

Q. When the Board endeavored to enact the two rules that are at issue in this case, part of the Board's mission is to protect public health?

A. Yes, definitely.

Q. Why didn't we just wait, Ms. Boyer, until there was some sort of a raging crisis with access being denied before we act? Wouldn't that be a better situation?

A. No.

Q. Why not?

A. The Board wanted to deal with this; they were very concerned about patients being denied and refused care.

* * *

A. The Board takes its mission very seriously. I have been very impressed with the professionalism of the Board and its concern for patient care and safety, and it's reflected here in the mission and it's reflected in these rules, and that was the intent of the Board in drafting these rules.

Q. So we have heard I don't know how many examples now, Ms. Boyer, of situations where a particular hypothetical may very well be a hardship for a pharmacy economically, logistically, whatever, all sorts of difficulties that are real and practical problems for the pharmacy. Yet, on the other hand, we have the duty of the Board to protect the public health.

So can you talk to the Court a little bit about the rules culture, the enforcement culture of the Board and how does the Board approach weighing the

tensions between delivering health care for our citizens and the economic realities for running a pharmacy?

A. Again, the Board takes very seriously its mission to protect public health and safety, and it's not here to protect business interests or any other economic interests. It's here to make sure patients are safe, they are getting their health care needs met, and that's simply the Board's mission.

ER 1123-33 Testimony of Gary Harris, former member, Board of Pharmacy.

Q. And then I have highlighted down there a little bit more about what was the content of the presentation. They went on to say that pharmacists in this state are refusing to fill prescriptions and particularly refusing to fill prescriptions for birth control.

Had you, in your work on the Board, heard that, that there were, in fact, some pharmacists in the state that were refusing to fill prescriptions?

A. I had heard that. I had not documented that. I had not personally seen it.

Q. Was that an issue that at least was of interest to the Board?

A. Oh, certainly.

Q. It goes on to say, "In so doing they are creating a significant new threat to women's reproductive healthcare. The impact of these refusals is not simply minor inconveniences, they pose significant barriers to necessary health care for women. These negative impacts are greatest for those with limited access to alternative pharmacies."

If, in fact, there were refusals going on, would you agree there was a health care issue there that needed some attention?

A. Certainly. And as came out in later testimony, areas where there is only one pharmacy open after certain hours of the day within a 20-mile radius, certainly there were issues.

Q. I take it that some of those issues related to Plan B?

A. By and large, the greatest part of the testimony that we had was centered around Plan B.

Q. Now, Plan B, would you agree, is a time-sensitive medication?

A. Yes.

Q. Could you elaborate on that a little bit to your understanding, from a pharmaceutical perspective?

A. Well, I think 72 hours is the timeframe that is said you should take the drug within 72 hours.

Q. Right.

A. Certainly as time passes, the effectiveness may be less for the particular drug.

Q. So although from your perspective – and I take it the Board's perspective – it wasn't just about Plan B. Plan B was at least a time-sensitive medication that would fit in the category where filling a prescription promptly would be important?

A. Yeah, but as we said all along, all medications, all patients, all situations.

Q. Was that what the Board had in mind?

A. Certainly what I had in mind from day one.

Q. Absolutely. So then – so was there also, though, I take it that HIV medicine is time-sensitive too, HIV/AIDS medicine?

A. Yes. The virus can mutate quickly, and if you miss even a small number of doses, the medication you are taking may no longer be effective. So when I worked

at Group Health, we had a program where folks that were taking HIV meds were on a cycling program, where we would be sure that they got their meds within the timeframe before they ran out of their correct refill.

* * *

Q. Okay. Then on the next page of the document, there is a reference to something that I think you've been commenting about, which is up at the top, a highlighted portion. "A referral is not a minor inconvenience for many women who live in towns with only one pharmacy or have to go to another town or across town. This is especially compelling when you think of emergency contraception where the efficacy of the drug is decreasing."

I take it that is consistent with your understanding that the availability of medicines can be more of a problem in some of these rural areas?

A. Yes. Where I work, some of the folks are low income. They don't have a car. They walk over to the pharmacy. They take a bus. So depending on the time of the day, they may not be able to very easily get to another pharmacy.

Q. That could happen in some of the larger populations?

A. Yes. I work in Seattle, north Seattle.

Q. If the patient has disabilities, blindness or deafness, it could compound the problem?

A. Yeah. I have one patient that needed a refill, had forgotten to reorder it. Mom is blind. The son, the patient, is developmentally disabled. And mom said:

"I am not going to send him out after dark to walk. It's about a mile to the store." So I said: "You know what, you are on my way home." I will bring it by to you on my way home. This was last week that I did that. So everything was fine, but some people definitely have –

Q. Different issues?

A. Yeah, they can't just hop in the car and go get the med.

* * *

Q. As the proceedings with respect to the hearings and receipt of letters and emails and things like that went on, did you in fact get additional information suggesting refusals by pharmacies to fill or difficulty in getting pharmacies to fill prescriptions?

A. Again, we had – and I didn't personally encounter any difficulties in getting prescriptions filled, but certainly we had letters to that effect.

* * *

Q. Then if we go to April 2007, which is roughly a year after the previous one, we have another meeting. This is the minutes of a Washington State Pharmacy Association on April 12th?

* * *

Q. It looks like you were present at this meeting?

A. Yes, I was.

Q. Do you recall what was going on with respect to the rules at this point in time?

A. This was April 2007?

Q. Yes.

A. Well, by that time, we would have had discussion at a number of meetings. I don't recall exactly what happened on that day, but I guess I am about to find out.

Q. . . . So apparently, the whole process was still in progress. Down at the bottom, there's a quote from you where you are quoted as saying, "Gary Harris confirmed, as stated in the SA, that the rules are needed to minimize barriers to health care and to reduce risks for a patient's health when there may be an emergent need for a prescribed drug or device or a timely preventive use is essential to drug efficacy."

Was that a fair representation of your thoughts at that point in time?

A. Yes.

Q. I take it that you are not referring to just any particular one medication; you are just referring to minimizing barriers to health care?

A. Certainly. I haven't, nor would I, mention any drug in particular. Again, I am referring to all medications, all situations.

Q. Then if we go on to the next page, this will give us an idea of where we are in the timeframe. At the top, Susan Teil Boyer acknowledges that it has been a difficult process, but also felt the proposed rules were well crafted and protecting patients, which is what the Board does.

Was that your sense of what the outcome of the 2007 process was?

A. Absolutely. We worked really hard on this. We would go over the language saying: Well, maybe we had "should" and we were advised no, you should have "shall" not "should." We looked at language. We looked at the wording, where the commas were placed. We really tried to make this a rule that would fit what we wanted to do, which was to apply to all medications –

Q. And so –

A. – for all patients.

* * *

ER 1163-65 Testimony of Lisa Hodgson, former Program Manager and former interim Executive Director, Board of Pharmacy.

Q. What was your sense of what the Pharmacy Association was recommending and what were the women's groups recommending as far as you can recall?

A. I recall that the Pharmacy Association was wanting to develop a referral process and the Northwest Women's Law Center was concerned about access to medications for patients.

Q. Was it also your sense that more of the kind of outspoken advocacy groups that were coming to the attention of the Board, that those groups by and large were really primarily interested at least in Plan B?

A. Correct.

Q. Was it your sense that that was the focus of the Board in considering this issue?

A. No, the focus of the Board was always on access to all medications, all lawfully safe medications for patients.

Q. And once the Board decided to go ahead and open rule-making on this issue, what was your sense of what was the Board trying to accomplish with the rules that ultimately they wound up adopting?

A. I think the Board was trying to promote patient safety. They wanted to make sure that the patients had access to safe medications, that there weren't burdens or barriers being put in place that would preclude a patient from getting a safe medication.

* * *

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.

ER 1165-73 Testimony of Lisa Hodgson, former Program Manager and former interim Executive Director, Board of Pharmacy.

Q. Okay. Let me turn your attention to another aspect of what the Board does in terms of the potential discipline side of the Board and how that process works from your perspective as a staff person assisting the board.

To start with, who actually has authority to potentially issue discipline against a licensee; is it the Board of Pharmacy or the Department of Health?

A. The Board of Pharmacy.

Q. And so can you describe for us, then, from the Department of Health side of things, how does the complaint investigation charging process work and getting to the time when a complaint actually comes in to the department?

A. The department will receive a complaint. The Board will look at that complaint and determine whether or not it should be investigated, so a panel of the Board will look at that investigation or the complaint. If they decide that an investigation should be conducted, it is assigned out for investigation.

If they determine that the complaint allegation does not fall within the jurisdiction of the Board or if it's below threshold, they would close that investigation.

If it is assigned out to investigation, an investigator will conduct that investigation and gather the facts. That information then comes back to the Board for their review and determination

whether or not they believe a violation has taken place.

Q. In terms of actually authorizing an investigation to proceed after a complaint comes in, who has the authority to make that decision and actually have an investigation begin?

A. Well, currently the Board is the one that must decide that.

Q. And when you say currently, is it your understanding that there has been some change or development in Washington law in terms of how investigations get authorized?

A. Yes. Throughout the years, a couple court cases have influenced or changed the way the Board does authorize their investigations.

Q. And so can you explain to me just a little bit more about what the change was? So before the change in the case law, as you understand, how did it work previous to the way it works today?

A. Previously a case management team would look at the complaint and decide whether an investigation should be conducted. And that case management team included the executive director and the chief investigator and other staff members. But there was a current – there was court cases that have changed the way that process is done, and now it requires that the Board authorize that investigation.

Q. Okay, so the Department of Health staff no longer sit on the group that makes the decision on whether or not to initiate investigation?

A. They are not decision makers.

Q. They still may assist in terms of supplying information or background but they don't have authority to actually –

A. They actually sit in and facilitate the Board receiving the documents but they do not make any decision.

Q. And what's your memory of this in terms of when this change came about?

A. 2005, 2006, I am not sure; I am sorry.

Q. Okay. All right, so when a complaint actually comes in before it comes actually to the Board members to consider, we had some testimony yesterday that had talked about some information being redacted on the complaint. Are you aware of that?

A. That is correct; the complaints are redacted.

Q. How does that happen? When does that happen in the process?

A. Our disciplinary case managers redact the information, so that happens after we log the complaint in and we do redact it. We redacted any identifying information from that complaint.

Q. And who actually does that redacting work?

A. I believe it's our disciplinary case manager that redacts it.

* * *

Q. You mentioned that identifying information is redacted. Can you explain what does that mean when you say identifying information?

A. So we would redact the respondent, whoever the complaint was against, we would redact patient names, we would redact the addresses.

Q. What is the purpose for redacting identifying information from the complaint before the Board sees it?

A. It's just so there's an impartial review of the facts.

Q. So the first time any Board member would see a complaint, it would have been redacted; is that correct?

A. Correct.

Q. And so as a Board member begins to look at a complaint that was filed, they wouldn't know which pharmacy or which pharmacist the complaint was about; is that correct?

A. That's correct.

Q. Would they be able to tell after the redaction happened, whether or not the pharmacy – had come from a pharmacy that had a particular religious affiliation?

A. I don't believe so.

Q. So the information gets redacted, then the complaint moves on to – what happens next?

A. Then a panel of the Board would look at that complaint and determine whether or not it should be investigated.

Q. And how many Board members does the panel consist of?

A. No less than three.

Q. No less than three. Is it by majority vote on whether or not a complaint moves forward?

A. Yes.

Q. So if the majority voted at that stage of the proceedings not to move forward, then what happens?

A. Then the complaint would not be assigned.

Q. And it's closed at that point?

A. It would be.

Q. Then if the Board – the vote of the Board is to initiate an investigation, then what happens?

A. Then an investigator is assigned to go out and gather the facts around the case.

Q. Is there a timeframe that the investigators have in order to go out and gather what information they think might be material?

A. They have 170 days, is the timelines for completing an investigation.

Q. Do the investigators, when they go out to perform the investigation, are they kind of given instructions by the Board on here is what we want you to do, or is it a case where they are turned over, given the complaint, and then kind of at their discretion to gather what they need, or a combination of both?

A. Occasionally the Board would say – would direct them to collect certain items, but generally it's just, they use standard protocol to gather the information.

* * *

Q. All right, so let's say the investigation has been authorized by the Board, the investigator goes back, brings back the information to the Board, then what happens?

A. The Board will review the facts, they will determine whether or not they believe a violation has occurred.

Q. When you say the Board, does the information come back to the Board that authorized the information or –

A. It goes back to a particular reviewing Board member and then that reviewing Board member makes a presentation to a panel of the Board.

Q. That could be a panel of four or a presentation to the whole Board?

A. It could be a presentation to the whole Board. I believe it's generally a panel.

Q. Okay. So the presentation gets made. What is the decision that happens next?

A. The reviewing Board member makes a recommendation, so they could close the case or propose a notice of correction or other types of disciplinary action.

Q. So the reviewing Board member actually makes a recommendation about what he thinks the panel should do: Either close the case, charge the case, or whatever?

A. Correct.

Q. So does that reviewing Board member then also vote on the disposition of the case at that stage?

A. No. The panel does.

Q. The panel could close the case or take some other action; is that correct?

A. Correct.

Q. If the panel decides to move forward at that point, with some action other than closing of the case, then what happens next?

A. Then our legal department, our staff attorneys work with that reviewing Board member to issue either statement of charges, notice of correction, whatever the disciplinary document recommended is.

Q. When you say issue a statement of charges, what is that?

A. A statement of charges is a document that puts the respondent on notice that the Board believes also that unprofessional conduct has occurred, and specifically lists out the conduct.

Q. Then what happens next if a statement of charges has been issued?

A. The respondent has an opportunity to either enter into settlement negotiations or request a hearing before the Board.

Q. And if a hearing is requested and the case gets that far, who then hears the case? Is it the same people who decide the charge, or is it a different group, or the whole Board; who resolves that?

A. It could be the same group or it could be the entire Board. The reviewing Board member does not participate.

* * *

Q. If the Board does impose some sort of action against the licensee, does the licensee then have the opportunity to appeal that decision to another body?

A. Yes, they do.

* * *

ER 1188-94 Testimony of Lisa Hodgson, former Program Manager and former interim Executive Director, Board of Pharmacy.

Q. So in looking through the spreadsheet of all the complaints relating to refusal to dispense medicine for whatever reason, were you able to identify any cases in which the disposition of the case was something other than ultimately the case being closed?

A. Yes.

Q. And what did you find in that regard?

A. I believe there were four instances where the Board issued a notice of correction, and one instance where the Board issued an agreed order.

Q. What does that mean when the Board issues an agreed order?

A. That's an order of the Board that forms its discipline against the pharmacist.

Q. Did any of those instances involve Plan B?

A. They did not.

Q. Is it correct in looking at the complaints that we had in this case, that arose from the situation at Ralph's Thriftway, that other than the cases that had been stayed by this proceeding, that all of those cases have been closed or dismissed by the Board?

A. That is correct.

Q. Is it possible in looking at the information that the Board processes to know whether or not we have any complaints that have been filed with the Board that arose from a Catholic outpatient pharmacy?

A. Yes.

Q. Are there any such complaints that you are able to identify?

A. I was not able to identify any.

Q. Let me back up to one other question that I think I overlooked earlier, Lisa, in this case.

In terms of the process when the Board is working through a complaint and we're to the point in the process where the responsible Board member is making a recommendation to either charge or not charge a particular case that's pending, when that recommendation is being made, does the panel, the other panel on the Board at that point, do they know who the respondent is?

A. They do not. The reviewing Board member does not review that identity of the respondent.

* * *

Q. First turning to Exhibit A-41 that you were just discussing with Mr. Tomisser, it's accurate that based on your review of the Board of pharmacy disciplinary records, the Board of Pharmacy has never disciplined any pharmacy for refusing to dispense Plan B, correct?

A. That's correct.

Q. And you mentioned that there are five other instances in which the Board has disciplined pharmacies; is that right?

A. There's far more than five other instances in history, but on this spreadsheet is what I was – there were five instances.

Q. I think I spoke inartfully. There's five instances between 1995 and 2008 that involved pharmacy refusals that resulted in discipline, correct?

A. Not entirely correct.

Q. Okay.

A. There were, I believe, three instances where pharmacists received notices of correction for not issuing a medication in a timely fashion.

There was another case where a notice of correction was issued because there was a medication error, somewhere in the complaint allegation we received, so it was identified on the spreadsheet. And on the agreed order the pharmacist failed to cancel a patient when the patient returned to the pharmacy to ask the pharmacist about a potential misfilled prescription, and the pharmacist delegated authority to the technician to communicate with that patient.

Q. Is it – it is accurate, however, that in those five instances, none of those situations dealt with Plan B?

A. That's correct.

* * *

Q. Have you ever perceived that the Board enforces its rules differently as applied to certain pharmacies or organizations as compared to others?

A. No.

Q. I believe you testified that you now work with a different Board of Pharmacy board, a division; is that right?

A. I work with a different set of health professions.

* * *

Q. And in your experience working with those other professions, do all operate similarly to the Board of Pharmacy in terms of the investigations they authorize; in other words, are all of those complaint driven?

A. Yes, they are.

Q. Are you aware of any board associated with the Department of Health that isn't complaint driven?

A. I am not.

* * *

ER 1209-12 Testimony of Lisa Hodgson, former Program Manager and former interim Executive Director, Board of Pharmacy.

Q. Are you aware of any other pharmacy in the history of the Board, at least that you are aware of, that has been the object of such an intense and unremitting effort to use the Board's complaint and disciplinary process to go after that pharmacy?

A. The Board in the past had received a number of complaints against another pharmacy, Rite Aid pharmacy, for medication errors and for other types of complaints.

Q. How many?

A. I don't know.

Q. What happened to those complaints?

A. Some of them resulted in notices of correction. Some of them were closed.

Q. Let's just focus on the Plan B complaints themselves in the 2006-2008 timeframe. There were the pill patrol focusing on the Olympia area, and filed complaints against Ralph's and against Sav-On, Walgreens and Rite Aid, correct?

A. Correct.

Q. Of those complaints that were filed, 80 percent were against Ralph's. Do you know why that is?

A. I did not.

Q. Really?

A. Because they wouldn't dispense the medication.

Q. Well the other pharmacies, Sav-On, Walgreens, they didn't have the medication to stock either, did they?

A. They did not.

Q. What was the reason they didn't have it?

A. They were temporarily out of stock of the medication.

Q. So once they told you we're just temporarily out of stock, and that's the reason that we didn't have it for those patients and they told you they'd get it in stock, that was enough to close the file against them, right?

A. I believe the investigator did look at their drug purchases to determine whether or not they had purchased the medication in the past.

Q. So you did that to determine if there had been a demand and if they had in fact had it in stock at some point; is that what you are saying?

A. Yes.

Q. So once the reason given was we were temporarily out of stock, that was the basis foreclosing those complaints, right?

A. Correct.

Q. But in the Stormans case, because they said publicly that for conscientious objector reasons they were not going to stock Plan B, they got quite a few more complaints, did they not?

A. For whatever reason they got complaints.

Q. Did that trouble you at all that a pharmacy that stated publicly, for religious reasons, it wasn't going to stock a drug, it got unremitting, continuous complaints and pharmacies that said we are just temporarily out of stock, they didn't get any more complaints; did that trouble you at all?

A. No.

Q. You also took a look at the average of complaints – this again is based on your spreadsheet over the 1995-2007 time period. There was a low of one complaint in one year and a high of 17. The average was about 8.6 complaints per year. Do you see that? And then there was this gigantic explosion of complaints in 2006, over the average. Do you know what the cause of that was or why that is so?

A. I believe that's the result of the Plan B complaints.

Q. So did that concern the Board of Pharmacy that there had been an average of refusal complaints and then there was this giant spike because of this concerted effort to file complaints against my client?

A. I think the Board would be concerned any time there might be an access to medication issue, whether it be Plan B or any other drug.

Q. Would you agree with me that Plan B complaints are more frequently investigated than other medications?

A. No.

ER 1254, 1257-58 Testimony of Gary Harris, former member, Board of Pharmacy.

Q. Okay. Now, I'm turning – would like to turn your attention for a moment to Tim Fuller. Do you know Tim Fuller –

A. Oh, yeah, um hum.

Q. – in connection with the Board of Pharmacy? And what is his position, as you know it?

A. He is a pharmacist consultant. So a lot of times when individuals, pharmacists, other licensees call in and want to know if they can do something or what does it take for me to be able to do this or that, and he gives them direction as to where to look or sends them the packet of information.

Q. Okay. And he's testified here before and I just wanted to be clear as to his authority in his position. Is he authorized to speak for and bind the Board of Pharmacy in his position?

A. Uh, really, only the Board of Pharmacy when they take a vote can make a decision on – on the board.

* * *

Q. Now, the – there were a lot of hypotheticals that were asked in questions posed to you by Ms. Waggoner and I assumed that the issues that were in those hypotheticals to your knowledge have never been presented to the board for actual action, have they?

A. Do you have an example of one of the hypotheticals?

Q. Oh, various hypotheticals about how the rules would apply in this situation and that situation and there were – there were dozens, if not scores, of them.

A. Yes. And the thing about a hypothetical is that that's what it is, it's hypothetical. The board has to make a decision to open a case or not open a case based on the information that we have about that particular case. And then whether action is taken against that respondent would be after it would – the case was reviewed by the reviewing board member, evidence was collected, and we have a discussion and vote as to how we're going to – what we're going to do.

Q. And so I mean no disrespect in asking this, but so the – your answers to the questions which you were directed to answer and the questions that you were asked on those hypotheticals, they're not any kind of a formal ruling by the Board of Pharmacy, are they?

A. No. No. I'm just responding as to what I – what I thought was the correct answer, but yes, on a hypothetical case, I don't think we can possibly know what might happen until we actually have that case in front of us.

ER 1429-30 Testimony of Gary Harris, former member, Board of Pharmacy.

Q. If I were to tell you that three of the four Catholic health systems have similarly stated like Ralph's to this Court that they too would not stock Plan B or Ella in their retail pharmacies under any circumstances, you would likewise conclude that they too are violating both the stocking rule and the pharmacy responsibility rule, correct?

* * *

THE WITNESS: Unless a complaint came from a Catholic outpatient pharmacy, the board doesn't necessarily have any knowledge that they had been in defiance. So, again, we are complaint-driven.

BY MS. WAGGONER:

Q. Yes, we've heard that, but let's assume for purposes of this question that the board is aware that three of the four Catholic health systems refuse to stock Plan B and Ella. Under those circumstances, you would also agree that they're in violation of the stocking rule and the pharmacy responsibility rule, right?

* * *

THE WITNESS: And if a complaint were filed against them, we would evaluate that complaint on the merits that were presented to us.

* * *

ER 1468-69 Testimony of Gary Harris, former member, Board of Pharmacy.

Q. I assume there were still many stakeholders presenting points of view in terms of what they wanted the Board to do; is that right?

A. Yes. The two principle groups were still – yeah, presenting their particular cases.

Q. When you say the two groups, what is kind of the general category that you described those two groups as being, at least from your perspective?

A. One was pro religious objection and one was not. Is that what you are looking for?

Q. Was that your perception of the two?

A. Yeah, that was my perception, is that one group was over here and one group was over here.

Q. Is it uncommon in the rule-making process that you can get stakeholders who are really only interested in one aspect of the rules?

A. Yeah, and I guess if you look at some of the exhibits that we have here, from day one, way back when, I was saying this isn't about one drug. This isn't about – this is about all drugs, all patients, all situations. This is not a one-drug issue, and yet still when I came in today, the guard downstairs says: "Oh, you are here for Plan B." So still –

Q. Did you get a sense that the Board was constantly in a struggle to clarify what it was focused on, as opposed to what any individual stakeholder group might be interested in?

A. Yeah, I did a couple radio interviews with Ken Schram, and I was a little bit nervous about doing that, but it turned out okay. But still – and again, in that I am saying all drugs, all situations, all patients, and Ken would say: "Oh, yeah, Plan B. What are you going to do about Plan B?"

In my opinion, it's unfortunate that it has come to one drug because that has never been what this was – in my opinion, it has never been what this was about.

ER 1485 Testimony of Susan Teil-Boyer, former member, Board of Pharmacy.

Q. So if someone filed a complaint and said my pharmacy won't unit dose, and they referred me to a pharmacy that specializes in doing that, you would consider that to be a violation of the rule?

A. The Board would take that case up, yes, definitely.

Q. You can't tell me, sitting here today, whether that would be a violation of the rule; you would have to wait for the Board to decide?

A. We would.

ER 1531-32 Testimony of James Doll, Pharmacist Investigator, Department of Health.

Q. You recall in the course of your discussions with Mr. Stormans, that he told you that it was his decision on behalf of Stormans not to stock Plan B because of his religious objection?

A. Religious and moral.

Q. Religious and moral objections?

A. Reasons, correct.

Q. Did you relay that information to the Board of Pharmacy that that was his reasoning for not wanting to stock Plan B?

A. Yes, that was part of my investigative report.

Q. And when did that investigative report go in to the Board of Pharmacy with that information?

A. These were put into before the new rule was put into effect, because these cases were in 2006.

Q. So at that point in time, potentially, if Stormans pharmacy had a demand for Plan B, their failure to have Plan B in stock would be a violation; is that correct?

A. Correct.

Q. So with the admission of Kevin Stormans to the Board that he was going to refuse to stock the drug regardless of patient demand, is it the case that the Board of Pharmacy still dismissed the complaints other than the three that were stayed by the lawsuit?

A. It appears so, yes.

Q. Mr. Doll, if it was the case that the Board of Pharmacy was motivated to single out and pursue the Stormans pharmacy because of their religious objections, wasn't the unabashed admission of Kevin Stormans that he wasn't going to stock that drug no matter what, all the evidence that the Board of Pharmacy needed to go and take his license?

A. Yes.

Q. But they didn't do that, did they?

A. No.