NO. 12-35221 and 12-35223

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

STORMANS INC, doing business as Ralph's Thriftway; et al.,

Plaintiffs – Appellees,

v.

MARY SELECKY, Secretary of the Washington State Department of Health; et al.,

Defendants – Appellants,

and

JUDITH BILLINGS; et al.,

Defendant – Intervenors.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON AT TACOMA

No. 3:07-cv-05374-RBL
The Honorable Ronald B. Leighton
United States District Court Judge

APPELLANTS' OPENING BRIEF

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I. INTRODUCTION

In 2005, the Washington Board of Pharmacy learned that some pharmacists or pharmacies in other states had denied lawful and lawfully-prescribed medicines to some patients for reasons unrelated to patient safety or medical efficacy. The Board determined its existing rules governing retail pharmacies and pharmacists did not adequately address such situations in Washington. It initiated rulemaking to determine whether new or amended rules should be adopted and, if so, to adopt them.

From the outset, the Board's purpose in this rulemaking was to ensure that patients who need lawfully-prescribed medicines can obtain them in a timely manner. The Board was concerned both about access to medicines generally and also about access to time-sensitive medicines—i.e., medicines which needed to be obtained and used promptly to serve their medical purpose.

The Board's rulemaking received substantial public attention, in large part because certain advocacy groups were concerned about patient access to one specific time-sensitive medicine—an emergency contraceptive known as "Plan B." Consequently, the great majority of lobbying and public comments the Board received addressed Plan B. The Board acknowledged those comments and concerns, but maintained a much broader focus on access to

medicines generally. After nearly two years of public process, hearings, and consideration of several options, the Board ultimately adopted one rule and amended another in an effort to ensure that patients in Washington have access to all medicines when and where they need them. The new rule applies to all retail pharmacies in Washington, imposing the general requirement that they timely deliver medicines needed by their patients. The amended rule applies to all retail pharmacists in Washington, addressing their general professional responsibilities to patients while recognizing the pharmacist's individual right to refuse to dispense a particular medication.

Plaintiffs, a pharmacy owner and two pharmacists employed at other pharmacies, challenged the two rules, alleging that the rules violate their free exercise of religion under the First Amendment of the United States Constitution, equal protection under the Fourteenth Amendment, the Supremacy Clause based on Title VII, and due process under the Fourteenth Amendment. ER at 686-704. The district court agreed and issued a preliminary injunction against the rules in November 2007. ER at 1579-1635. This Court reversed and remanded. *Stormans, Inc. v. Selecky*, 586 F.3d 1109 (9th Cir. 2009). In doing so, this Court held that the rules are neutral and

generally applicable, and therefore subject to rational basis review. *Id.* at 1137-38.

Instead of applying rational basis review on remand, the district court denied the Board's motion for summary judgment and allowed Plaintiffs to engage in extensive discovery into the lobbying and disagreements amongst various factions during the two year rulemaking process. The differing opinions on why the rules were adopted and conjecture from a variety of individuals about how the Board might apply the rules in innumerable hypothetical questions became the focus of trial and the basis of the district court's decisions.

The rules at issue are neutral and generally applicable on their face and in their real operation. Although Plaintiffs conducted scores of depositions, obtained reams of documents, and adduced thousands of pages of testimony, they have not shown the object of the Board in adopting the rules was to burden licensees with religious objections to Plan B. Their claims ultimately rest entirely on the fact that each Plaintiff feels the rules individually burden his or her religious exercise. On that basis, they claim the Board's failure to exempt them from the rules constitutes impermissible targeting of their religious freedom and denial of equal protection.

This case is not one in which government has sought to infringe on the religious beliefs or conduct of any person. It is not a case in which the Board has singled out religious pharmacists or pharmacy owners for unfavorable, disadvantageous, or unequal treatment. It is not a case involving rules that have been subtly "gerrymandered" to accomplish in fact what they do not accomplish on their face.

Rather, this is a case in which three Plaintiffs seek to superimpose a specific, individualized, religiously-based exemption from one particular application of neutral and generally applicable rules, because they, as individuals, feel burdened by the rules. The Plaintiffs raise no objection to complying with the stocking and delivery requirements for hundreds of time-sensitive medications, but seek to be excused from compliance when their religious objections conflict with the rules for time-sensitive emergency contraceptives.

Their claims fail as a matter of law. "We have never held that an individual's religious beliefs excuse him from compliance with an otherwise valid law prohibiting conduct that the State is free to regulate." *Employment Div., Dep't of Human Resources of Oregon v. Smith,* 494 U.S. 872, 878-79 (1990) (explaining that "more than a century of our free exercise jurisprudence

contradicts that proposition"). "[A] law that is neutral and of general applicability need not be justified by a compelling government interest even if the law has the incidental effect of burdening a particular religious practice." *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah,* 508 U.S. 520, 531 (1993).

The rules have not changed since this Court held them to be neutral and generally applicable, but the district court again concluded that the rules are unconstitutional as applied to these three Plaintiffs. The district court has now erred twice in its legal analysis. Its legal conclusion rests on the misapplication of controlling Supreme Court decisions buttressed only by irrelevant and speculative testimony that was improperly admitted. This Court should reverse the district court, vacate its decisions and orders, and dismiss Plaintiffs' complaint.

II. JURISDICTIONAL STATEMENT

The district court's jurisdiction is based on 28 U.S.C. §§ 1331 and 1367.

On March 23, 2012, the State Defendants timely appealed to this Court under Fed. R. App. P. 4. The State appealed the district court's Judgment, dated February 23, 2012; amended Opinion, dated February 22, 2012; Findings of Fact and Conclusions of Law, dated February 22, 2012; Permanent

Injunction, dated February 22, 2012; and all rulings relating to the First Amendment's Free Exercise Clause or the Fourteenth Amendment's Equal Protection Clause. ER at 9-155, 1315-24.

This Court has jurisdiction under 28 U.S.C. § 1291.

III. STATEMENT OF THE ISSUES

1. Whether the challenged rules and the stocking rule are neutral, generally applicable and rationally related to the State's legitimate interests in promoting the health care of its citizens.

2. Where neither the text nor the actual operative effect of the Board's rules reference religion in any way, and where those rules impose no burdens on licensees with religious beliefs that are not imposed on all licensees, did the district court err in concluding that the rules were gerrymandered to burden religion because of religious animus?

3. Whether the district court erred in allowing opinions about hypothetical disciplinary cases to form the basis for determining either the operative effect of the rules or that a future Board would selectively enforce the rules in an unconstitutional manner.

4. Whether the district court erred in concluding that Catholic-affiliated outpatient pharmacies would be treated differently under the Board's rules than other outpatient pharmacies?

5. Whether the district court erred in enjoining the rules under a selective enforcement theory when none of the Plaintiffs have been disciplined under the rules and there is no history of any licensee being disciplined for violation of the rules?

IV. STATEMENT OF THE CASE

A. Identification Of The Parties

The three Plaintiffs are each licensed by the Board of Pharmacy. Stormans, Inc., a for-profit corporation, operates a retail pharmacy within a grocery store and is licensed as a retail pharmacy. Rhonda Mesler and Margo Thelen are both licensed pharmacists, but neither is employed by Stormans. ER at 520-39, 686-701.

Defendant-Intervenors are seven Washington residents who have been denied, or are concerned about being denied, timely access to time-sensitive medications, such as emergency contraceptives and medicines to treat HIV/AIDS. ER at 672-85.

The State Defendants include former Board members, one current Board member (Gary Harris), the Board's former Executive Director (Susan Boyer) (who also is a former Board member), and the current Secretary of the Department of Health (Mary Selecky). Board member Gary Harris is the only current Board member who was a member of the Board when the challenged rules were adopted in 2007. Mr. Harris' second and final term of service expires on January 19, 2013. At that point, the entire composition of the seven-member Board will have turned over and no member of the Board that approved the 2007 rules will be on the Board in either a rulemaking or disciplinary capacity. ER at 1738.

B. Course Of Proceedings

The two rules challenged in this case were approved by the Board of Pharmacy in April 2007, following an extensive public process lasting more than two years. ER at 955-64. Both rules were intended to ensure patient access to prescription medicines, especially those medicines that are time-sensitive. ER at 982. There are approximately 200 time-sensitive medications currently approved by the Federal Drug Administration and on the market. ER at 1567-73. One rule amended and clarified the professional responsibility rules of licensed pharmacists in Washington. Wash. Admin. Code 246-863-

095. The other rule, a new rule, required pharmacies to assure delivery of a time-sensitive medication or a therapeutic equivalent on-site if the pharmacy has the medication in stock. Wash. Admin. Code 246-869-010.

On the same day the rules were to take effect, July 26, 2007, the three Plaintiffs filed a complaint to enjoin the rules. The Plaintiffs asserted a constitutional right to be exempt from compliance with the rules with respect to the emergency contraceptive Plan B under the Free Exercise Clause.[1] In November 2007, the district court granted Plaintiffs' request for preliminary injunction, ruling that the rules violated their right to free exercise of religion when viewed under an intermediate "means/end" standard of scrutiny. ER at 686-704. The district court enjoined the Board from enforcing the rules against *any* licensed pharmacy or pharmacist refusing on religious grounds to deliver or dispense the emergency contraceptive Plan B. ER at 686-704.[2]

The State Defendants and Defendant-Intervenors appealed the preliminary injunction and sought a stay pending appeal. *Stormans Inc. v.*

[1] The complaint also alleged violations of equal protection, Title VII of the Civil Rights Act, and substantive due process. The complaint was amended shortly before trial to add another brand of emergency contraceptive, *ella,* to the request for an injunction.

[2] Wash. Admin. Code 246-869-150, the "stocking rule," was also enjoined by the District Court although the Plaintiffs did not cite that rule or plead for that relief in their complaint. The stocking rule was adopted in 1967, decades before the emergency contraceptives Plan B or *ella* were developed.

Selecky, 526 F.3d 406 (9th Cir. 2008). Although the motion to stay was denied, Circuit Judge Tashima's dissent foreshadowed the subsequent unanimous decision of this Court rejecting the merits of Plaintiffs claims:

> Here, the regulations are rationally related to Washington's legitimate interest in ensuring that patients have their lawful prescriptions dispensed without delay.
>
> *Smith* and *Lukumi* require only that the regulations treat religious belief and practice no differently than secularly-motivated belief and practice. The regulations do just that. The Supreme Court has never held that the Free Exercise Clause creates a private right to ignore generally applicable laws. Instead, it declared that the creation of such a right would be "a constitutional anomaly." *Smith,* 494 U.S. at 882, 885-86.

Stormans, 526 F.3d at 416.

On October 28, 2009, this Court issued its decision on the merits of the Plaintiffs' free exercise argument. *Stormans,* 586 F.3d at 1109. Like Judge Tashima, this Court applied the analytical framework mandated by *Smith* and *Lukumi* and found that the rules apply to all time-sensitive medications and do not require a licensee with religious objections to stock, deliver, or dispense medications any differently than a licensee working without religious preferences. *Stormans,* 586 F.3d at 1134-36. This Court found the exceptions to the rules to be narrowly crafted and neither under-inclusive nor over-

inclusive as to suggest an intent to burden religion. *Stormans,* 586 F.3d at 1134-36.

This Court vacated the preliminary injunction and remanded the case to allow the district court to make a finding as to whether the rules were supported by a rational basis:

> The record before us does not suggest that Appellees have negated every conceivable basis supporting the new rules, so it appears that the new rules are rationally related to Washington's legitimate interest in ensuring that its citizen-patients receive lawfully prescribed medications without delay.
>
> The district court, however, has not yet had the opportunity to analyze or to make the appropriate factual findings as to whether the new rules are rationally related to a legitimate governmental purpose. Whether the rules pass muster under the rational basis test must be determined by the district court in the first instance.

Stormans, 586 F.3d at 1137-38.

In April 2010, State Defendants and Defendant-Intervenors moved for summary judgment based on this Court's analysis and instructions on remand. ER at 586-608, 609-37. On June 15, 2010, the district court denied the motions for summary judgment without ruling on whether the Board's rules were supported by a rational basis or identifying any material dispute of fact that prevented summary judgment. ER at 1574-78. The only explanation of the district court's reasoning was a comment that this case would be decided by the

United States Supreme Court and they would want "as broad a public record" as possible. ER at 1024.

Trial commenced on November 28 and concluded on December 27, 2011. There were no changes to the Board's rules, to the exceptions contained in the rules, or to any of the Board's official statements about the rules between this Court's 2009 decision and the trial. The trial was spent asking witnesses their opinions on why the Board adopted the 2007 rules, on the positions of various lobbying groups during the rulemaking process, and on innumerable hypothetical questions as to whether the Board would find various particular circumstances to be a violation of the rules.

The district court formally provided its decision in favor of the Plaintiffs' free exercise and equal protection claims on February 22, 2012, issuing its Judgment the following day. ER at 9-155, 1323-24. The State Defendants and the Intervenors timely appealed the district court's free exercise and equal protection rulings. [3]

[3] The district court ruled against the Plaintiffs' Title VII and substantive due process claims. The Plaintiffs did not cross-appeal those rulings.

V. STATEMENT OF FACTS

A. The Mandate And Authority Of The Board Of Pharmacy

By statute, the Board of Pharmacy regulates the practice of pharmacy in the State of Washington. Wash. Rev. Code § 18.64. The Board's responsibilities include licensing pharmacies and pharmacists, promulgating rules for all Board licensees, inspecting pharmacies, and the professional discipline of its licensees. Wash. Rev. Code § 18.64.005. Rules are adopted and disciplinary decisions are made only through the collective will of the Board, not by any individual board member acting alone.

Board members are appointed by the Governor to a four-year term and, at the Governor's discretion, can be appointed to a second term. By statute, the Board is composed of seven members—five licensed pharmacists and two lay members who represent the public—all of whom are volunteers. The staggered terms of Board members results in a continually evolving and changing membership. ER at 1738.

1. The Rulemaking Function Of The Board

When adopting rules governing the practice of pharmacy, the Board is statutorily mandated to protect and promote the public health, safety, and welfare. Wash. Rev. Code § 18.64.005(7). Rules adopted by the Board do not

require legislative or executive approval to become effective. Neither the Governor nor the Secretary of the Department of Health has a vote in or a veto over the substance of rules adopted by the Board.[4]

When filing the rules for permanent adoption on June 25, 2007, the Board filed three documents mandated by Washington's Administrative Procedure Act: a Concise Explanatory Statement, a Significant Legislative Analysis, and a Small Business Economic Impact Statement. *See* Wash. Rev. Code §§ 34.05.325, .328, and .320(1)(j) (cross-referencing Wash. Rev. Code § 19.85.030). ER at 730-38, 982-94, 995-1006, 1202-05, 1459. These publications explain why the rules were adopted, how they are intended to work, and how they may impact small businesses. In addition to the text of adopted rules, these three publications are the only official explanations prepared by the Board about how the Board intends the rules to work and how they will impact the practice of pharmacy in Washington.

The Board can act to adopt rules and to enforce discipline for violations of the rules only through collective action. ER at 1254. Whether the Board would consider any particular situation to be a violation of the rules and whether discipline would be issued can only be determined in a quasi-judicial

[4] The Department of Health provides administrative support and personnel to assist the Board.

proceeding when an actual case is presented to the Board. ER at 1052, 1258. *See Stormans,* 586 F.3d at 1133.

2. The Board Inspects Pharmacies

The Board also inspects pharmacies approximately every two years pursuant to Wash. Rev. Code §§ 18.64.245 and 69.41.041. The inspection process is designed to identify and correct noncompliance in the pharmacies through a cooperative technical assistance process. ER at 1533-35. *See* Wash. Rev. Code § 43.05. The inspections cover a wide range of issues from the safety and cleanliness of the physical space to checking the medications on the shelf for proper labeling, outdated medications, and proper storage conditions. ER at 1682-83.

Inspection deficiencies are not immediately presented to the Board for disciplinary action. ER at 1534-35. Although an enforcement action eventually could be taken against a licensee who cannot or will not cure deficiencies, Mr. Doll explained that the enforcement culture of the Board has been to work with licensees to bring them into compliance rather than restrict or revoke the license, ER at 1534-35, consistent with the technical assistance mandate in Wash. Rev. Code § 43.05.

The Board has never interpreted its rules to require that any pharmacy stock every medicine approved by the federal Food and Drug Administration. There simply are too many approved medicines. ER at 1484. Rather, the stocking requirement always has been applied with respect to patient need—a pharmacy must plan for and stock a representative assortment of the medicines needed by its patients. Wash. Admin. Code 246-869-150(1); ER at 1484.

3. The Disciplinary Process Is Complaint Driven

Another method of regulating pharmacies and pharmacists is the investigation of complaints made against licensees and the initiation of enforcement action if the investigation reveals there may be grounds to take action against the licenses. Wash. Rev. Code §§ 18.64.160, .163, .165; and 18.130.170, .180. The issuance of discipline by the Board is a quasi-judicial function governed by the Uniform Disciplinary Act, Wash. Rev. Code § 18.130, and includes the right to appeal to the superior court.

Complaints can be filed by anyone and the Board does not restrict the rights of citizens to file complaints. However, not all complaints require further investigation. By law, each investigation must be individually authorized by the Board. Wash. Rev. Code § 18.130.080(2); *Seymour v. Dep't of Health, Dental Quality Assurance,* 152 Wash. App. 156, 216 P.3d 1039

(2009); *Client A v. Yoshinaka,* 128 Wash. App. 833, 116 P.3d 1081 (2005). ER at 1490-95, 1116, 1167, 1194. The authorization to investigate a complaint includes a procedure in which all information identifying the involved pharmacy, pharmacist, patient and complainant is redacted and withheld from the panel of Board members who are deciding whether to initiate an investigation or to close the complaint. An investigation is not disciplinary action. ER at 1116, 1119, 1470, 1475, 1168-70.

If an investigation is authorized, then a single Board member is assigned to serve as the reviewing board member. The reviewing board member receives the unredacted information, including investigative documents and reports. ER at 1116-17, 1471-72. The reviewing board member then presents the case to the Board or a panel of the Board, without revealing the name of the pharmacy, pharmacist, patients, and other identifying information, describing only the nature of the complaint and what the investigation revealed. ER at 1472. The reviewing board member makes a recommendation on whether charges should be issued, a statement of allegations (less than formal discipline) should be issued, or the matter should be closed. ER at 1171-73, 1472-74. The reviewing Board member does not cast a vote. ER at 1464.

These steps are taken to avoid bias and other improper motivations for conducting investigations or initiating disciplinary action.

Under Wash. Rev. Code § 43.70.075, certain complainants are entitled to whistleblower protections. If the complainant chooses not to sign a waiver of the whistleblower protections allowing his or her identity to be revealed, the complaint typically must be closed without an investigation because the material inquiries would necessarily identify the complainant. ER at 1171, 1192, 1465, 1533, 1536-37.

B. The 2007 Rulemaking Proceedings

In the summer of 2005 the Executive Director of the Board, Steve Saxe, provided a brief report to the Board about media stories of pharmacists in other states refusing to dispense medications and confiscating or destroying lawful prescriptions for non-clinical reasons. The Board's staff also received telephone calls from members of the public and from pharmacists asking whether such conduct would be permissible in Washington. ER at 1081, 1162, 1726-36.

At the regular Board meeting on January 26, 2006, the Washington State Pharmacy Association (WSPA) submitted a report to the Board, listing various acts which they recommended should be considered "unprofessional

conduct"—i.e., a legal basis for the Board to initiate action against a pharmacist's license. The report included recommendations on when a pharmacist should be allowed to refuse to dispense a medication. The statute enumerating the grounds for unprofessional conduct, Wash. Rev. Code § 18.130.180, did not include all the acts being recommended by the WSPA. ER at 932-45, 1447.

The Board reviewed its rules and determined its rule were not clear on when a licensee could refuse to provide a lawful medication to a patient. The review highlighted questions over patient access to medications and, in particular, the problems for patients caused by delays in accessing time-sensitive medication. The Board decided to initiate the rule-making process. ER at 932-45, 1448.

Between the January 2006 meeting and June 25, 2007, the Board conducted a number of public hearings, reviewed thousands of public comments, and prepared successive drafts of administrative rules. The rules were finally adopted on June 25, 2007. ER at 1675. None of the three Plaintiffs attended the Board's public hearings, nor did they submit written

comments for the Board's consideration as the Board worked through the rules development process. ER at 1467[5], 1529, 1674-81.

Throughout the rule-making, while much of the public testimony focused on emergency contraceptives, the Board consistently focused on timely access to all medications. In particular, the Board was concerned that non-clinical barriers to accessing time-sensitive medications should be reduced. ER at 1032-33, 1124, 1163-64, 1468-69, 1544, 1552-54. Accordingly, the pharmacies' responsibilities rule (delivery rule), Wash. Admin. Code 246-869-010, was adopted to require pharmacies to assure delivery of the medication or a therapeutic equivalent of medications that are in stock on-site if a pharmacist in their employ refused to dispense and the medication. ER at 730-38, 1676-81.[6] Having placed responsibility on pharmacies as businesses to assure timely delivery, the Board amended the pharmacists' responsibilities rule, Wash.

[5] Ms. Thelen contacted the Board staff several times to inquire about the draft rules in May 2006, but did not attend a public hearing or submit public comments to the Board.

[6] The mandate to deliver time-sensitive drugs on site is not absolute. The Board adopted longstanding exceptions when patient safety could be at risk with a contra-indicated prescription, fraudulent prescriptions, or in situations where a patient could not pay for the medication. Wash. Admin. Code 246-869-010 (1)(a)-(e) and (2)

Admin. Code 246-863-095, to acknowledge that individual pharmacists could refuse to dispense medication for any reason.[7] ER at 730-38, 1676-81.

1. A Survey Of Pharmacies Did Not Reveal A Disproportionate Impact On Religiously Motivated Pharmacies

As part of its rulemaking process, the Board conducted a survey to assist in preparing the small business economic impact statement and significant analysis. ER at 1684-1725. One hundred twenty-one pharmacies responded. ER at 1684-1725. The survey covered a wide range of potential impacts the new rules might have on pharmacies. Of particular relevance to this lawsuit, Question 8 of the survey asked how the pharmacy would comply if the Board adopted a rule requiring pharmacies to dispense all lawful prescriptions. ER at 1684-1725. Of the 113 pharmacies responding to Question 8, 86 did not expect significant impact under the new delivery mandate. Seventeen pharmacies anticipated they would be impacted and would have to hire additional full-time or temporary staff in order to comply. Six pharmacies said

[7] Consistent with its intent to protect patients' lawful access to medicine, the Board also amended Wash. Admin. Code 246-863-095 to prohibit the destruction of lawful prescriptions, refusals to return lawful prescriptions, violations of patient privacy, discrimination against patients as prohibited by state and federal laws, intimidation or harassment of patients, and other technical amendments. None of these amendments are at issue in this lawsuit.

they would not comply with the rule. The remainder was unsure if they would be impacted. ER at 1435-36, 1452-54, 1684-1725.

Question 11 in the survey asked about emergency contraceptives. Twenty-eight pharmacies responded that they did not typically stock emergency contraceptives. ER at 1684-1725. Twenty-six of those pharmacies explained their reasons for not stocking emergency contraceptives was low demand or that it was more convenient to refer these patients elsewhere. ER at 1684-1725. Only two out of those 28 pharmacies cited personal or religious reasons for not stocking emergency contraceptives. ER at 1684-1725. The survey did not distinguish between personal or religious reasons for not carrying emergency contraceptives. Significantly, the survey showed the delivery rule would not just impact the two pharmacies citing religious or personal reasons—the rule impacts all 28 pharmacies that do not typically carry emergency contraceptives, if their patient population includes patients seeking emergency contraceptives. ER at 1684-1725.[8]

These numbers demonstrate that the Board's rules were not disproportionately or selectively impacting those pharmacies with religious

[8] The Board has made no determination whether the Stormans' pharmacy has a patient population needing emergency contraceptives and thus no determination on whether the stocking rule would require Stormans to carry that medication.

objections to emergency contraceptives. At least 17 pharmacies would be impacted by having to hire additional staff or take some other action to comply with the rules and the 28 pharmacies that do not typically carry emergency contraceptives would have to change that practice if their patient population needs emergency contraceptives. The survey shows a greater number of pharmacies being impacted by the rules than only the two pharmacies citing personal or religious objections. ER at 1684-1725.

VI. SUMMARY OF THE ARGUMENT

A. An Overview Of The Operation Of The Rules

The Plaintiffs challenged only the pharmacy delivery rule and the pharmacist responsibility rule. Over the course of the proceedings, it became clear that their real disagreement lay much more with the stocking rule, which was adopted in 1967. The stocking rule has been subject to only minor revisions over the years. The material portion of the stocking rule 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). [9]

[9] The Stormans refuse to stock Plan B regardless of patient need. Because they refuse to stock the drug, it is never available on the shelf for delivery to patients at the Stormans' pharmacy. As noted above, the Board has

The plain language of the stocking rule controls the assortment of medications that a pharmacy must maintain by making it depend on patient need. Conversely, if the patient population of a particular pharmacy does not need a drug, then the pharmacy would be under no obligation to stock the drug. The stocking rule does not require a pharmacy to maintain a representative assortment of every drug that has been approved by the federal Food and Drug Administration (FDA), but only those drugs needed by its particular patient population. The rule does not necessarily require a pharmacy to stock Plan B or any other particular type of medication.

The stocking rule contains requirements addressing out-dated or contaminated drugs and requiring proper FDA labeling and storage conditions. Wash. Admin. Code 246-869-150(2)-(6). These additional stocking rule requirements are obviously necessary for patient safety.

The pharmacy delivery rule adopted in 2007 requires the pharmacy to deliver time-sensitive medications to its patients on-site rather than refusing to serve the patient or referring the patient to another pharmacy. The Board adopted patient safety exceptions to the delivery rule for situations such as

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made no determination on whether Stormans' pharmacy actually has a patient need for emergency contraceptive such that the stocking rule would require them to stock that medication.

obvious medication errors, contra-indicated prescriptions and fraudulent prescriptions. Wash. Admin. Code 246-869-010(1)(a) and (d). The Board also included an exception when national or state shortages affect availability of the medication, and when specialized equipment would be necessary to safely produce or store the drug. Wash. Admin. Code 246-869-010(a) and (c).

The Board also recognized as a practical matter that a pharmacy may miscalculate demand for a drug and run out of a drug it normally stocks. If the drug is unavailable despite good faith compliance with the stocking rule, the pharmacy does not have to deliver the drug on-site. Wash. Admin. Code 246-869-010(e). Finally, the pharmacy is not required to deliver a drug that the patient cannot pay for Wash. Admin. Code 246-869-010(2).

Where an individual pharmacist declines to dispense a medication, the pharmacy has the obligation of finding a way to deliver the medication to the patient if the medication or the patient's individualized circumstances make the delivery time sensitive. There is no duty on the pharmacy to have a medication available and to deliver medication that is not mandated by the stocking rule, nor is there a duty to deliver a medication that a pharmacy normally maintains, but is temporarily out-of-stock despite good faith compliance with the stocking rule.

As noted above, the duty of the pharmacy to deliver a medication would only arise for medications it was required to have in stock and that are actually sitting on the shelf when the patient requests the medication, but the delivery rule should not be undermined by simply refusing to stock a medication needed by the pharmacies' patients.

B. Free Exercise Jurisprudence As Applied To the Rules

Although the Plaintiffs raised other claims, the core and substance of their case is their free exercise claim. The right to freely exercise one's religion does not relieve an individual of the obligation to comply with a valid and neutral law of general applicability on that ground that the law prescribes conduct that conflicts with the individual's religion. *Smith,* 494 U.S. at 879. A law that is neutral and of general applicability need not be justified by a compelling governmental interest, even though the law has the incidental effect of burdening a particular religious practice. *Lukumi,* 508 U.S. at 531. The validity of the law is not determined by reference to the religious beliefs of persons affected by the law. *Smith*, 494 U.S. at 885.

A law is neutral and generally applicable, even though it may incidentally infringe or restrict religious conduct, unless the object of the law is to prohibit or restrict a particular religious practice or group. *Smith*, 494 U.S.

at 878-79; *Lukumi*, 508 U.S. at 531, 533. Whether a law is neutral is determined from its text, both on its face and from "the effect of a law in its real operation" as determined from the text. *Lukumi*, 508 U.S. at 533-40. A law is not generally applicable if it selectively imposes burdens only on conduct motivated by religious belief. *Lukumi*, 508 U.S. at 543. There is no dispute that the Board's rules are neutral on their face. *Stormans,* 586 F.3d at 1130.

Beyond facial neutrality, this Court previously found the rules also operate neutrally: "They do not suppress, target, or single out the practice of any religion because of religious content . . . . [T]he object of the rules was to ensure safe and timely patient access to lawful and lawfully prescribed medications." ER at 1131. This Court found the regulations to be generally applicable because the rules apply equally to all retail pharmacies and pharmacists and to all lawful medications, "not just those that pharmacies or pharmacists may oppose for religious reasons" and not just to "pharmacies and pharmacists who may have a religious objection to Plan B." ER at 1131.

The Board's survey of pharmacies demonstrated that the rules would impact more pharmacies than only those with religious objections. ER at 432. Among the responding pharmacies, 17 stated they would be impacted by

delivery rules and potentially 28 would have to change their practices regarding emergency contraceptives, but only two pharmacies stated they would be impacted for personal or religious reasons. ER at 432. The Board's survey of pharmacies demonstrates that pharmacies without personal or religious objections to the rules were going to be impacted in greater numbers than pharmacies with personal or religious objections.

Because the challenged rules are neutral and generally applicable, they should have been subjected to rational basis review. *Lukumi,* 508 U.S. at 531; *Stormans*, 586 F.3d at 1137. This Court specifically directed the district court to apply rational basis review on remand. *Stormans*, 586 F.3d at 1137-38. The district court did not comply with that directive and instead applied strict scrutiny.

The district court impermissibly allowed, and indeed directed, a trial focused on discovering the individual intent of Board members, Board staff, the Governor of Washington and her advisors, and persons who testified in public hearings before the Board. Although this evidence is voluminous, none of it constitutes the position of the Board, and it therefore is immaterial to the analysis mandated by *Smith* and *Lukumi.*

The district court abandoned its role as evidentiary gatekeeper, allowing Plaintiffs to repeatedly solicit speculative testimony about how the rules *could* be interpreted or *might* be enforced in scores of hypothetical situations. The district court then cherry-picked among the opinions about what the Board might do and used that speculation as a basis for its findings. ER at 1140-1446, 1481-83.

The district court also erred by developing and affirming its own theory of selective enforcement. In the face of uniform evidence that the Board has not and would not treat Catholic pharmacies any differently than other pharmacies, the district court repeatedly insisted and was emphatic in stating its belief that if a complaint were filed against a Catholic pharmacy, the Board would not enforce its rules. The district court was so fixed in its belief that it became the district court's justification for concluding that the Board's rules did not have rational basis. ER at 11-58. This is a distinction that is not only utterly baseless in the record, but is actually contrary to the testimony of every witness the district court asked about it.

The State Defendants, supported by Defendant-Intervenors, provided abundant and sufficient evidence that the challenged regulations are neutral and generally applicable and were adopted to address a compelling government

interest—timely and efficient access by patients to lawfully-prescribed medicines. Plaintiffs' tortured interpretations of the regulations, supported only by irrelevant evidence of motive or speculative evidence of possible operation, are insufficient to overcome that showing. The district court erred by ruling otherwise. This Court should reverse and vacate the decision and orders entered by the district court, and remand with directions to dismiss the complaint.

C. Free Exercise

1. *Smith* Set the Standard For Reviewing Free Exercise Claims—Rational Basis Review Applies To A Law That Is Neutral And Generally Applicable

The Free Exercise Clause, applicable to the states through the Fourteenth Amendment, *Cantwell v. State of Connecticut*, 310 U.S. 296, 303 (1940), provides that "Congress shall make no law . . . prohibiting the free exercise [of religion]," U.S. Const., amend. I. The right to freely exercise one's religion, however, "does not relieve an individual of the obligation to comply with a 'valid and neutral law of general applicability on the ground that the law proscribes (or prescribes) conduct that his religion prescribes (or proscribes).'" *Smith,* 494 U.S. at 879 (*quoting United States v. Lee,* 455 U.S. 252, 263 n.3 (1982) (Stevens, J., concurring in judgment)). "[A] law that is neutral and of

general applicability need not be justified by a compelling governmental interest even if the law has the incidental effect of burdening a particular religious practice." *Lukumi,* 508 U.S. at 531.

The standard enunciated in *Smith* and *Lukumi*—that a neutral and generally applicable law need not be justified by a compelling governmental interest, even if the law has the incidental effect of burdening a particular religious practice—reflects the Supreme Court's free exercise jurisprudence from the beginning, as this Court recognized in *Stormans*, 586 F.3d at 1127-30. The Supreme Court, in its first case addressing the Free Exercise Clause, upheld a federal statute prohibiting the practice of polygamy despite the burden it places on persons for whom polygamy was part of their religious practice. *Reynolds v. United States,* 98 U.S. 145, 166 (1878). The Court explained that Congress was "free to reach actions which were in violation of social duties or subversive of good order," *id.* at 164, because "[l]aws are made for the government of actions, and while they cannot interfere with mere religious belief and opinions, they may with practices," *id.* at 166.

In *Reynolds*, the Court distinguished between religious belief and religiously-motivated actions. That dichotomy was reaffirmed explicitly when

the Free Exercise Clause was applied to the States in *Cantwell*, 310 U.S. at 303-04:

> [The Free Exercise Clause] embraces two concepts—freedom to believe and freedom to act. The first is absolute but, in the nature of things, the second cannot be. Conduct remains subject to regulation for the protection of society.

This distinction is rooted in the recognition that allowing individual exceptions based on religious beliefs from laws governing general practices "would . . . make the professed doctrines of religious belief superior to the law of the land, and in effect [ ] permit every citizen to become a law unto himself." *Reynolds,* 98 U.S. at 167 (quoted in *Smith*, 455 U.S. at 879). *See also United States v. Lee*, 455 U.S. 252, 261 (1982) ("When followers of a particular sect enter into commercial activity as a matter of choice, the limits they accept on their own conduct as a matter of conscience and faith are not to be superimposed on the statutory schemes which are binding on others in that activity."); *Gillette v. United States*, 401 U.S. 437, 461 (1971) ("Our cases do not at their farthest reach support the proposition that a stance of conscientious opposition relieves an objector from any colliding duty fixed by a democratic government." (quoted in *Smith*, 494 U.S. at 882).

Laws that burdened religiously-motivated conduct consistently have been upheld if they were general laws that advanced legitimate secular goals

and were neutral toward religion. *See*, *e.g.*, *Bowen v. Roy*, 476 U.S. 693, 699 (1986) ("Our cases have long recognized a distinction between the freedom of individual belief, which is absolute, and the freedom of individual conduct, which is not absolute.").

In *Cantwell*, for example, the Court invalidated a state statute requiring a license for religious solicitation because the issuing officer was to determine, as a condition for the license, whether the applicant had a "religious cause." The Court explained, however, that the law would not have been "open to any constitutional objection" had it been neutral toward religion (if it did "not involve any religious test") and of general applicability (a "general regulation"). *Cantwell*, 310 U.S. at 305.

In *Braunfeld v. Brown,* 366 U.S. 599 (1961), the Court found no violation where Orthodox Jews, who voluntarily closed their businesses on Saturday for religious reasons, claimed interference with the free exercise of their religion because of economic hardship caused by laws prohibiting retail sales on Sunday. The Court held that the law "simply regulate[d] a secular activity," *id.* at 605, and reiterated the same position it had taken since *Reynolds*:

> Compulsion by law of the acceptance of any creed or the practice of any form of worship is strictly forbidden . . . [but] the freedom

> to act, even when the action is in accord with one's religious convictions, is not totally free from legislative restrictions.

Id. at 603.

In the more recent *Smith* decision, the plaintiff had been fired from his job after he used peyote for sacramental purposes as part of a religious ceremony. Because his termination rested on his use of peyote in violation of state law, the State denied his application for unemployment compensation. *Smith*, 494 U.S. at 874. The Court started with the familiar premise that government may not regulate religious *beliefs*, but rejected Smith's argument that the Free Exercise Clause bars government from "requiring any individual to observe a generally applicable law that requires (or forbids) the performance of an *act* that his religious belief forbids (or requires)." *Id.* at 878 (emphasis added). "We have never held that an individual's religious beliefs excuse him from compliance with an otherwise valid law prohibiting conduct that the State is free to regulate." *Id.* at 878-79. "[T]he right of free exercise does not relieve an individual of the obligation to comply with a '*valid and neutral law of general applicability* on the ground that the law proscribes (or prescribes) conduct that his religion prescribes (or proscribes).'" *Id.* at 879 (quoting *Lee*, 455 U.S. at 263 n.3 (Stevens, J., concurring in judgment)) (emphasis added).

The Court held that it "contradicts both constitutional tradition and common sense" to make an individual's obligation to obey a neutral and generally applicable law "contingent upon the law's coincidence with his religious beliefs, except where the State's interest is 'compelling'—permitting [each individual], by virtue of his beliefs, 'to become a law unto himself'." *Id.* at 885 (quoting *Reynolds*, 98 U.S. at 167). Government's ability to enforce neutral and generally applicable laws "cannot depend on measuring the effects of a governmental action on a religious objector's spiritual development." *Id.* (quoting *Lyng v. Northwest Indian Cemetery Protective Ass'n,* 485 U.S. 439, 451 (1988). As the Court explained,

> Precisely because "we are a cosmopolitan nation made up of people of almost every conceivable religious preference," and precisely because we value and protect that religious divergence, we cannot afford the luxury of deeming *presumptively invalid*, as applied to the religious objector, every regulation of conduct that does not protect an interest of the highest order. [That rule] would open the prospect of constitutionally required religious exemptions from civic obligations of almost every conceivable kind—ranging from compulsory military service, to the payment of taxes, to health and safety regulation . . . . The First Amendment's protection of religious liberty does not require this.

Smith, 494 U.S. at 888-89 (citations omitted, emphasis in original).

2. *Lukumi* Affirmed The *Smith* Standard And Applied It To Ordinances That Targeted A Particular Religious Practice Of A Single Religious Group

The rule in *Smith* was affirmed in *Lukumi*: "a law that is neutral and of general applicability need not be justified by a compelling government interest even if the law has the incidental effect of burdening a particular religious practice." *Lukumi*, 508 U.S. at 531. However, the city's ordinances at issue in *Lukumi* were neither neutral nor generally applicable—they unambiguously targeted a particular religious practice (ritual animal sacrifice) of a single religious group (adherents of the Santeria religion) and prohibited that practice. The *Lukumi* Court thus dealt with special case— laws whose specific object was "suppression of the central element of the Santeria worship service." *Id.* at 534.

a. Neutrality

In applying the rule from *Smith*, the *Lukumi* Court began by assessing whether the city ordinances prohibiting the killing of animals was neutral. The Court looked first for language that on its face discriminated against religion, reasoning that a law that is facially discriminatory is not neutral. *Lukumi*, 508 U.S. at 533. The challenged ordinances used words with strong religious

connotations ("ritual" and "sacrifice") but their inclusion was not determinative of neutrality because those words also have secular meanings. *Id.* at 534.

The Court next looked at a formal resolution the City had adopted together with the ordinances, and in that document the Court found language specifically targeting a particular religious group, which it identified from the record as the Santerians. *Id.* at 534-35.

Finally, the Court found evidence that the ordinances targeted Santerians by looking at the "effect" of the ordinances in "real operation." *Id.* at 535. The Court determined the "real operation" by examining the texts of the ordinances themselves—not the speculative opinions of witnesses or the parties as to how the ordinances might operate in hypothetical situations. *Id.* at 535-36. Indeed, the only source the Court referenced, beyond the text of the ordinances and the state statute incorporated by reference therein, was a formal advisory opinion the Florida Attorney General had issued on the interpretation of the state statute. *Id.* at 535-36.[10] The Court looked no further to find that the ordinances targeted Santerians and therefore were not neutral. 508 U.S. at 536-39.

[10] *See* Op. Fla. Att'y Gen. 87-56 (1987), available at http://www.myfloridalegal.com/ago.nsf/Opinions/2CF2A00641F0F180852565720056A3AA (last visited Aug. 8, 2012).

Justice Kennedy also would have looked at historical evidence to detect discriminatory intent, but only Justice Stevens joined that portion of the opinion. 508 U.S. at 540-542. The *Lukumi* Court did not approve of inquiries into legislative intent when assessing neutrality; it held that neutrality is determined from the law's text and the effect of its "real operation."[11]

b. General Applicability

The general applicability requirement is intended to prevent government from imposing burdens only on conduct motivated by religious belief. *Lukumi*, 508 U.S. at 543. The Court in *Lukumi* did not define a standard for assessing general applicability, in part because the challenged ordinances were substantially underinclusive, and in part because the City conceded the ordinances were not generally applicable to the killing of animals. *Id.* at 543-

[11] Indeed, one of the attorneys who represented the Santerians in *Lukumi* has written,

> Whatever else it may be, *Lukumi* is not a motive case. . . . We have two votes for motive; we have three votes with no need to consider motive because they think that *Smith* was wrongly decided; we have two votes that say *Smith* was right, but motive is irrelevant to *Smith*; and we have two votes that said nothing about motive one way or the other. Seven Justices failed to find bad motive, but nine voted to strike down the ordinances.

Douglas Laycock, *The Supreme Court and Religious Liberty*, 40 Cath. Law. 25, 28 (2000-2001) (footnotes omitted).

45. The ordinances were underinclusive because they were "drafted with care" to exclude almost all religious and secular conduct except Santerian ritual sacrifice, even though the excluded conduct would produce the very harms the ordinances purported to prevent. *Id.* That was enough for the Court to conclude the ordinances targeted only Santerians and thus were not generally applicable.[12]

The Court also concluded the ordinances selectively imposed burdens "only against conduct motivated by religious belief" because a wide variety of nonreligious animal deaths or kills were either approved or excluded from the prohibitions contained in the ordinances, even though those other deaths or kills invoked the same public concerns the ordinances purported to address. Lukumi, 508 U.S. at 542-46. "[T]he texts of the ordinances were gerrymandered with care to proscribe religious killings of animals but to exclude almost all secular killings." *Id.* at 542.

[12] The Court recognized that neutrality and general applicability are interrelated. *Lukumi*, 508 U.S. at 531. *See also id.* at 557 (Justice Scalia, concurring, joined by Chief Justice Rehnquist).

3. Summary: Rules For Evaluating A Free Exercise Claim

The rules for evaluating a free exercise claim flow from these cases and also were articulated by this Court in its 2009 decision reversing the district court's preliminary injunction in this case, *Stormans,* 586 F.3d 1109:

(1) Government may not regulate religious belief. *Cantwell*, 310 U.S. at 303-04; *Smith*, 494 U.S. at 877. *See also Stormans*, 586 F.3d at 1128.

(2) However, the right of free exercise does not relieve an individual of the obligation to comply with a valid and neutral law of general applicability on the ground that its requirements are inconsistent with the individual's religious beliefs. *Reynolds*, 98 U.S. at 166; *Braunfeld*, 366 U.S. at 603; *Gillette*, 401 U.S. at 461; *Lee*, 455 U.S. at 261; *Bowen*, 476 U.S. at 699; *Lyng*, 485 U.S. at 451; *Smith*, 494 U.S. at 878-79; *Lukumi*, 508 U.S. at 531. *See also Stormans*, 586 F.3d at 1127-28.

(3) The compelling interest test is not applied to a neutral and generally applicable law. *Smith*, 494 U.S. at 885; *Lukumi*, 508 U.S. at 531. *See also City of Boerne v. Flores*, 521 U.S. 507, 514 (1997) (summarizing rule from *Smith*). *See also Stormans*, 586 F.3d at 1127-28.

(4) A law is neutral and generally applicable, even though it may incidentally infringe or restrict religious conduct, unless the object of the law is

to prohibit or restrict a particular religious practice or group. *Smith*, 494 U.S. at 878-79; *Lukumi*, 508 U.S. at 531, 533. *See also Stormans*, 586 F.3d at 1129-30.

(5) Whether a law is neutral is to be determined from its text, on its face and in its "real operation"—not from the use of history to attempt to discern the intent of the lawmakers. *Lukumi*, 508 U.S. at 533-40. *See also Stormans*, 586 F.3d at 1130.

(6) A law is not generally applicable where "in a selective manner [it] impose[s] burdens only on conduct motivated by religious belief." *Lukumi*, 508 U.S. at 543. *See also Stormans*, 586 F.3d at 1134.

(7) Only if a law is found not to be neutral and generally applicable does the Court then assess whether any substantial burden on religious practice imposed by the law must be justified by a compelling government interest and narrowly tailored to advance that interest. *Smith*, 494 U.S. at 882-85; *Lukumi*, 508 U.S. at 531, 533. *See also Stormans*, 586 F.3d at 1137 (rational basis review applies where the challenged law is neutral and generally applicable). Unconstitutionality must be demonstrated; it is not presumed if a statute is facially neutral. *Locke v. Davey*, 540 U.S. 712, 720 (2004) (such a

presumption "would extend the *Lukumi* line of cases well beyond not only their facts but their reasoning").

4. The Challenged Rules Are Neutral And Generally Applicable In Their Real Operation

The plain text of the Board's rules and the Board's official statements are neutral on their face making no references to any religion or distinguishing between different religions. The finding of the district court that the rules make distinctions between Catholic pharmacies and other faith-based or even secular pharmacies is not supported in the language of the rules or in any explanatory statements published by the Board.

Beyond the text of a rule the Court in *Lukumi* held that a rule would not be neutral "where the object of the law is to infringe upon or restrict religious practices because of their religious motivation." *Lukumi,* 508 U.S. at 533. In conducting the inquiry into neutrality, the Court looked at whether the ordinance was under-inclusive impacting only religious practices, but not others. *Lukumi,* 508 U.S. at 536. The Court also examined whether a rule was suspect by being over-inclusive impacting only a religious practice in a manner unnecessary to support the purpose of the ordinance. *Lukumi,* 508 U.S. at 538.

Applying the principles in *Likumi* to this case, the Board's rules are neither underinclusive nor over-inclusive relative to their stated objective of

improving access to time- sensitive medications; the rules therefore are neutral. The stocking rule requires a pharmacy to maintain a representative assortment of the medications needed by its patients. Wash. Admin. Code 246-869-150(1). This requirement applies neutrally to all medications and has been in effect since 1967. Because the stocking rule was adopted decades before Plan B, or any other emergency contraceptives were on the market, there can be no colorable argument that the "object of [the stocking rule] is to infringe upon" the Plaintiffs religious objections to Plan B. *See Lukumi,* 508 U.S. at 533. There is no serious dispute that the requirements of the stocking rule are completely neutral regarding religion and any impact on Plaintiffs religious objections to Plan B are incidental to that long-standing rule.

The plain text of the 2007 delivery rule applies to all of the approximately 200 time sensitive medications, not just to Plan B or *ella.* Wash. Admin. Code 246-869-010; ER at 1675. There are no statements by the Board suggesting the delivery rule is required only for Plan B and *ella,* nor are the exceptions to the delivery rule crafted in such a way that only Plan B or *ella* would have to be delivered on-site from the shelf to the patient. There is simply no reasonable construction of the text of the rules or of any other document or position adopted by the Board that supports the district court's

conclusion that the object of the Board was to gerrymander the delivery rule so that it would apply only to Plan B and *ella*[13].

The district court's conclusion that the burden of complying with rules falls almost exclusively on religious objectors to Plan B also is bereft of support in the language of the rules or in the Board's official statements. Further, that conclusion necessarily ignores the facts revealed by the Board's survey. The survey showed that 17 responding pharmacies would have to hire additional staff in order to comply with the new rules. Twenty-eight pharmacies may have to change their stocking practices for Plan B depending on their patient needs, not just the two pharmacies with religious objections. ER at 1684-1725. There is no factual basis for the District court's conclusion that only religious objectors to Plan B are impacted by the rules. In fact, the evidence from the survey shows a greater number of pharmacies being impacted by the rules that are not religious objectors. ER at 1684-1725.

As previously noted by this Court:

[13] There is an implied assumption in much of district court's thinking, and certainly in Plaintiffs' arguments, that any rules requiring the stocking or delivery of Plan B are the product of anti-religious animus. There is no support for such an assumption. That Plaintiffs' religious beliefs compel them to oppose Plan B does not mean that people who support the availability of Plan B are anti-religious.

> That the rules may affect pharmacists who object to Plan B for religious reasons does not undermine the neutrality of the rules. The Free Exercise Clause is not violated even though a group motivated by religious reasons may be more likely to engage in the proscribed conduct.

Stormans, 586 F.3d at 1131. Based on the survey, it does not even appear that religious objectors to Plan B are more likely to be impacted by the rules then licensees working without personal or religious objections. ER 1684-1725.

A requirement for a pharmacy to get a medication from its shelf and to its patient, unimpeded by non-clinical barriers promotes access to medication. The "access" issue promoted by the delivery rule is not concerned with the general availability of time-sensitive medications across the state or within a community, but with getting that time- sensitive medication across the counter when it is sitting right on the shelf and the patient needs it.

There are approximately 200 time sensitive medications currently on the market. ER at 1567-73. The stocking and delivery rules apply to all of them. The fact that the Plaintiffs and various lobbyists were focused only on Plan B and *ella* does not narrow the application of the rules as adopted by the Board. The rules are neither underinclusive nor over-inclusive in promoting access to medications. As previously explained by this Court:

> How much the new rules actually increase access to medications depends on how many people are able to get medication that they might previously have been denied based on religious or general moral opposition by a pharmacist or pharmacy to the given medication. Whatever that number, it will not be smaller than the number of pharmacists or pharmacies affected by the regulation, so it cannot be shrugged off as insignificant.

Stormans, 586 F.3d at 1135.

Most exceptions found in the delivery rule involve situations where patient safety is at issue due to contra-indications, lack of specialized equipment and expertise, or fraudulent prescriptions. Wash. Admin. Code 246-869-010. Other exceptions are made for situations where national or state emergencies result in shortages or rationing, or where a pharmacy cannot deliver a medicine that is unavailable despite good faith compliance with the stocking rule. Wash. Admin. Code 246-869-010. Finally, the pharmacy does not have to deliver a medication if the patient cannot pay for it. Wash. Admin. Code 246-869-010.

These exceptions are unchanged from the last time this Court reviewed them and found them to be narrow and not subject to serious question. *Stormans,* 586 F.3d at 1135. The fact that there are some exceptions to the delivery mandate does not mean the Board is required to grant all requests for exemptions. *Id*.

The Plaintiffs and the district court labeled all of the exceptions to the stocking and delivery rules as "secular" exceptions. Of course, any exception that is not grounded in religion is a secular exception. The district Court's conclusion that the neutrality and generality of the rules are undermined because they allow "countless secular exceptions, but not religious ones" misunderstands the holding of *Lukumi* as to when exceptions support a finding of religious animus. It is not the number of "secular" exceptions that is significant, rather, it is when a secular exception is allowed and a similar religious exception is not. *Lukumi,* 508 U.S. at 536-37. No situation under the rules, or in the Board's disciplinary history, has been identified in which a religious objection is not allowed, but a similar secular reason is allowed.

If the stocking or delivery rules allowed a licensee to decline to comply based upon personal biases, dislikes, or prejudices, but not on religious grounds, then the district court would have a point. However, nothing in the rules makes such distinctions. Nor does the enforcement history of the Board support a finding that only religious objectors are subjected to discipline for violations of the rules while complaints based on similar secular conduct are being dismissed. The exemptions do not excuse licensees with no religious objections to the rules from compliance with the delivery rules in any

circumstance in which they would not also excuse those with religious objections to the rules. The circumstances when a pharmacy can refer a patient to another pharmacy rather than stock and deliver a medication are identical for licensees with religious objections as for licensees without religious objections.

5. The Errors Of The District Court Were Largely Driven By Its Incorrect Understanding Of The Distinction Between The Operation Of The Rules And Disciplinary Enforcement Of The Rules

A consistent and erroneous theme from the district court was that the rules are only "enforced" against religious objectors to Plan B. ER at 40, 42. This is incorrect on two different grounds. First, once the rules are adopted they are the law of the land for all licensees and are 'in force' as to all licensees and medications. Second, neither the Plaintiffs nor any other licensee with religious objections to Plan B has been subjected to discipline for not providing the medicine.

For example, the fact that the Board has not found it necessary to discipline a licensee for violating the stocking rule during the rule's 45-year existence does not mean the rule is not in force or that licensees do not have to comply with the stocking rule. The obligation of licensees to comply with adopted regulations and the decision of the Board on when to take disciplinary

action are two different things that were consistently conflated by the district court.

Enforcement of the rules by the Board is ultimately done through the disciplinary process. The findings of the district court that the rules are not neutral and general because the rules are not being enforced against Catholic or secular licensees improperly conflates the free exercise and equal protection analysis. Whether the Board is selectively enforcing the rules against the Plaintiffs in violation of the Equal Protection Clause is a separate analysis with different elements than the Free Exercise Clause analysis. The district court's summary conclusion that those analyses are the same is in error.

D. There Is No Evidentiary Support For The District Court's Conclusion That The Board Has Selectively Enforced Its Rules Against The Plaintiffs

Under the Equal Protection Clause of the Fourteenth Amendment a neutral and general rule can be enjoined on an as-applied basis when it is proven that the rule is being selectively enforced upon impermissible grounds, such as religious bias. *Rosenbaum v. City & County of San Francisco,* 484 F.3d 1142, 1152-54 (9th Cir. 2007). To establish a selective enforcement claim, there must be evidence that enforcement had a discriminatory effect and the Board was motivated by a discriminatory purpose. *Rosenbaum,* 484 F.3d at

1152. Discriminatory effect is proven by showing similarly situated individuals were not disciplined. *Rosenbaum,* 484 F.3d at 1153, citing *United States v. Armstrong*, 517 U.S. 456 (1996). Discriminatory purpose is proven by showing that the disciplining authority selected a course of action "because of, not merely in spite of, its adverse effects upon an identifiable group." *Rosenbaum,* 484 F.3d at 1153.

When a rule is facially neutral a plaintiff is required to demonstrate discriminatory intent in enforcement decisions. *Wayte v. United States,* 470 U.S. 598, 610 (1985). As stated by this Court in *Bloodworth:*

> The conscious exercise of some selectivity in enforcement is not in itself a federal constitutional violation. *Freeman v. City of Santa Ana,* 68 F.3d 1180, 1188 (9th Cir.1995); *Bordenkircher v. Hayes,* 434 U.S. 357, 364 (1978). To establish impermissible selective enforcement, Plaintiffs must show (1) that Defendants did not take action against others similarly situated to Plaintiffs, and (2) that the selective action against Plaintiffs "was deliberately based upon an unjustifiable standard such as race, religion, or other arbitrary classification." *Hayes,* 434 U.S. at 364; *U.S. v. Lee,* 786 F.2d 951, 957 (9th Cir. 1986).

Bloodworth v. City of Phoenix, 26 Fed. Appx. 679, 682 (9th Cir. 2002).

The findings of the district court that the Board has exercised enforcement of its rules only against religious objectors to Plan B has no support in the record. ER at 1737. No disciplinary action to enforce the rules has been entered by the Board against these Plaintiffs, or against any licensee

with religious objections of any type to any rule. On the five occasions in which the Board has issued disciplinary action against a licensee under the stocking rule, none of those cases involved emergency contraceptives or licensees with religious objections to the rules. ER at 1461. No licensee has been disciplined under the new delivery rule. ER at 1461.

Regarding the Stormans pharmacy specifically, there were a total of 24 complaints filed against Stormans including the filings against its Responsible Pharmacist, Mr. Berdinka. ER at 1739-43. These complaints were all filed at nearly the same time during the period when Ralph's Thriftway and its pharmacy were being picketed by members of the community and all involved failure to provide Plan B. ER at 1739-43. Rather than using the complaints as an opportunity to target Stormans, the Board dismissed every single complaint until the district court ordered the Board to stop processing complaints involving the Stormans. ER at 643-69, 1185, 1530-32, 1537, 1561:3-16.

The threshold element of a selective enforcement claim–that the Plaintiff was treated differently than a similarly situated person–cannot be established where the Plaintiff has not been disciplined by the regulatory body. *Rosenbaum,* 484 F.3d at 1152. There is no pattern of discipline being issued by the Board supporting any inference of anti-religious bias, nor could there be

when no licensee citing religious objections has ever been disciplined and the only licensee who have been disciplined were not religious objectors. The equal protection claim based on the selective enforcement theory should have been dismissed by the district court.

E. The Board's Complaint Driven System of Discipline Does Not Violate Equal Protection

The Board has historically followed a passive enforcement model in which disciplinary action is triggered when a complaint is filed with the Board. The witnesses familiar with the Board's practices referred to this as a "complaint-driven system". ER at 1449, 1477-78. Passive enforcement models do not violate equal protection. *Wayte,* 470 U.S. at 608.

In *Wayte,* the Supreme Court reviewed a passive enforcement policy in which only non-registrants who actually came to the attention of the Selective Service by filing written notice of their non-compliance were selected for prosecution. *Wayte,* 470 U.S. at 605. The Court did not find the passive enforcement policy to be unlawful selective enforcement under the First or Fifth Amendments even though the Department of Justice could have located and prosecuted non-registrants who did not file written notice. *Wayte,* 470 U.S. at 610.

In this case the district court found the Board's passive enforcement model, or complaint-driven system, to violate the Plaintiffs equal protection rights under a selective enforcement theory. In particular, the district court found in favor of its sua sponte theory that selective enforcement as to these Plaintiffs was established because the Board was not prosecuting other violations, and in particular, was not taking disciplinary action against Catholic-affiliated out-patient pharmacies. ER at 112, 147. It is undisputed that no complaints have been filed against Catholic-affiliated out-patient pharmacies and thus there has been no basis for the Board to consider discipline under it complaint driven process.

The district court's single-minded focus on Catholic pharmacies was untroubled by the different treatment that would arise if the Board were to follow the Court's preference and begin disciplining Catholic outpatient pharmacies without an underlying complaint. ER at 1109-10. Further, the district court never explained how the lack of prosecution against other licensees establishes selective prosecution of the Plaintiffs when the Plaintiffs have not been prosecuted.

The district court also found that the complaint-driven system was allowing unwritten exceptions to be built into the rules through a system of

simply not prosecuting the violations of the rules. ER at 39, 42. As described above, the district court's findings of "unwritten exceptions" stem from two sources: 1) the opinions of various witnesses about what the Board might or might not do in a hypothetical situation, and 2) the erroneous premise that failure to prosecute violations is the same thing as adopting an exception to the rules.

Between 1995 and 2008, there were 170 complaints for refusing to dispense or failure to stock medications, and untimely filling of prescriptions. ER at 750, 1176-77. Of these 170 complaints, 111 were closed without investigation and investigations were authorized for 54 complaints.[14] ER at 1177-80, 1737. Out of the 54 complaints for which investigations were authorized, only 14 involved Plan B and the remaining 40 involved drugs other than Plan B. ER at 751, 1181-82. In addition, the Board did not authorize investigations for 19 complaints involving Plan B. ER at 751, 1182;. With the exception of five instances, all of the investigations for refusals to dispense medications were closed. ER at 1188-89. For the five cases that were not closed, four resulted in a notice of correction and the fifth case resulted in an

[14] The status of two complaints is unknown because the records could not be located, and three complaints were placed on hold as a result of the preliminary injunction and the conditions in the agreed order staying the trial pending this Court's decision on the appeal of the preliminary injunction.

agreed order. ER 1189. Notably, none of the five cases where the Board took enforcement action involved Plan B or religious objections to the rules. ER at 1189.

Witnesses consistently testified that if complaints were filed for the multitude of scenarios encompassed by Plaintiffs in their hypothetical questions, those complaints would be treated the same with respect to the process for investigative authorization. The religious affiliations or preferences of the licensee are not a factor in the decision whether to take enforcement action by issuing charging documents. Nothing in the text of the rules, in the official Board publications about the rules, or its actual enforcement of the rules suggests any religiously based distinctions have been made by the Board. ER at 1118-19, 1234, 1430-31, 1433-34, 1436, 1476, 1479-80, 1485, 1538-43, 1545-51.

Witnesses during the trial consistently stated that there would be no difference in the processing of complaints against Catholic-affiliated out-patient retail pharmacies and non-religiously affiliated out-patient retail pharmacies.[15] No evidence or enforcement history showing different treatment

[15] Catholic-affiliated hospital in-patient pharmacies stock and deliver emergency contraceptives to sexual assault patients presenting in their emergency rooms as required by Wash. Rev. Code § 70.41.350. ER at 1486-

by the Board for Catholic-affiliated pharmacies was presented. ER at 1107-10; 1456-57; 1429-30; 1437-39.[16] No witness opined that the Board would treat Catholic affiliated out-patient pharmacies any differently than other religiously affiliated out-patient pharmacies, nor differently than pharmacies with no religious affiliation. As of the dates of trial, no complaints had been filed against Catholic-affiliated out-patient pharmacies for failing to timely deliver medications to patients. ER at 1189-90.

There has been no enforcement action against any pharmacy or pharmacist for failing to stock or dispense Plan B. ER at 1450-51. Nor has there been any enforcement action against any pharmacy for a violation of the delivery rule, Wash. Admin. Code 246-869-010. Accordingly, there is no history of enforcement rulings and thus no ability to discern any pattern of religious animus.

There is no evidence supporting a selective enforcement violation of the Equal Protection Clause and those claims should have been dismissed.

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89. When licensed hospitals are inspected, their compliance with Wash. Rev. Code § 70.41.350 is verified. No Catholic-affiliated hospital has been found to be non-compliant with this requirement between June 2009 and December 2011. ER at 1509-10.

[16] These witnesses also consistently testified that these would be Board decisions, not the decision of a Board employee or a single member of the Board. ER at1254-55; 1458.

1. The Rules Have A Rational Connection To Washington's Legitimate Interest In Promoting The Health Care Of It's Citizen-Patients

Once the rules are found to be neutral and general (and free of selective enforcement issues), the only remaining question is whether the rules are rationally related to a legitimate governmental interest. The mere ability to hypothesize reasons that are arguable or plausible warrants upholding the enactment under the rational basis test. *Brandwein v. California Bd. Of Osteopathic Examiners,* 708 F.2d 1466, 1471 (9th Cir. 1983). Under both the Free Exercise Clause and the Equal Protection Clause, a Plaintiff bears the burden to negative every conceivable basis for the rules under the rational basis standard of review. *Brandwein,* 708 at 1471.

Disputed questions of fact do not doom a rule when the question is whether a rational basis exists for an enacted rule. *F.C.C. v. Beach Commc'n, Inc.,* 508 U.S. 307, 315, (1991):

> [B]ecause we never require a legislature to articulate its reasons for enacting a statute, it is entirely irrelevant for constitutional purposes whether the conceived reason for the challenged distinction actually motivated the legislature. Thus, the absence of 'legislative facts' explaining the distinction "[o]n the record" has no significance in rational-basis analysis. In other words, *a legislative choice is not subject to courtroom fact-finding and may be based on rational speculation unsupported by evidence or empirical data.*

Id., 508 U.S. at 315 (internal citations omitted, emphasis added).

A rule should not be stricken under the rational basis test because the court believes the rule to be unwise, unlikely to achieve its goal, or that the rule provides only a partial solution to a problem. *F.C.C. v. Id.,* 508 U.S. at 315. In applying the rational basis test to health care licensing, the Ninth Circuit has held:

> [W]e do not require that the government's action actually advance its stated purposes, but merely look to see whether the government *could* have had a legitimate reason for acting as it did. We need only determine whether the licensing scheme has a "conceivable basis" on which it might survive rational basis scrutiny.

Nat'l Assoc. for Advancement of Psychoanalysis v. California Bd. of Psychology, 228 F.3d 1043, 1050 (9th Cir. 2000) (internal citations omitted).

The district court ruled that the rules lack even a rational basis because of how the district court believed the rules and the Board's application of the rules treat Catholic out-patient pharmacies differently. The complete absence of any evidence to support that opinion was explained above. However, because of its admittedly single-minded focus on Catholic pharmacies, the district court did rule on whether the rules are rationally related to legitimate governmental interests. ER 1034-1036; 1109; 1248. As this Court recognized

in *Stormans,* 586 F.3d at 1139, there is a rational relationship between rules that reduce barriers to patient access are rationally related to Washington's interest in ensuring that patients receive their medications in a timely manner.

Courts judge neither the wisdom nor the fairness of the rules, but only whether a rational basis exists for the adopted rules. *Nat'l Assoc. for Advancement of Psychoanalysis,* 228 F.3d at 1051. The Plaintiffs' arguments that there are other ways, or even better ways, to promote the State's interest in accessing medications without delay is immaterial to the rational basis test.

The rational basis of the rules promoting access to time-sensitive medications was not negative by the Plaintiffs. The rules should be upheld under the rational basis test.

VII. CONCLUSION

The district court erred in declaring Wash. Admin. Code 246-869-010, -150, 246-863-095 unconstitutional, as applied to Plaintiff-Appellees, under the Free Exercise Clause of the First Amendment and the Equal Protection Clause of the Fourteenth Amendment; and in permanently enjoining Defendants-Appellants from enforcing those administrative rules against Plaintiffs-Appellees. This Court should reverse the district court, vacate its decisions and orders in this case, and dismiss Plaintiff-Appellees' complaint.

RESPECTFULLY SUBMITTED this 27th day of August, 2012.

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STATEMENT OF RELATED CASES

The State is aware of Case Number 12-35224, in which Legal Voice (formerly the Northwest Women's Law Center), a non-party to the litigation, appeals the district court's orders related to third-party discovery. The issues presented there have nothing to do with the merits issues presented in these consolidated appeals, however.

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