Nos. 12-35221 & 12-35223

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

STORMANS INC., doing business as Ralph's Thriftway, *et al.*,
Plaintiffs-Appellees,

v.

MARY SELECKY, *et al.*,
Defendants-Appellants,

and

JUDITH BILLINGS, *et al.*,
Intervenors-Appellants.

On Appeal from the United States District Court
for the Western District of Washington
No. 07-CV-05374-RBL
(Hon. Ronald B. Leighton)

BRIEF OF AMICI CURIAE AMERICAN PHARMACISTS ASSOCIATION, WASHINGTON STATE PHARMACY ASSOCIATION, AND 33 OTHER NATIONAL AND STATE PHARMACY ASSOCIATIONS IN SUPPORT OF PLAINTIFFS-APPELLEES

Jason A. Levine
Eric A. White
VINSON & ELKINS LLP
2200 Pennsylvania Avenue, N.W.
Suite 500 West
Washington, D.C. 20037
Telephone: (202) 639-6755
Facsimile: (202) 639-6604
jlevine@velaw.com

Counsel for Amici Curiae

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, all amici curiae state that they do not have parent corporations and no publicly held corporations own 10% or more of their stock.

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INTEREST OF AMICI CURIAE[1]

Drawing upon over a century of work representing pharmacists, amici present to the Court vital information about historical state regulation of pharmacy practice and the harsh economic and ethical consequences of the Washington regulation. Amici are four national pharmacy associations and state pharmacy associations from 31 States, including Washington:

National Pharmacy Association Amici

The **American Pharmacists Association** ("APhA") was founded in 1852 as the American Pharmaceutical Association. It is the first-established and largest national pharmacist organization in the United States, representing more than 62,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians. The APhA provides professional information and education for pharmacists and advocates for improving medication use and advancing patient care in the United States. The APhA has participated as amicus curiae in other litigation involving regulations similar to those at issue in this appeal. *See Morr-Fitz, Inc. v. Blagojevich*, 901 N.E.2d 373 (Ill. 2008).

[1] All parties have consented to the filing of this brief. Fed. R. App. P. 29(a). Pursuant to Fed. R. App. P. 29(c)(5), amici curiae hereby certify that this brief was authored solely by amici and their counsel listed on the cover, and that no person other than amici and their members contributed money that was intended to fund preparing or submitting this brief.

Other amici nationwide pharmacy associations with interests similar, if not identical, to APhA's are: **American Association of Colleges of Pharmacy**, **International Association of Compounding Pharmacists**, and **National Alliance of State Pharmacy Associations**.

State Pharmacy Association Amici

Founded in 1890, the **Washington State Pharmacy Association** ("WSPA") is a professional association representing Washington pharmacists, technicians, student pharmacists, and pharmacies practicing in all areas of healthcare. The WSPA's members care for patients in wide variety of settings, including community pharmacies, hospitals, clinics, and long term care facilities.

Joining the WSPA as amici are 30 other state pharmacy associations with the same interest as the WSPA's for their respective States: **Alabama Pharmacy Association**, **Alaska Pharmacists Association**, **Arizona Pharmacy Association**, **Connecticut Pharmacists Association**, **Florida Pharmacy Association**, **Georgia Pharmacy Association**, **Hawaii Pharmacists Association**, **Illinois Pharmacists Association**, **Kansas Pharmacists Association**, **Kentucky Pharmacists Association**, **Maryland Pharmacists Association**, **Massachusetts Pharmacists Association**, **Minnesota Pharmacists Association**, **Missouri Pharmacy Association**, **Nebraska Pharmacy Association**, **New Mexico Pharmacists Association**, **North Carolina Association of Pharmacists**, **North Dakota**

Pharmacists Association, **Ohio Pharmacists Association**, **Oklahoma Pharmacists Association**, **Oregon State Pharmacy Association**, **Pennsylvania Pharmacists Association**, **Pharmacists Society of the State of New York**, **Pharmacy Society of Wisconsin**, **South Carolina Pharmacy Association**, **South Dakota Pharmacists Association**, **Tennessee Pharmacists Association**, **Texas Pharmacy Association**, **Virginia Pharmacists Association**, and **West Virginia Pharmacists Association**.

SUMMARY OF ARGUMENT

Washington's "delivery" rule marks a radical departure from past regulation of the pharmacy industry. *First*, it breaks with the longstanding tradition by which pharmacies enjoyed considerable discretion to choose for themselves which of the thousands of available prescription drugs to offer. Those stocking choices are a routine decision for pharmacies, which they make for a wide variety of business, economic, or convenience reasons. Indeed, that many pharmacies have established themselves as "niche" pharmacies, deliberately stocking only certain kinds of drugs to serve a particular market, is a testament to the independence pharmacies have long enjoyed under state "stocking" rules. *Second*, the rule effectively does away with a pharmacist's right *not* to participate in actions he conscientiously opposes, even though a "right of conscience" is widely seen as an integral part of the ethical practice of pharmacy. Such a right could easily be harmonized with the

patient's interest in receiving prescription drugs through the time-honored practice of facilitated referral—which the Washington rule bans for instances of conscientious objection. Instead, Washington's "accommodation"—allowing a second pharmacist at a given pharmacy to fill the prescription if the first objects—will be of little comfort to the many pharmacists working at small pharmacies that cannot afford to have a second pharmacist on duty. *Third*, the rule establishes Washington as an outlier—not only among the vast majority of States that protect referrals for reasons of conscience, but even among the small handful of States that also have a "delivery" rule.

ARGUMENT

The Washington regulation conflicts with the discretion state regulations have historically recognized pharmacies need to exercise over stocking decisions, and runs roughshod over the well-established conscience rights of pharmacists. Although a policy of "facilitated referral" would permit pharmacists to serve patients fully while also preserving their conscientious objections, the Washington regulation bans referrals based on conscience.

I. Pharmacies Have Historically Exercised Broad Discretion Over What Drugs To Stock, Demonstrating the Overbreadth of the Washington Regulation.

Amici have long supported "the rights and responsibilities of individual pharmacists to determine their inventory and dispensing practices based on patient

need, practice economics, practice security, and professional judgment."[2] Running a successful pharmacy is no easy endeavor—and one of the hardest, and most crucial, tasks for any pharmacy is managing its stock inventory of prescription drugs. That inventory "represents the pharmacist[']s biggest investment."[3] Traditionally, state regulation of stocking decisions has left pharmacies with significant discretion in determining the type and quantity of prescription drugs they offer.

A. Pharmacy Inventories Vary Widely Given the Vast Number of Stockable Drugs and the Rise of Niche Pharmacies.

As of October 2012, there were 6,348 FDA-approved drugs.[4] With interchangeable generics, this number climbs to well over 10,000.[5] Unsurprisingly, "no pharmacy can stock everything." Susan Alverson, *Managing Inventory in a Pharmacy*, J. Pharm. Soc'y of Wis. 59, 59 (Jan./Feb. 2011). Indeed, as the APhA

[2] *E.g.*, APhA, *1983 Stocking a Complete Inventory of Pharmaceutical Products*, Am. Pharm. NS23(6):52 (June 1983) (reviewed 2004, 2010); *accord* APhA, *Current APhA Policies Related to the Practice Environment & Quality of Worklife Issues* (2002), https://www.aphafoundation.org/AM/Template.cfm?Section=Home&ContentID=2573&template=/CM/ContentDisplay.cfm.

[3] Nat'l Community Pharm. Ass'n, *Managing the Pharmacy Inventory* (2008), http://www.ncpanet.org/members/pdf/ownership-managinginventory.pdf.

[4] *See* Food & Drug Admin., *Drugs@FDA*, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Search_Drug_Name.

[5] *See, e.g.*, Matthew Perrone, *Defective Generic Pill Revives Quality Concerns*, StarTribune (Oct. 4, 2012), *available at* http://www.startribune.com/printarticle/?id=172724731 ("'There are approximately 10,000 FDA-approved interchangeable generics in the U.S.'") (quoting Ralph Neas, CEO of the Generic Pharmaceutical Association).

stated in congressional testimony, "[w]ith more than 10,000 medications on the market today, it is impossible for a typical pharmacy to carry all medications—and unnecessary as well."[6] Accordingly, "most pharmacies only stock about 15% of available drugs on a given day" and "pharmacies choose to stock only those medications that best match the needs of the community they serve." Robin Fretwell Wilson, *The Limits of Conscience: Moral Clashes Over Deeply Divisive Healthcare Procedures*, 34 Am. J.L. & Med. 41, 54 (2008).

The basic decision of which and how many drugs to stock is one of the most important for any pharmacy, big or small. When a pharmacy *under*stocks drugs that are popular with its customers, it is "[unable] to fill prescriptions,"[7] "result[ing] in lost sales." Yasar A. Ozcan, *Quantitative Methods in Health Care Management: Techniques and Applications* 252-53 (2d ed. 2005). Conversely, when a pharmacy *over*stocks, "money is lost while products sit on the shelf," Medvedeff, *supra* note 7; this cost "can be staggering" for a number of reasons, including "interest, insurance, taxes (in some States), depreciation, obsolescence,

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[6] *Freedom of Conscience for Small Pharmacies: Hearing Before the H. Comm. on Small Business*, 109th Cong. 66 (2005) (statement of Linda Garrelts MacLean, APhA, *available at* http://www.gpo.gov/fdsys/pkg/CHRG-109hhrg22612/pdf/CHRG-109hhrg22612.pdf (hereafter "MacLean Testimony").

[7] David Medvedeff, *Building Business Management Skills Provides Additional Opportunities for Professional Growth*, Pharm. Student 14 (May/June 2005), *available at* https://www.aphafoundation.org/AM/Template.cfm?Section=Building_Business_Management_Skills_Provides_Additional_Opportunities_for_Professional_Growth.

deterioration, spoilage, pilferage, and breakage." Ozcan, *supra*, at 252-53. But maintaining the delicate balance between having too little or too much of any one drug is nothing new. These kinds of pharmacy stocking decisions are a decades-old problem integral to the profession. *See, e.g.*, Frank A. Delgado & Arthur A. Kimball, *The Professional Pharmacy*, 22 J. Am. Pharm. Ass'n 883 (1933) (discussing strategies for maintaining the most common ingredients for drugs).

A host of factors, including the pharmacist's "preferred practice, [the] organization's mission, space restrictions, and budget . . . influence stocking decisions."[8] By and large, these decisions are made at the individual pharmacy level, based on the perceived needs of the pharmacy's customers or the pharmacy's chosen business practices. As even the United States Government recognizes in its own pharmacies: "[We do] not stock all medications. The VA has a list of medications . . . that meets the needs of our veterans. This list is often updated and new drugs are added while some are removed." U.S. Dep't of Veteran Aff., *Philadelphia VA Medical Center Pharmacy*, http://www.philadelphia.va.gov/services/pharmacy.asp; *accord* Department of the Air Force, *Fact Sheet*, http://www.scott.af.mil/library/factsheets/factsheet_print.asp?fsID=16369&page=1

[8] Marie A. Chisholm-Burns et al., *Pharmacy Management, Leadership, Marketing, and Finance* 166 (2011); *see also id.* ("Although the demands and expectations of your market are important, so are your own expectations or those of your organization. . . . Beyond preferred options of items to stock, a variety of factors will influence . . . the choice to stock or not to stock.").

("Although we do not stock every drug, our formulary is very robust and is designed to meet the majority of our beneficiaries' prescription needs."); *see also, e.g.*, Fla. Atlantic U. Student Health Servs. Pharmacy, *Over-the-Counter Products* 2, http://www.fau.edu/shs/healthinfo/091649_Pharmacy_Brochure.pdf ("In order to keep costs at a minimum, the pharmacy does not stock every prescription medication."); Apopka Discount Drug Store, http://www.apopka discountdrugs.com ("We decide locally and independently what to carry to fulfill our customers' needs."). This is no different in Washington. *See, e.g.*, *Stormans, Inc. v. Selecky*, 854 F. Supp. 2d 925, 933 (W.D. Wash. 2012).

Indeed, even major pharmacy chains with locations throughout the country make stocking decisions at the local level. For instance, CVS stocks its pharmacies "based on the prescribing needs of the community, so inventory levels for different medications will vary by location based on those needs."[9] Walgreens also decides what drugs to stock primarily based on local "supply and demand."[10]

Further, not all stocking decisions are purely a matter of economics. Pharmacies have a wide variety of reasons for stocking or not stocking particular drugs. For example, an increasing number of pharmacies have decided not to stock

[9] John M. Annese, *Legitimate Users Fall Victim to Rx Drug Abusers*, Staten Island Advance (Mar. 26, 2011), http://www.silive.com/news/index.ssf/2011/03/legitimate_users_fall_victim_t.html.

[10] *Id.*

drugs such as oxycodone or Roxicodone, both opiates subject to prescription drug abuse, in part due to the increased risk of burglary and theft from drug abusers.[11] One pharmacy, operating as part of a free clinic, chooses not to stock any "controlled drugs, psychotropic drugs, medical marijuana or narcotics of any sort."[12] Indeed, many clinics have made the decision not to seek regulatory authority to carry controlled substances. The pharmacy at the University of North Carolina-Wilmington is one such example; it advises patients that it "does not stock any controlled substances, so these prescriptions will need to be filled at a local drug store."[13] Pharmacies routinely make these sorts of stocking (and referral) decisions for reasons wholly aside from just staying in business. *See, e.g.*, *Stormans*, 854 F. Supp. 2d at 953-54 (listing examples of the "wide variety of business, economic, and convenience reasons" pharmacies choose not to stock particular drugs); *see also id.* at 955-56 (listing examples of the "wide variety of business, economic, or convenience reasons" pharmacies refer patients elsewhere).

Some pharmacies have taken routine stocking decisions one step further, deciding to maintain a particular stock of drugs to generate for themselves a unique and loyal customer base. These niche pharmacies have become increasingly

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[11] *Id.*

[12] Ferndale Free Clinic, Inc., *Volunteering at the Clinic*, http//ferncare.org/volunteer.

[13] UNCW Pharmacy, *Frequently Asked Questions*, http://uncw.edu/healthservices/documents/PharmacyFAQ_000.pdf.

popular, especially for small, independent pharmacies. As in any industry, major chains often enjoy pricing and branding advantages over smaller competitors, so "[m]any independent pharmacies find a niche and specialize."[14] Indeed, pharmacies have long been moving in the niche direction for several reasons, from allowing pharmacists to specialize in medication concerning particular diseases or age-groups, to providing the freedom to carry only products the pharmacists believe in, to enabling more in-depth consultations with patients.[15]

Myriad examples of this new type of specialty pharmacy can be found across the country. To take just a few, Assured Pharmacy operates a store in Kirkland, Washington, where it specializes in "treating patients with long-term, acute, chronic pain conditions,"[16] providing pain medication that other pharmacies often do not stock.[17] In the small town of Placerville, California, Grandpa's

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[14] Stephanie Flores, *Independent Pharmacists Stage a Niche-Based Comeback*, Sacramento Bus. J. (Oct. 5, 2006), http://www.bizjournals.com/sacramento/stories/2006/10/09/focus3.html?page=all (citing Nancy DeGuire, assistant dean at the University of the Pacific Long School of Pharmacy and Health Sciences).

[15] *See, e.g.*, Linda Roach Monroe, *New Rx for Pharmacists*, L.A. Times (Nov. 7, 1989), *available at* http://articles.latimes.com/1989-11-07/news/vw-1164_1_california-pharmacists.

[16] Assured Pharmacy, http://www.assuredrxservices.com; Assured Pharmacy, *Locations*, http:// www.assuredrxservices.com/locations.html.

[17] Quality$tocks Daily Blog, *StockGuru Blog: Assured Pharmacy's Reason for Being Explains Success* (June 7, 2007, 9:27 A.M.), http://blog.qualitystocks.net/qualitystocks-stock-newsletters/stockguru-blog-assured-pharmacy%E2%80%99s-reason-for-being-explains-success/.

Compounding Pharmacy specializes in "compound prescriptions."[18] With locations in Fort Lauderdale, Miami, and West Palm Beach, Florida's Commcare Pharmacy specializes in "dialysis, hepatitis, and organ transplant management programs" for "high-risk patients."[19] Meanwhile, in Chicago, the Braun Pharmacy carved out a niche for itself providing "infertility medication and hormone replacement for women."[20] These are only a handful of examples.

The widespread proliferation of niche pharmacies stocking only certain drugs at their choosing is a testament to the light-handed approach state regulations have traditionally taken regarding pharmacy inventories, as discussed below.

B. State Regulations Historically Have Not Impeded Pharmacy Stocking Decisions.

Pharmacies have long enjoyed nearly unfettered control over stocking decisions. In theory, some States, including Washington, have regulated these decisions with so-called "stocking" rules. In practice, however, these regulations

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[18] Robin J. Moody, *Independent Pharmacists Fill Niche*, Portland Bus. J., http://www.bizjournals.com/Portland/stories/2004/06/07/story3.html?page=all (last modified June 6, 2004).

[19] Arlene Satchell, *Niches Help Independent Pharmacies Amid Growing Chain Competition*, Sun Sentinel (Jan. 31, 2011), http://articles.sun-sentinel.com/2011-01-31/health/fl-independent-pharmacy-survival-20110128_1_pharmacies-chain-competition-niches.

[20] Haley Westbrook, *Lincoln Park Pharmacy Beats Odds While Holding Onto Its Past*, Medill Reports Chicago (May 15, 2008), http://news.medill.northwestern.edu/chicago/news.aspx?id=89249.

have been unobtrusive and rarely enforced, leaving pharmacies generally in control over what drugs they offer.

Washington's over-40-year-old stocking rule provides: "The 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) (1967) (recodified 1991). On its face, the regulation does not actually do much regulating. Any pharmacy that does not "meet the pharmaceutical needs of its patients" is unlikely to stay in business for long. But more importantly, the history of the Washington stocking rule speaks to the degree of freedom enjoyed by pharmacists to make stocking decisions for themselves: Despite being on the books for decades, there is no public record of any Washington pharmacy being penalized for violating the stocking rule.

This is not unusual. The existence of nearly unfettered pharmacy control over stocking decisions is also evident in other States that have stocking rules. Pennsylvania, for instance, requires pharmacies to stock what is "appropriate to the practice of that pharmacy"; but aside from requiring that pharmacies have an inventory with "at least $5,000 worth of nonproprietary drugs and devices, at cost, from a licensed wholesaler or manufacturer," Pennsylvania leaves the specific stocking decisions to individual pharmacies. 49 Pa. Code § 27.14(a) (2010). New York's regulation has similarly broad terms, providing that "[t]o secure and retain

a registration, a pharmacy must be equipped with facilities, apparatus, utensils and stocks of drugs and medicines sufficient to permit the prompt and efficient compounding and dispensing of prescriptions, as prescribed by regulation." N.Y. Educ. Law § 6808(2)(a)(3) (McKinney 2012). New York does not require a pharmacy to carry anything like even a representative assortment of drugs requested by its customers and inquirers, nor does it require pharmacies to order all drugs requested. Essentially, a licensed pharmacy in New York must have on hand enough drugs (of some kind) to operate as a pharmacy in fact. Some stocking regulations are even more permissive. Florida's stocking rule, for example, requires pharmacies to have adequate storage space for stock—but does not actually require licensed pharmacies to carry any particular stock at all. *See* Fla. Admin. Code Ann. r. 64B16-28.102(2) (2002).

Of course, pharmacies do maintain stock. But decisions about what that stock comprises on a day-to-day basis—*i.e.*, what drugs to carry and in what quantities—have been left to the sound business judgment of pharmacists and pharmacy owners. It is simply untrue that "Washington, like other states, heavily regulates the practice of pharmacy," Br. of Intervenors-Appellants 7—at least when it comes to stocking decisions. Pharmacies continue to make stocking decision based on business, economic, convenience, and clinical reasons despite the passage of the regulation at issue. Indeed, the fact remains that "most

pharmacies only stock about 15% of available drugs on a given day" and "pharmacies choose to stock only those medications that best match the community they serve." Wilson, *supra*, at 54.

II. The Ethical Practice of Pharmacy Includes Facilitated Referral for Reasons of Conscience, Which the Washington Regulation Would Ban.

Contrary to Washington's implicit regulatory premise, a pharmacist's right to act according to his conscience does not necessarily (or logically) need to come at the expense of his patients getting the drugs they are medically and legally entitled to receive. Nor does the patient's access need to come at the expense of the pharmacist's personal ethics. The false dichotomy asserted by Washington does not justify the "delivery" rule.

Since 1998, the APhA has supported the "individual pharmacist's right to exercise conscientious refusal *and* the establishment of systems to ensure patient's access to legally prescribed therapy without compromising the pharmacist's right of conscientious refusal." JAPhA 38(4): 417 (July/Aug. 1998) (emphasis added). Both the patient's and the pharmacist's interests can be accommodated through a policy of facilitated referral, by which a pharmacist calls ahead to ensure that a drug is available at a nearby pharmacy. This "alternative system for delivery of

patient care" allows the pharmacist to "step away, not in the way" of the patient.[21] Unfortunately, Washington's regulation at issue here scuttles this approach, and unnecessarily burdens the pharmacist's right to exercise his conscience.

A. Pharmacists Should Be Able To Exercise Rights of Conscience.

Amici "support[] the ability of a pharmacist to opt out of dispensing a prescription or providing a service" if doing so would violate the pharmacist's right of conscience.[22] Indeed, "[t]he ability of health professionals to opt out of services they find personally objectionable is an important component of the health care system."[23] Put another way, "[p]atients should receive their medications without harassment and interference, but pharmacists should not be compelled to participate in activity they find objectionable."[24]

Amici are not alone in recognizing and supporting a pharmacist's right of conscience:

- The American Society of Health-System Pharmacists, a leading "membership organization that works on behalf of pharmacists who

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[21] APhA, *Government Affairs Issue Brief: Federal Conscience Clause* 3 (Mar. 2009), http://test.pharmacist.com/AM/Template.cfm?Section=Issues&ContentID=20005&template=/CM/ContentDisplay.cfm.

[22] APhA, *Conscience Clause*, http://test.pharmacist.com/AM/Template.cfm?Section=Issues&Template=/TaggedPage/TaggedPageDisplay.cfm&TPLID=86&ContentID=16999.

[23] *Id.*

[24] MacLean Testimony, *supra* note 6, at 68.

practice in hospitals and health systems,"[25] also recognizes "the right . . . of pharmacists . . . to decline to participate in therapies they consider to be morally, religiously, or ethically troubling."[26]

- The American College of Clinical Pharmacology, a membership organization "dedicated to advancing clinical pharmacology,"[27] similarly "supports the prerogative of a pharmacist to decline to personally participate in situations involving the legally sanctioned provision and/or use of medications and related devices or services that conflict with that pharmacist's moral, ethical, or religious beliefs."[28] It provides, as a specific example of such a situation, the "provision of medications or services to facilitate . . . termination of pregnancy[] or contraception."[29]

- The Academy of Managed Care Pharmacy, a "national professional association of pharmacists, health care practitioners and others who develop and provide clinical, educational and business management services on behalf of more than 200 million Americans covered by a managed pharmacy benefit,"[30] with over 6,000 members, likewise "supports a pharmacist's right to refuse to fill a prescription on the

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[25] Am. Soc'y of Health-System Pharmacists, http://www.ashp.org.

[26] Am. Soc'y of Health-System Pharmacists, *Practice & Policy, Ethics, Policy Position 0610: Pharmacist's Right of Conscience and Patient's Right of Access to Therapy*, Ethics-*Statements* 149, *available at* http://www.ashp.org/DocLibrary/BestPractices/EthicsStSuicide.aspx.

[27] Am. Coll. of Clinical Pharmacology, *ACCP History, Objectives and Vision*, http://www.accp1.org/history_objectives.shtml.

[28] Am. Coll. of Clinical Pharmacy, *Position Statement: Prerogative of a Pharmacist to Decline to Provide Professional Services Based on Conscience* (Aug. 2005), *available at* http://www.accp.com/docs/positions/positionStatements/pos31_200508.pdf.

[29] *Id.*

[30] Acad. of Managed Care Pharmacy, *About AMCP*, http://www.amcp.org/AboutUs.aspx?id=8821.

basis of the pharmacist's moral, religious, or ethical convictions."[31]

APhA's stance also follows from similar ethics recognitions made in other medical fields. The American Medical Association's ("AMA's") Code of Medical Ethics, for instance, provides that absent exceptional circumstances that inhibit a patient's free choice (*e.g.*, "where there is loss of consciousness"), a physician shall "be free to choose whom to serve, with whom to associate, and the environment in which to provide care."[32] Indeed, the AMA even goes on to recognize that, "in choosing or accepting treatment in a particular hospital, the patient is thereby accepting limitations upon free choice of medical services." *Id.* The World Medical Association was founded in 1947 as "an international organization representing physicians" from around the world, boasts members from 100 national medication associations, and exists to "ensure the independence of physicians, and to work for the highest possible standards of ethical behaviour

[31] Letter from Acad. of Managed Care Pharmacy to Office of Pub. Health & Sci. Dep't of Health & Human Servs. 2 (Sept. 24, 2008), *available at* http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=10824 (hereafter "AMCP Letter").

[32] Am. Med. Ass'n, *AMA Principles of Medical Ethics, Preamble*, *available at* http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/principles-medical-ethics.page; *see also* Am. Med. Ass'n, *AMA Code of Medical Ethics, Opinion 9.06 -Free Choice*, *available at* http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion906.page.

and care by physicians, at all times."[33] It, too, recognizes that a "physician should be free to make clinical and ethical judgements without inappropriate outside interference," adding that "[p]rofessional autonomy and the duty to engage in vigilant self-regulation are essential requirements for high quality care."[34]

According respect to a pharmacist's right of conscience recognizes pharmacists as the medical professionals that they are. Physicians have long enjoyed a right of conscience under federal law[35] and the laws of 46 States, including Washington.[36] Like physicians, "pharmacists undergo extensive academic and in-the-field training."[37] They are required to complete a minimum of two years of pre-pharmacy coursework with a strong focus on science and math, earn a doctorate of pharmacy, complete internship requirements, and pass the

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[33] World Medical Ass'n, *About the WMA*, http://www.wma.net/en/60about/index.html.

[34] World Medical Ass'n, *WMA Statement on Professional Responsibility for Standards of Medical Care* (Oct. 2006), *available at* http://www.wma.net/en/30publications/10policies/m8/.

[35] *See* Consolidated Appropriations Act, 2005, Pub. L. No. 108-1447, § 508(d)(2), 118 Stat. 2809, 3163 (2004).

[36] *See* Jessica D. Yoder, *Pharmacists' Right of Conscience: Strategies for Showing Respect for Pharmacists' Beliefs While Maintaining Adequate Care for Patients*, 41 Val. U. L. Rev. 975, 983 n.38 (2006) (collecting state laws; the four outliers are Alabama, Connecticut, New Hampshire, and Vermont); *see also id.* at 1011 ("A doctor may refuse to prescribe emergency contraception solely on the basis of a conscientious objection, even when the prescription would be medically appropriate.").

[37] Nell O. Kromhout, *Crushed at the Counter: Protection for a Pharmacist's Right of Conscience*, 6 Ave Maria L. Rev. 265, 292 (2007).

North American Pharmacist Licensure Examination and a state exam before obtaining a license to practice."[38] Although a pharmacist necessarily has a different relationship with a patient than does a physician, a pharmacist is not a mere automaton dispensing medication to anyone with a prescription. A pharmacist has a professional obligation to "collaborate with physicians and patients" and be on the lookout for situations that might prove harmful to the patient, such as when a prescription might be contraindicated by other prescriptions or cause a potentially fatal allergic reaction.[39]

A pharmacist also has important ethical obligations to his profession and to his patients. The pharmacy profession's Code of Ethics, which is promulgated by APhA, reminds pharmacists that they have a *duty* "to act with conviction of conscience."[40] That is, "[j]ust like physicians, pharmacists abide by a Code of Ethics for the delivery of health care. Just as physicians are not required to provide all medical services, pharmacists should not be required to provide all pharmacy

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[38] *Id.*; *see also* Judith A. Cahill et al., *Pharmacist Critique Woefully Outdated and Uninformed* (May 2006), *available at* http://test.pharmacist.com/AM/Template.cfm?Section=Pharmacy_News&template=/CM/ContentDisplay.cfm&ContentID=5656%20.

[39] MacLean Testimony, *supra* note 6, at 65.

[40] APhA, *Code of Ethics*, *available at* http://www.pharmacist.com/code-ethics.

services."[41] By nullifying considerations of conscience, the Washington regulation at issue flies in the face of these professional obligations.

B. The Time-Honored Practice of Facilitated Referral Protects Pharmacists' Rights of Conscience While Ensuring Patients Have Access to Prescription Drugs.

At the same time that the APhA "recognizes the individual pharmacist's right to exercise conscientious refusal,"[42] it "supports the establishment of systems so that the patient's access to appropriate health care is not disrupted."[43] Other organizations that support a pharmacist's right of conscience join the APhA in its call to balance a pharmacist's rights with appropriate patient protections. For instance, the American College of Clinical Pharmacy recognizes that a pharmacist who exercises his right of conscience "has a concurrent professional and ethical responsibility to assure that in situations where patients are seeking access to legally prescribed medications . . . such patients are referred to another pharmacist or other health care provider in an effective, professional, timely confidential, and non-judgmental manner."[44] And at all times, the pharmacist should show "full respect for the patient's needs, interests, dignity, confidentiality, and welfare and should assure that any professional action or decision that occurs because of

[41] MacLean Testimony, *supra* note 6, at 69.

[42] APhA, *Issue Brief*, *supra* note 21, at 3.

[43] APhA, *Conscience Clause*, *supra* note 22.

[44] Am. College of Clinical Pharmacy, *Position Statement*, *supra* note 28.

conscientious objection does not result in patient harm."[45]

The Academy of Managed Care Pharmacists maintains, as well, that "managed health care systems must ensure that procedures are established that protect the patient's right to obtain legally prescribed and medically necessary treatments consistent with the benefit coverage provided."[46] The APhA believes that when these patient-protection procedures are "implemented correctly, and proactively, [they are] seamless to the patient."[47] Put differently, "[t]he patient gets his or her medication and the pharmacist steps away from an activity he or she may find objectionable."[48]

The APhA maintains that the best way to strike the appropriate balance between the pharmacist's right of conscience and the patient's access to drugs is through a policy of facilitated referral, by which the pharmacist would "refer[] the customer to a nearby provider and, upon the patient's request, call[] the provider to ensure the product is in stock." *Stormans*, 854 F. Supp. 2d at 944 (quoting Dkt. #441, Stipulation of the State of Washington, ¶ 1.2). The Washington "delivery"

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[45] *Id.*

[46] AMCP Letter, *supra* note 31, at 2.

[47] APhA, *Issue Brief*, *supra* note 21, at 3.

[48] News Release, APhA, Statement of the American Pharmacists Association (APhA) and the Illinois Pharmacists Association (IPHA): Illinois Governor Denigrates Pharmacy Profession (Dec. 2, 2005), *available at* https://www.aphafoundation.org/AM/Template.cfm?Section=Home&ContentID=4882&template=/CM/ContentDisplay.cfm.

rule, which bans facilitated referral for conscientious objections, appears to view the pharmacist-patient relationship as a zero-sum matter, in which the pharmacist or patient is able to achieve what he wants only at the expense of the other. But that is not the case. Under a policy of facilitated referral, the objecting pharmacist can "step away" and all the while "the patient gets clinically safe, legally prescribed therapy."[49] It is a model of excellent and conscientious care.

As the district court noted, even the State of Washington recognizes that facilitated referral "'is a time-honored practice'" that "'help[s] assure timely access to lawfully prescribed medications,'" and, indeed, "'is often the most effective means to meet the patient's request when the pharmacy or pharmacist is unable or unwilling to provide the requested medication or when the pharmacy is out of stock.'" *Stormans*, 854 F. Supp. 2d at 944 (quoting Dkt. #441, Stipulation of the State of Washington, ¶ 1.5). By abolishing that solution for instances in which a pharmacist is conscientiously opposed to dispensing a drug, Washington creates a conflict between the objecting pharmacist and the patient seeking his or her prescription that does not need to exist. Neither the pharmacist nor the patient needs to "lose" for the other's rights to be protected. "When alternative systems are established proactively, the patient is unaware of the pharmacist's actions and

[49] News Release, APhA, *supra* note 48.

both the patient's right to care and the pharmacist's need to step away from certain activity are accommodated."[50]

Referrals are far from a novel matter for pharmacies. They occur regularly in nearly every pharmacy in the country for reasons well beyond conscientious objection. As the district court proceedings revealed, referrals are necessitated by the business realities of running a successful pharmacy. *Stormans*, 854 F. Supp. 2d at 934, 955. For one, as discussed above, no pharmacy has every available drug in stock. It is thus often necessary for pharmacies to refer patients elsewhere to obtain the drugs they were prescribed. But referrals go beyond situations where a given pharmacy does not stock the type or quantity of a drug requested by patients. Pharmacies may, for instance, refer a patient elsewhere because they do not accept the patient's insurance, do not dispense the requested drug in the required dose, or because the pharmacist would have to compound drugs. *Id.* As with stocking decisions, referrals are not all strictly about business. So it is no surprise that many pharmacies have decided to refer patients elsewhere for controlled over-the-counter medications, such as Sudafed, whether because of concerns about the additional recordkeeping needed or the clientele. *Id.*

The point is, even aside from situations where a particular drug is out of stock, referral is just one more tool at the pharmacist's disposal in order to best

[50] MacLean Testimony, *supra* note 6, at 63.

serve the patient. To take just one example, in testimony before Congress, a pharmacist and spokeswoman for the APhA recounted a recent situation where she referred a patient to Planned Parenthood in order to save the patient needless expense, because her pharmacy did not accept the patient's insurance.[51] That kind of action is commonplace.

Referral works just as well in a right-of-conscience setting. After all, a facilitated referral policy for exercising rights of conscience builds on the groundwork of commonplace referrals to create an even more seamless system for the patient. As the APhA spokeswoman put it in her testimony before Congress:

> [I]f a pharmacist must step away because of a conscience clause, that pharmacist still has the obligation to ensure that a woman gets what she needs.
>
> What I can tell you is, that is what I see day in and day out. Whether it is because we don't have this particular expensive drug on the shelf, if it is emergent, and that patient needs a drug, I can call five pharmacies and transfer the prescription. I can ensure I have taken care of that patient.

MacLean Testimony, *supra* note 6, at 32. Indeed, a number of proactive solutions enabled by effective communication among prescribers and pharmacists exist to

[51] MacLean Testimony, *supra* note 6, at 17: ("I had a person come into the pharmacy not too long ago [who] was able to pay for the emergency contraceptive, that we would be able to administer . . . and dispense. [But w]e were unable to bill the type of insurance that she had, and so I picked up the phone, I called Planned Parenthood, and I said I think this is a candidate for you, can you help me out? So I acted as the patient's advocate. I was able to find out if they took her insurance, what the hours were, and I got instructions on how to get her there. [T]he pharmacist can be a facilitator.").

ensure patients get access to drugs. Patients seeking particular drugs could, for instance, be "directed proactively to pharmacies that carry certain drugs, such as emergency contraceptives." *Id.* at 62. Already, patients seeking emergency contraceptives can use a national toll-free hotline or website run by the Association of Reproductive Health Professionals, both of which give patients "a list of providers who provide emergency contraception services." *Id.* at 62. In States such as Washington that give pharmacists prescriptive authority for certain types of emergency contraception, potential patients could even be "directed to pharmacists who participate in [an] emergency contraceptive care program, [further] streamlining the process for the patient." *Id.* at 62-63; *see also id.* at 11. Even in the unlikely event that there is no prescriber in a given area that prescribes emergency contraception, patients could still get access to drugs from a prescriber who can dispense the product himself. *Id.* at 62. Implemented proactively, the result is "[s]imilar to the situation where a medication is simply out of stock on any given day": "[I]f the pharmacist is unable to dispense the prescription, then the patient must be made aware of the options available to . . . fulfill his or her medication needs." *Id.* at 63. These are just some of the many ways facilitated referral can and does work in practice.

C. Washington's Regulation Does Not Reasonably Accommodate Pharmacists' Rights of Conscience

Despite Washington's prohibition of facilitated referral, appellants claim that a pharmacist's right of conscience is nonetheless sufficiently accommodated because a second pharmacist on duty could dispense any medication the objecting pharmacist wishes not to dispense. *See* Br. of Intervenors-Appellants 11; *see* Br. of Appellants 21-22, 25. That is hardly an accommodation. For one, on its face, it does not in any way accommodate an objecting *pharmacy owner* who chooses not to stock emergency contraception. But even individual pharmacists are unlikely to see any benefit because, for the majority of pharmacies—particularly small, independent ones (*see* MacLean Testimony, *supra* note 6, at 37)—paying a second pharmacist to be on call at all hours is not a feasible option. The so-called "accommodation" does not reflect the economic reality of running an independent pharmacy. This is an industry where, "[f]or every 1% change in an average pharmacy's cost of goods, profits may increase or decrease by . . . more than 20%."[52] And, in recent years, the rise in popularity of mail-order prescription programs has reduced many pharmacies' customer bases, further squeezing already thin profit margins. *See, e.g.*, Bridget M. Olson, *Approaches to Pharmacy Benefit*

[52] Jeff Blackburn, *Fundamentals of Purchasing and Inventory Control for Certified Pharmacy Technicians: A Knowledge Based Course* 3 (Texas Tech Univ. Health Scis. Ctr. Sch. of Pharmacy, 2010), *available at* http://secure.jdeducation.com/JDCourseMaterial/FundPurch.pdf.

Management and the Impact of Consumer Cost Sharing, 25 Clinical Therapeutics 250, 257 (2003).

Pharmacies, particularly independent ones, also have little negotiating power over the federal government's establishment of reimbursement rates—and private insurers tend to follow the federal government's formulas.[53] Not surprisingly, reimbursement rates have steadily declined since the implementation of Medicare Part D in 2007. Joshua J. Spooner, *A Bleak Future for Independent Community Pharmacy Under Medicare Part D*, 14 J. Managed Care Pharmacy 878, 878 (2008). In some cases, reimbursement falls even below pharmacies' costs for filling the prescriptions. Timothy P. Stratton, *The Economic Realities of Rural Pharmacy Practice*, Rural Crossroads 77, 79-80 (2001). Additionally, "delays in payment have increased the cash flow issues faced by independent pharmacies, forcing them to borrow more from their lines of credit . . . . Interest payments on these credit lines erode the pharmacy's operating margin, leaving less money available for paying salaries, marketing, and capital investments." Spooner, *supra*, at 878-79. All of this has steadily driven down profit margins, even forcing some pharmacies—particularly independent ones serving rural areas—to close. *See*,

[53] Lisa L. Causey, *Nuts and Bolts of Pharmacy Reimbursement: Why It Should Matter to You* 2-3 (Univ. of Hous. Health Law Perspectives, June 2009), *available at* http://www.law.uh.edu/healthlaw/perspectives/2009/(LC)%20Pharmacy.pdf.

e.g., Donald G. Klepser et al., *Trends in Community Pharmacy Counts and Closures Before and After the Implementation of Medicare Part D*, 27 J. Rural Health 168, 172 (2010).

Far from accommodating objecting pharmacists, the Washington regulation is likely to force objecting pharmacists to choose between exercising their rights of conscience and keeping their jobs. *See Stormans*, 854 F. Supp. 2d at 961-62. Under the Washington regulation, cash-strapped pharmacies will have every incentive not to hire pharmacists who are personally opposed to dispensing emergency contraception because doing so would require that they pay another pharmacist to be available in the event a patient shows up requesting one of the drugs. Small, independent pharmacies that hire on-call pharmacists in order to protect objecting pharmacists' rights will be forced to bear a significant cost for doing so. Indeed, a regulation purportedly created to ensure "patient access" to drugs (Br. of Appellants 1) might well have the effect of *reducing* access by driving some pharmacies out of business.

III. The Vast Majority of States Protect Referrals for Reasons of Conscience, Contrary to the Washington Regulation.

The practice in the vast majority of States accords with Amici's belief that facilitated referral is the optimal solution for pharmacists who object to dispensing emergency contraception for reasons of conscience. Washington's ban on that

practice is out of step not only with the many pharmacist organizations that endorse it but with the legislative judgments of its sister States.

As of this filing, 29 states had not enacted regulations specifically addressing a pharmacist's right of referral. In these States, conscience-based medication refusals are neither specifically protected nor prohibited. Absent a ban on facilitated referral, or its inclusion in the State's rules concerning unprofessional conduct, the default rule would seem to allow pharmacists to refer patients to other pharmacies if they conscientiously object to dispensing the drug. *See* Br. of Appellees 13. Some of these States also have broad refusal clauses that may be interpreted to include pharmacists.[54]

Thirteen States have gone a step further, enacting laws or regulations explicitly allowing a pharmacist to refuse to dispense medication for reasons of conscience. Six of those States—Arizona, Arkansas, Georgia, Idaho, Mississippi, and South Dakota—do not require the objecting pharmacist to refer the patient to a pharmacy willing to dispense the medication, although, of course, neither do they prevent it.[55] The other seven—Alabama, Delaware, New York, North Carolina,

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[54] *E.g.*, Nat'l Conference of State Legislatures, *Pharmacist Conscience Clauses: Laws and Information*, http://www.ncsl.org/issues-research/health/pharmacist-conscience-clauses-laws-and-information.aspx (last updated May 2012) (listing Colorado, Florida, Illinois, Maine, and Tennessee).

[55] *See* Ariz. Rev. Stat. § 36-2154(B) (2009); Ark. Code Ann. § 20-16-304(4) (2009); Ga. Comp. R. & Regs. § 480-5-.03(n) (2009); Idaho Code Ann. § 18-611

Oregon, Pennsylvania, and Texas—require referral or other similar patient protections.[56]

By contrast, only eight States—California, Illinois, Maine, Massachusetts, Nevada, New Jersey, Washington, and Wisconsin—have enacted some form of a "duty-to-dispense" rule.[57] Even among this handful of States, Washington's regulation is an outlier. This is due to the combination of Washington's new "delivery" rule and a new, more-stringent interpretation of its "stocking" rule.

Washington's delivery rule forces pharmacies "to deliver lawfully prescribed drugs to patients" with no option for facilitated referral for rights of conscience. Wash. Admin. Code § 246-869-010 (2007). For all the reasons discussed above, Amici believe the delivery rule is an incorrect approach—but it at

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(2010); Miss. Code Ann. § 41-107-1 to -13 (2009); S.D. Codified Laws § 36-11-70 (2009).

[56] *See* Del Code Regs. 24.2500 § 3.1.2.4 (2009); 49 Pa. Code § 27.103 (2010); Nat'l Women's Law Ctr., *Pharmacy Refusals: State Laws, Regulations, and Policies* (Apr. 24, 2012), http://www.nwlc.org/resource/pharmacy-refusals-state-laws-regulations-and-policies (discussing state pharmacy board interpretations in Alabama, New York, North Carolina, Oregon, and Texas).

[57] *See* Cal. Bus. & Prof. Code § 733 (2009); Ill. Admin. Code. tit. 68, § 1330.500 (2010); 02-392 Me. Code. R. ch. 19 § 11 (2009) (citing Me. Rev. Stat. Ann. tit. 32, § 13795(2) (2009)); Nev. Admin. Code § 639.753 (2008); N.J. Stat. Ann. § 45:14-67.1 (West 2009); Wash. Admin. Code § 246-869-010 (2007); Wis. Stat. Ann. § 450.095 (2009). Illinois's regulation was recently enjoined as violation of that state's Health Care Right of Conscience Act, 745 ILCS 70/1 to 14 (West 2010), as applied to the two pharmacists who brought suit. *See generally Morr-Fitz, Inc. v. Quinn*, No. 4-11-0398, 2012 WL 4320611 (Ill. App. Ct. Sept. 20, 2012).

least accords with the practice in a few other States.[58] The Board's new interpretation of the stocking rule, however, enforces the new delivery rule in a truly radical way: If a patient requests emergency contraception, the pharmacy is in violation of the law if it declines to stock those drugs for reasons for conscience.[59] As a result, if the Washington regulation stands, not only is a pharmacist there required to dispense Plan B, but a pharmacy is required to stock Plan B if its reasons for not stocking it to do not fall within the secular exceptions to the rule. That kind of intrusion into pharmacies' routine stocking decisions is grossly out of step with state regulatory practice.

CONCLUSION

Accordingly, this Court should affirm the judgment of the District Court.

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[58] Though even some of these States do not go so far as to ban facilitated referral for reasons of conscience. In California, for instance, "[a] pharmacist may decline to provide a drug . . . if the pharmacist's employer can provide a reasonable accommodation of the pharmacist's refusal without imposing an undue hardship on the employer." Joshua T. Shaw, *Conceiving Plan B: A Proposal to Resolve the Conflict Between Women and Conscientiously Objecting Pharmacists over Access to Emergency Contraceptives*, 16 Wash & Lee J. Civ. Rts. & Soc. Just. 563, 573 (2010) (discussing Cal. Bus. & Prof. Code § 733 (2009)).

[59] *See, e.g.*, *Stormans*, 854 F. Supp. 2d at 956 (discussing the new, more stringent interpretation of Washington's stocking rule); *see also* Shaw, *supra*, at 575 n.83 ("On top of its pharmacies' duty to dispense medications, Washington requires pharmacies to maintain a stock of contraceptives, so long as doing so reflects the pharmaceutical needs of its patients.").

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Respectfully submitted,

/s/ Jason A. Levine
Jason A. Levine
Eric A. White
VINSON & ELKINS LLP
2200 Pennsylvania Avenue, N.W.
Suite 500 West
Washington, D.C. 20037
Telephone: (202) 639-6755
Facsimile: (202) 639-6604
jlevine@velaw.com

Counsel for Amici Curiae

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitations of Fed. R. App. P. 32(a)(7)(B) because it contains 6,934 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman 14-point font.

Dated: November 20, 2012

/s/ Jason A. Levine
Jason A. Levine

Attorney for Amici Curiae
American Pharmacists Association,
Washington State Pharmacy Association,
and 33 Other National and State Pharmacy
Associations

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing Brief of Amici Curiae American Pharmacists Association, Washington State Pharmacy Association, and 33 Other National and State Pharmacy Associations with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on November 20, 2012.

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/s/ Jason A. Levine
Jason A. Levine