### IN THE

# Supreme Court of the United States

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

v.

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

Respondents.

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

BRIEF OF NATIONAL AND STATE PHARMACISTS' ASSOCIATIONS AS *AMICI* CURIAE SUPPORTING PETITIONERS

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### IN THE

# Supreme Court of the United States

No. 15-862

STORMANS, INC., DOING BUSINESS AS RALPH'S THRIFTWAY, RHONDA MESLER, AND MARGO THELEN, Petitioners,

v.

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

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BRIEF OF NATIONAL AND STATE PHARMACISTS' ASSOCIATIONS AS AMICI CURIAE SUPPORTING PETITIONERS

### INTEREST OF AMICI CURIAE

*Amici* are five national pharmacy associations and pharmacy associations from thirty-three states.<sup>1</sup> This case is important to all *amici* because it directly affects the central roles that pharmacists play in advancing pub-

<sup>&</sup>lt;sup>1</sup> Pursuant to this Court's Rule 37.6, *amici* affirm that no counsel for a party authored this brief in whole or in part, that no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief, and that no person other than *amici* and their counsel made such a monetary contribution. Counsel of record for petitioners and respondents have filed a blanket consent to the filing of this and other *amicus* briefs. See this Court's Rule 37.2.

lic health. Drawing upon over 150 years of work representing pharmacists and advocating for the safe and effective provision of medicines and devices (and advice about their proper use) that patients need, *amici* offer the Court the historical and practical perspective of the groups targeted by the state regulation at issue here.

### **National Organizations**

Amici include five national pharmacy organizations. 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. APhA provides professional information and education for pharmacists and advocates for improving medication use and advancing patient care in the United States. It has participated as amicus in other litigation involving regulations similar to those at issue here. E.g., Morr-Fitz, Inc. v. Blagojevich, 901 N.E.2d 373 (Ill. 2008).

Other national *amici* sharing these interests include:

- Academy of Managed Care Pharmacy,
- American Association of Colleges of Pharmacy,
- American College of Clinical Pharmacy, and
- National Alliance of State Pharmacy Associations ("NASPA").

## **State Organizations**

NASPA—founded in 1927 as the National Council of State Pharmacy Association Executives—plays the unique role of a national organization dedicated to enhancing the success of state pharmacy associations in their efforts to advance the profession of pharmacy. NASPA's membership comprises state pharmacy associations and over seventy other stakeholder organizations. NASPA promotes leadership, sharing, learning, and poli-

cy exchange among its members and pharmacy leaders nationwide.

The state organization most directly affected by this case is the Washington State Pharmacy Association ("WSPA"). Founded in 1890, WSPA is a professional association representing Washington pharmacists, technicians, student pharmacists, and pharmacies practicing in all areas of healthcare. Like their colleagues in every state, WSPA's members care for patients in a wide variety of settings, including community pharmacies, hospitals, clinics, and long-term care facilities. WSPA has a particular interest in this case because the regulatory action at issue here *directly* governs its members.

Other state pharmacy organizations likewise have an interest in the outcome of this case because of the Ninth Circuit's conclusion that states may subject pharmacists to broad-ranging regulation that intrudes on the core ethical tenets of the profession without any corresponding benefit to public health. Accordingly, thirty-two additional state pharmacy organizations from every corner of America appear here as *amici* alongside their Washington colleagues. They include:

- Alabama Pharmacy Association,
- Arizona Pharmacy Association,
- California Pharmacists Association,
- Connecticut Pharmacists Association,
- Florida Pharmacy Association,
- Georgia Pharmacy Association,
- Idaho State Pharmacy Association,
- Illinois Pharmacists Association,
- Iowa Pharmacy Association,
- Kansas Pharmacists Association,
- Kentucky Pharmacists Association,
- Maryland Pharmacists Association,

- Michigan Pharmacists Association,
- Minnesota Pharmacists Association,
- Mississippi Pharmacists Association,
- Missouri Pharmacy Association,
- Montana Pharmacy Association,
- Nebraska Pharmacists Association,
- New Hampshire Pharmacists Association,
- Pharmacists Society of the State of New York,
- North Carolina Association of Pharmacists,
- North Dakota Pharmacists Association,
- Oklahoma Pharmacists Association,
- Oregon State Pharmacy Association,
- Pennsylvania Pharmacists Association,
- South Carolina Pharmacy Association,
- South Dakota Pharmacists Association,
- Tennessee Pharmacists Association,
- Texas Pharmacy Association,
- Virginia Pharmacists Association,
- West Virginia Pharmacists Association, and
- Pharmacy Society of Wisconsin.

### SUMMARY OF ARGUMENT

Pharmacists, like other professionals who play vital public-health roles, do not oppose proper regulatory oversight. But the Ninth Circuit's decision upheld a radical departure from past regulation of the pharmacy industry. This Court should grant the petition and reverse.

First, the judgment below cemented a break with the longstanding and constitutionally unobjectionable tradition by which pharmacies exercise considerable discretion to choose for themselves which of the thousands of available prescription drugs to offer. Those stocking choices, which they make for a wide variety of reasons, are routine for pharmacies, and appropriate state "stock-

ing" rules have not threatened pharmacies' ability to make sound decisions. Many pharmacies, for example, have established themselves as "niche" pharmacies, deliberately stocking only certain kinds of drugs to serve a particular market—often drugs that could *only* be routinely stocked by a specialist. That development is a testament to pharmacies' long-standing independence and to their collective ability to serve all patients' needs.

Second, the Ninth Circuit's decision effectively eliminated pharmacists' right not to participate in actions they conscientiously oppose, even though a "right of conscience" has always been integral to the ethical practice of pharmacy. Such a right could easily be—and long has been—harmonized with patients' interest in receiving prescription drugs through the time-honored practice of "facilitated referrals." But Washington's "delivery rule" provides an illusory "accommodation"—allowing a second pharmacist at a given pharmacy to fill the prescription if the first objects. Many small pharmacies cannot afford to have a second pharmacist on duty, even if the pharmacy itself is willing to stock the particular drugs. Washington's regulation impinges the rights both of pharmacies and pharmacists.

Finally, the Ninth Circuit opened the door to patient complaints and regulations based not merely on conscientious objection, but also on business decisions that have traditionally been left to pharmacists. By so burdening pharmacists in an already delicate business, the Ninth Circuit's decision, if left standing, threatens to *reduce* patient access to medication by forcing some pharmacies—particularly small, independent ones that often survive by providing specialty services not provided elsewhere—to close. That result would be ironic indeed given a state regulation purporting to ensure access to pharmacists' services.

### **ARGUMENT**

Amici agree with petitioners' arguments about the need for this Court's review to resolve the division among the courts of appeals and state supreme courts regarding core legal questions, and also to address the serious First Amendment implications of the judgment below. But rather than reiterate the petition's carefully articulated arguments, this brief emphasizes an additional reason for the Court to summarily reverse or grant plenary review—the importance of the case to pharmacists and those they serve, which includes virtually all of the American people.

Pharmacists are indispensable to the health and wellbeing of modern society, and their autonomy in selecting drugs to stock and deliver is central to the practice of pharmacy. Recognizing this, states traditionally have deferred to pharmacists regarding such decisions. Facilitated referrals to other pharmacies have ensured patient access when a drug is unavailable, whether that unavailability results from business reasons or from pharmacists exercising the right of conscience. This system protects patients' health without needlessly burdening pharmacies. The district court recognized this, and explained why Washington's new delivery rule could not withstand constitutional scrutiny. By reversing that judgment, the Ninth Circuit has undermined pharmacists' business autonomy and rights of conscience. And an unanticipated consequence is that it will, ironically, diminish rather than enhance patient access to medications.

# I. PHARMACISTS PLAY A VITAL AND TRUSTED ROLE IN INTEGRATED HEALTHCARE SYSTEMS

"[T]he pharmacy has always represented a first line of defense for health information and wellness." As

<sup>&</sup>lt;sup>2</sup> Nosta, Digital Health and the Pharmacy: A Prescription for Success, Forbes (Aug. 20, 2013, 3:48 PM), http://www.forbes.com/sites/

members of the third largest health profession,<sup>3</sup> pharmacists are well equipped to tackle this vital role by engaging in numerous responsibilities, including

- dispensing medications,
- monitoring patient health and progress to maximize response to the medication,
- educating consumers and patients on the use of prescriptions and over-the-counter medications, and
- advising physicians, nurses, and other health professionals on drug decisions.<sup>4</sup>

In short, "pharmacist[s'] knowledge of clinical drug therapy [has become] a more critical component of the healthcare delivery system." Tootelian et al., Essentials of Pharmacy Management 20 (2d ed. 2012).

One may think that, "for most, the pharmacist simply isn't considered a healthcare provider but a dispenser of drugs." While this may have been closer to the truth thirty years ago, see Tootelian, *supra*, at 19-20, in recent times, the role of pharmacists in our changing healthcare system has evolved, for example, "to include providing direct care to patients as members of integrated health care provider teams," Isasi & Krofah, Nat'l Governors Ass'n, The Expanding Role of Pharmacists in a Trans-

johnnosta/2013/08/20/digital-health-and-the-pharmacy-a-prescription-for-success/#54cb39ed44f27520d8d044f2.

<sup>&</sup>lt;sup>3</sup> Am. Ass'n of Colleges of Pharmacy, About AACP, http://www.aacp.org/ABOUT/Pages/default.aspx.

<sup>&</sup>lt;sup>4</sup> Am. Ass'n of Colleges of Pharmacy, Role of a Pharmacist, http://www.aacp.org/resources/student/pharmacyforyou/Pages/roleofa pharmacist.aspx.

<sup>&</sup>lt;sup>5</sup> Nosta, Fixing Healthcare Can Be As Close As Your Neighborhood Pharmacy, Forbes (April 10, 2014, 1:36 PM), http://www.forbes.com/sites/johnnosta/2014/04/10/fixing-healthcare-can-be-as-close-as-your-neighborhood-pharmacy/#3701b043624650bac36e3624.

formed Health Care System 1 (2015).6

It should therefore be unsurprising that "[p]harmacists are consistently ranked among the most trusted professionals, and research shows high levels of satisfaction with pharmacist services." Kelly et al., Patient Attitudes Regarding the Role of the Pharmacist and Interest in Expanded Pharmacist Services, 147 Can. Pharm. J. 239 (2014). In fact, a December 2015 Gallup poll ranked pharmacists second of twenty-one selected professions—behind only nurses—for honesty and ethical standards. Jones & Saad, Gallup News Service: December 2-6, 2015 - Final Topline 2-3 (Gallup, Inc. 2015).

Effective healthcare depends on this mutual trust between pharmacists and patients that has developed over many years. Such relationships are in high demand. Nearly 70% of Americans are on at least one prescription drug—and over 50% are on two or more. News Release, Mayo Clinic, Nearly 7 in 10 Americans Take Prescription Drugs, Mayo Clinic, Olmsted Medical Center Find (June 19, 2013). Indeed, there will soon be excess demand for primary health care providers due to factors such as "an aging population, a rise in chronic conditions, and policy changes such as those associated with the Affordable Care Act." Letter from Patient Access to Pharmacists' Care Coal. (PAPCC) to Fed. Trade Comm'n (April 30, 2014).

<sup>&</sup>lt;sup>6</sup> Available at http://www.nga.org/files/live/sites/NGA/files/pdf/2015/1501TheExpandingRoleOfPharmacists.pdf.

<sup>&</sup>lt;sup>7</sup> Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4212442.

<sup>&</sup>lt;sup>8</sup> Available at http://www.gallup.com/file/poll/187892/Honesty\_Ethics 15121.pdf.

<sup>&</sup>lt;sup>9</sup> Available at http://newsnetwork.mayoclinic.org/discussion/nearly-7-in-10-americans-take-prescription-drugs-mayo-clinic-olmsted-medical-center-find/.

<sup>&</sup>lt;sup>10</sup> Available at http://www.nacds.org/ceo/2014/0508/papcc.pdf.

Enter pharmacists. "For many Americans, the pharmacy is their most accessible form of healthcare," as "nearly 95 percent of the population lives within 5 miles of a pharmacy." Indeed, "[p]harmacists are increasingly being promoted as 'first port of call' health professionals, ... providing advisory and health care services." Harding & Taylor, Occupational Status of Pharmacy, in Pharmacy Practice 199, 209 (Harding & Taylor eds., 2d ed. 2016).

Patients rightly accord their pharmacists these high levels of trust in dealing with potentially life-threatening drugs. This trust includes pharmacists' ability to ethically and sensibly make decisions about the business aspects of their profession. The Ninth Circuit's threat to the practice of pharmacy is all the clearer because of its disregard of this historically granted trust.

## II. PROVISION OF OPTIMAL HEALTHCARE REQUIRES ALLOWING PHARMACIES TO MAKE THEIR OWN STOCKING DECISIONS AND TO REFER PATIENTS TO OTHERS WHEN NECESSARY

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." Am. Pharmacists Ass'n, House of Delegates Current Adopted Policy Statements 1963-2015, at 81 (2015) (quoted policy adopted in 1983). Successfully running a 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" biggest invest-

<sup>&</sup>lt;sup>11</sup> PAPCC, The Value of Pharmacy, http://pharmacistscare.org/access-to-care/the-value-of-pharmacy/.

<sup>&</sup>lt;sup>12</sup> Available at https://pharmacist.com/sites/default/files/files/ 15576%202015\_Currents%20-01\_07.pdf.

ment." Nat'l Community Pharmacists Ass'n, Managing the Pharmacy Inventory 4 (2008). Traditionally, state regulation of stocking decisions has left pharmacies with significant discretion in determining the type and quantity of prescription drugs they offer because that discretion is inherent to the practice of pharmacy.

### A. Pharmacy inventories vary widely

Including interchangeable generics, there are "more than 10,000 medications on the market today," and as such, "it is impossible for a typical pharmacy to carry all medications—and unnecessary as well." Freedom of Conscience for Small Pharmacies: Hearing Before the H. Comm. on Small Business, 109th Cong. 66-67 (2005) (statement of Linda Garrelts MacLean on behalf of the APhA) (hereinafter MacLean Testimony). 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." 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. Understocking drugs that are popular with customers "result[s] in lost sales because of . . . dissatisfaction." Ozcan, Quantitative Methods in Health Care Management: Techniques and Applications 271 (2d ed. 2009). Conversely, a pharmacy that overstocks "unnecessarily ties up funds that might be more productive elsewhere," and "the price tag can be staggering." *Ibid.* 

A host of factors, including the pharmacist's "pre-

<sup>&</sup>lt;sup>13</sup> Available at http://bccpharmacytech.weebly.com/uploads/7/5/0/4/7504847/ownership-managinginventory.pdf.

<sup>&</sup>lt;sup>14</sup> Available at http://www.gpo.gov/fdsys/pkg/CHRG-109hhrg22612/pdf/CHRG-109hhrg22612.pdf.

ferred practice, [the] organization's mission, space restrictions, and budget . . . influence stocking decisions." Bouldin et al., Purchasing and Managing Inventory, in Pharmacy Management, Leadership, Marketing, and Finance 163, 166 (Chisholm-Burns et al. eds., 2d ed. 2014). A market's anticipated "demands and expectations . . . are important, [but] so are [pharmacists'] own expectations or those of [their] organization," and thus, "[b]eyond preferred options of items to stock, a variety of factors will influence . . . the choice to stock or not to stock." *Ibid.* By and large, therefore, these decisions are made at the individual pharmacy level, based on the perceived needs of the pharmacy's customers or its chosen business practices.

Further demonstrating that pharmacies' stocking decisions are not susceptible to broad fiat, 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." Walgreens also decides what drugs to stock primarily based on local "supply and demand." *Ibid*.

Yet not all stocking decisions are purely a matter of supply and demand. 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 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. See *ibid*. And many clinics have made the

<sup>&</sup>lt;sup>15</sup> 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 (quoting Mike DeAngelis, a CVS spokesperson).

decision not to seek regulatory authority to carry controlled substances. See, e.g., UNCW Pharmacy Frequently Asked Questions (advising patients that it "does not stock any controlled substances, so these prescriptions will need to be filled at a local drug store"). Pharmacies routinely make these sorts of stocking (and referral) decisions for reasons wholly separated from merely remaining in business. See, e.g., Pet. App. 162a-165a (listing examples of the "wide variety of business, economic, and convenience reasons" pharmacies choose not to stock particular drugs), 166a-168a (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 popular, especially for small, independent pharmacies. As in any industry, major chains often enjoy pricing and branding advantages over smaller competitors, so many independent pharmacies find a niche and specialize. 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 enabling more in-depth consultations with patients. See, *e.g.*, Monroe, New Rx for Pharmacists, L.A. Times, Nov. 7,

<sup>&</sup>lt;sup>16</sup> Available at http://uncw.edu/healthservices/documents/Pharmacy FAQ\_000.pdf.

<sup>&</sup>lt;sup>17</sup> Flores, Independent Pharmacists Stage a Niche-Based Comeback, Sacramento Bus. J. (Oct. 5, 2006) (citing Nancy DeGuire, assistant dean at the University of the Pacific Long School of Pharmacy and Health Sciences), http://www.bizjournals.com/sacramento/stories/2006/10/09/focus3.html?page=all.

1989.18

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." Florida's Commcare Pharmacy specializes in "patients dealing with chronic illnesses and complex medical conditions." And in Chicago, Braun PharmaCare provides "fertility, veterinary and hormone replacement therapies and medications." As with specialization in other industries, niche pharmacies can provide patients and doctors options that would otherwise be hard or impossible to find.

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. States 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, even those regulations have been unobtrusive and enforced consistently with the principle of leaving pharmacies generally in control over what drugs they offer.

Washington's stocking rule, adopted in 1967, provides that "[t]he pharmacy must maintain at all times a repre-

 $<sup>^{18}</sup>$  Available at http://articles.latimes.com/1989-11-07/news/vw-1164\_ 1\_california-pharmacists.

<sup>&</sup>lt;sup>19</sup> Assured Pharmacy, http://www.assuredrxservices.com.

<sup>&</sup>lt;sup>20</sup> Commcare Pharmacy, What Is Specialty Pharmacy, http://www.commcarepharmacy.com/node/4.

<sup>&</sup>lt;sup>21</sup> Braun PharmaCare, http://www.braunrx.com/.

sentative 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, this provision does not impose much substantive regulation. Any pharmacy that does not "meet the pharmaceutical needs of its patients" is unlikely to stay in business for The stocking rule, seen in that light, restates pharmacies' own ethical obligation to properly serve the community—but it does not supplant pharmacists' own judgment about how to do so. More importantly, the history of the Washington stocking rule speaks to the degree of freedom enjoyed by pharmacists to make sensible stocking decisions for themselves: despite being on the books for decades, there is no public record of any Washington pharmacy ever 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). New York's regulation is framed with similarly broad terms, providing that pharmacies "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). New York does not even demand that pharmacies carry a representative assortment of drugs requested by its customers and inquirers, or that they order all drugs requested. Some stocking regulations are still 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) (2005).

Of course, pharmacies do maintain stock—they hardly need a law or regulation for that. 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 safely and successfully left to the sound judgment of pharmacists and pharmacies.

# C. Facilitated referrals—not mandates on pharmacies—easily resolve any problems of access

To the extent there is a problem of access to begin with, <sup>22</sup> striking the appropriate balance between pharmacists' stocking rights (including their right of conscience) and patients' access to needed drugs is neither mysterious nor novel. The answer is the long-standing policy of facilitated referral, by which the pharmacist "refer[s] the customer to a nearby provider and, upon the patient's request, call[s] the provider to ensure the product is in stock." Pet. App. 115a (quoting *id.* at 334a (Respondents' stipulation)). Washington's delivery rule, however, bans facilitated referral for conscientious objections, viewing

<sup>&</sup>lt;sup>22</sup> The district court concluded that there was no problem of access to any drug in Washington. See Pet. App. 146a-152a (citing a survey conducted by respondents "confirm[ing] that there has been no problem of access to Plan B," and testimony by respondents' witnesses "confirm[ing] that there was no problem of access to Plan B or any other drug"). And in 2013 the FDA approved over-the-counter sales of Plan B, making it even more widely available. News Release, U.S. Food & Drug Admin., FDA Approves Plan B One-Step Emergency Contraceptive for Use Without a Prescription for All Women of Child-Bearing Potential (June 20, 2013), available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm358082.htm.

the pharmacist-patient relationship as a zero-sum matter, in which pharmacists or patients can achieve their goals only at the expense of one another. That is a false and dangerous image. Under a policy of facilitated referral, the objecting pharmacist ethically can "step away" without compromising patient access. MacLean Testimony, supra, at 62. It is a model of excellent and conscientious care.

1. The benefits of facilitated referrals for patients Referrals are nothing new for pharmacists. They occur regularly in nearly every pharmacy in the country for reasons including but extending far beyond conscientious objection. Pharmacies may, for instance, refer a patient elsewhere if they do not accept the patient's insurance, if delivery would require burdensome recordkeeping, or if the pharmacist would have to compound certain drugs. See Pet. App. 166a-168a. Or they may refer patients to protect pharmacists' right of conscience while helping the patient receive effective care. This is a facilitation of the patient's goals, not an imposition of the pharmacist's values.

Indeed, a number of solutions enabled by effective communication among prescribers and pharmacists exist to ensure patients get access to drugs. Patients could, for instance, be "directed proactively to pharmacies that carry certain drugs, such as emergency contraceptives." MacLean Testimony, *supra*, at 62. Already, patients seeking emergency contraceptives can use a national toll-free hotline and a website run by the Association of Reproductive Health Professionals, which give patients "a listing of providers who provide emergency contraception services." *Ibid.* Even in the unlikely absence of any pharmacist or grocery store in a given area to dispense emergency contraception, patients can still access drugs from physicians who choose to dispense the product themselves. See *id.* at 63. Implemented proactively, fa-

cilitated referral leads to results "[s]imilar to the situation where a medication is simply out of stock on any given day[:] if 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." *Ibid*. These are only some of the many ways facilitated referral can and does work in practice in the context of the dispute in this case.

2. The benefits of facilitated referrals for pharmacists

By allowing pharmacists to "step away" from certain circumstances without compromising patient care, the practice of facilitated referral supports pharmacists' professionally recognized right of conscience and ensures their professional autonomy in stocking for all other reasons.

Amici have long recognized and supported pharmacists' right of conscience. For example, the American College of Clinical Pharmacy ("ACCP"), a membership organization "dedicated to advancing clinical pharmacology," issued a statement in 2005 "support[ing] 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 the pharmacist's moral, ethical, or religious beliefs," ACCP, Position Statement: Prerogative of a Pharmacist to Decline to Provide Professional Services Based on Conscience 1 (2005).<sup>24</sup>

Likewise, the Academy of Managed Care Pharmacy ("AMCP"), a "national professional association [with over

<sup>&</sup>lt;sup>23</sup> ACCP History, Objectives and Mission, ACCP, http://www.accp1.org/Members/About/ACCP1/0About/History\_Objectives\_Mission.aspx?hkey=ae17f42c-8a96-4fd7-8f02-43682a0ab141

<sup>&</sup>lt;sup>24</sup> Available at http://www.accp.com/docs/positions/positionStatements/pos31\_200508.pdf.

8,000] 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,"<sup>25</sup> adopted a policy in 1999 "support[ing] a pharmacist's right to refuse to fill a prescription on the basis of the pharmacist's moral, religious, or ethical convictions," AMCP, Policy Digest 1999-Present: A Collection of AMCP's Position Statements on Professional and Practice Issues 33 (2015).<sup>26</sup>

Amici are not alone in their support of conscientious objection. For example, the American Society of Health-System Pharmacists ("ASHP"), a leading membership organization that "represents pharmacists who serve as patient care providers in acute and ambulatory settings," also "recognize[s] the right of pharmacists... to decline to participate in therapies they consider to be morally, religiously, or ethically troubling," ASHP, ASHP Policy Positions 1982-2015, at 160 (Hawkins ed., 2015)<sup>28</sup>; see also Cahill et al., Pharmacist Critique Woefully Outdated and Uninformed (2006) (responding to Wall & Brown, Refusals by Pharmacists to Dispense Emergency Contraception, 107 Obstetrics & Gynecology 1148 (2006), and signed by AMCP, ACCP, APhA, and ASHP).<sup>29</sup>

<sup>&</sup>lt;sup>25</sup> AMCP, About AMCP, http://www.amcp.org/AboutUs.aspx?id= 8821.

<sup>&</sup>lt;sup>26</sup> Available at http://www.amcp.org/uploadedFiles/Production\_Menu/Policy\_Issues\_and\_Advocacy/AMCP\_Positions/Policy\_Digest/AMCP%20Policy%20Digest%20July%202015.pdf.

<sup>&</sup>lt;sup>27</sup> About Us, ASHP, http://ashp.org/menu/AboutUs.

 $<sup>^{28}</sup>$  Available at http://www.ashp.org/DocLibrary/BestPractices/ASHP-Policy-Positions-2015.pdf.

<sup>&</sup>lt;sup>29</sup> Available at http://www.aacp.org/resources/studentaffairspersonnel/studentaffairspolicies/Documents/ProfessionalresponsetoObstet Gyneccommentary.pdf.

Amici's stance also adheres to 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."<sup>30</sup> See also Am. Med. Ass'n, AMA Code of Medical Ethics, Opinion 9.06 -Free Choice.<sup>31</sup> 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." Ibid. The World Medical Association, 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." World Med. Ass'n, Handbook of WMA Policies 155 (World Med. Ass'n, Inc. 2015).<sup>32</sup>

According respect to a pharmacist's right of conscience recognizes pharmacists as the medical professionals that they are. Pharmacists are not humanoid vending machines, mere automatons dispensing medication to anyone with a prescription. Rather, they have a professional obligation to "collaborate with physicians and patients" and to be watchful for situations that might prove harmful to the patient. MacLean Testimony, su-

<sup>&</sup>lt;sup>30</sup> 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.

<sup>&</sup>lt;sup>31</sup> Available at http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion906.page.

 $<sup>^{\</sup>rm 32}$  Available at http://www.wma.net/en/30 publications/10 policies/HB-E-2015-1.pdf.

*pra*, at 65.

Pharmacists also have important ethical obligations to their profession and patients. The pharmacy profession's Code of Ethics, which is promulgated by the APhA, reminds pharmacists that they have not merely the right but the duty "to act with conviction of conscience." APhA, Code of Ethics. 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 services." MacLean Testimony, supra, at 69. By nullifying considerations of conscience, the Washington regulation at issue flies in the face of these professional obligations.

# 3. Washington recognizes the efficacy of facilitated referrals

As both the district court and court of appeals have noted, even the State of Washington has acknowledged 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." Pet. App. 142a-143a; see also id. at 17a (court of appeals' recognition of Washington's stipulation regarding facilitated referrals). By abolishing that solution when a pharmacist is conscientiously opposed to dispensing a given drug, Washington needlessly creates a conflict between the objecting pharmacist and the patient seeking a Neither the pharmacist nor the patient prescription. needs to "lose" for the other's interest to be served.

<sup>&</sup>lt;sup>33</sup> Available at http://www.pharmacist.com/code-ethics.

## III. THE JUDGMENT BELOW DIMINISHES BOTH PHARMA-CISTS' TRADITIONAL AUTONOMY AND PATIENTS' RIGHT OF ACCESS

### A. The Ninth Circuit's decision

Amici agree with petitioners that Washington's delivery rule, interpreted correctly, cannot be characterized as "neutral" and thus violates the Free Exercise Clause. See, e.g., Pet. 20-22, 25-27, 30-32. Nor is this a matter of mere interpretation, for amici also agree that the record teems with evidence of the discriminatory intent behind the new rule. See id. at 35-38. No other regulation in the country so clearly targets pharmacists who conscientiously object to stocking or delivering certain drugs.

The Ninth Circuit "solved" this problem by fashioning an aggressive and unreasonable reading of the delivery rule that opened the door to unprecedented state control over stocking decisions. Rather than holding that conscientious objections may not be subjected to the whims of delivery-rule enforcers, the court anticipated the invalidation of a whole swath of reasons, both secular and nonsecular, for declining to stock or deliver certain drugs, thus expanding the regulation's potential harm beyond what respondents could have possibly intended. Indeed, to the district court's list of secular behavior exempted from the rule—such as the decision to "not deliver the drug over the counter because it requires extra recordkeeping (e.g., Sudafed), not stock the drug because it is an expensive drug, or not stock the drug because it would attract crime (e.g., Oxycontin)"—the Ninth Circuit answered that the district court "clearly erred by concluding that [respondents] permitted those practices or exempted them from enforcement." Pet. App. 31a-32a.

Contrary to the well-established role of pharmacists described above, *supra* Parts I & II, the Ninth Circuit thus greenlighted an expansive regime of potential regu-

lation. According to the court, "[t]he rules require, subject to specific exemptions, that *all* pharmacies deliver *all* lawfully prescribed drugs," Pet. App. 25a (emphasis added), and numerous reasons, whether grounded in religion or not, for declining to dispense certain drugs are no longer safely entrenched as one of the "specific exemptions." Instead, to the Ninth Circuit, they are now subject to state control.

This is an assault on the successful, decades-long tradition of permitting pharmacists to make sensible stocking and delivery decisions for reasons they—not state bureaucrats—deem meritorious. It compounds pharmacists' difficulties by adding to, rather than reducing, behavior subject to complaint and regulation. A proper solution would have been to recognize Washington's delivery rule for what it is: an overbroad, non-neutral attempt to stifle individuals' expression of their religious convictions without detriment to the patients in their care. The Ninth Circuit's failure to do so carries far-reaching consequences for pharmacists and patients alike.

## B. Consequences of the Ninth Circuit's decision

By forcing a square key into a round keyhole and thereby opening the door to complaints about stocking decisions based on both economic and non-economic reasons, the Ninth Circuit endangered both the traditional deference to pharmacist decision-making and the efficacy of facilitated referrals. Under the logic of the court's decision, pharmacies can no longer safely refuse to stock medications for a whole litany of reasons, including fear of theft, expense, and the time required to compound a In particular, niche pharmacies, which certain drug. stock a specialized selection of medications, are primed to be hit hard by the inevitable influx of complaints and regulations. As the district court put it, "With respect to Plan B, the [Commission] has interpreted the rule to mean that if 'patients' request the drug, then the pharmacy must stock Plan B. If applied to all drugs, a pharmacy's stock would be subject to the arbitrary requests of patients, and no specialized pharmacies could exist." Pet. App. 85a n.16. Indeed, the National Women's Law Center calls for not just action related to emergency contraceptives, but for supporters to "[a]sk the state pharmacy board or legislature to put in place policies that will ensure every consumer's right to access *legal pharmaceuticals*." Nat'l Women's Law Ctr., Pharmacy Refusals 101, at 4 (2015) (emphasis added).<sup>34</sup>

None of this would be a problem if the Ninth Circuit had properly held that the practice of facilitated referral exposed the Washington regulations as overbroad and therefore unconstitutional. But without such an outlet, the imposition on pharmacies' business decisions, and on individual pharmacists' right of conscience, remains.

Despite Washington's prohibition of facilitated referral, respondents have claimed 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 Opening Brief of Intervenors-Appellants Judith Billings et al. at 11, Stormans, Inc. v. Wiesman, 794 F.3d 1064 (9th Cir. 2015) (No. 20-2). That is hardly an accommodation. For one thing, on its face, it in no way accommodates an objecting pharmacy owner who chooses not to stock emergency contraception or other drugs. But even individual pharmacists are unlikely to see any benefit because, for the majority of pharmacies particularly small, independent ones—paying a second pharmacist to be on call at all hours is not a feasible op-See MacLean Testimony, supra, at 37. The socalled "accommodation" does not reflect the economic

 $<sup>^{34}</sup>$  Available at http://nwlc.org/wp-content/uploads/2015/08/pharmacy\_refusals\_101.pdf.

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%." 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). 35

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 Pet. App. 180a-183a (summarizing testimony of respondents' witness and noting that "firing the conscientious objector [is] the most likely option for employers that have only one pharmacist on shift at a time"). Under the Washington regulation, 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 an unreasonable cost for doing so or else fire the conscientious objector. See id. at 54a-55a. Indeed, a regulation purportedly created to ensure patient access to drugs likely would instead reduce access by driving some pharmacies out of business.

This need not be a battle between pharmacists' right of conscience and patients' right of access. Rather, the pharmacist-patient relationship is mutually reinforcing, and the time-honored practice of facilitated referral respects both the right of conscience and the right of access. *Amici* recognize that under certain circumstances,

<sup>&</sup>lt;sup>35</sup> Available at https://secure.jdeducation.com/JDCourseMaterial/FundPurch.pdf.

patients' right of access may be so essential that properly narrow regulations are necessary and therefore constitutional. But respondents' sky-is-falling scenario of patients in rural communities having zero access to emergency contraceptives without Washington's rule is highly implausible—yet ironically is a scenario that would be more likely if independent pharmacies in rural communities are forced to close in the face of invasive regulation.

To be clear, *amici* do not ask that the Court hold stocking decisions to be absolutely impervious to regulation, but rather that the government bears the burden to show that any such regulation is narrowly tailored to serve a compelling state interest. If respondents could show that the absence of this regulation *would* generate an irremediable lack of access to drugs, some regulatory response may well be justified, so long as it complied with constitutional requirements. But Washington in no way satisfied that burden here. Nothing in this record justifies the strident limits that Washington has imposed on pharmacists' responsible exercise of judgment.

### CONCLUSION

For the foregoing reasons, the Court should grant the petition.

Respectfully submitted.

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