A State’s Effort to Enhance Health Care: Empowering Pharmacists with Prescribing Authority

Madhav Y. Bhatt

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A STATE’S EFFORT TO ENHANCE HEALTH CARE:
EMPOWERING PHARMACISTS WITH PRESCRIBING AUTHORITY

ABSTRACT

High rates of unintended pregnancies and costs associated with them have been a concern for the health care system in the U.S. The State of Oregon took a unique approach to reduce unintended pregnancy rates within its borders. Oregon enacted a statute that authorized pharmacists to prescribe hormonal contraceptives, which expanded the scope of practice of pharmacists. This Article explores whether states, instead of the Food and Drug Administration (FDA), should regulate the scope of practice of health care professionals. This Article further explores the impact of Oregon’s law on access to hormonal contraceptives, safety of women’s health, and costs for patients or the health care system. This Article concludes that Oregon, and states in general, is in a better position than the FDA to regulate the practice of health care professionals. Also, Oregon’s law will increase access to hormonal contraceptives without jeopardizing the safety of women’s health and will not increase costs for patients or for the health care system.
I. INTRODUCTION

Contraception is named as one of the greatest public health achievements of the twentieth century by the Centers for Disease Control and Prevention (CDC).\(^1\) Still, however, the rates of unintended pregnancy are higher in the U.S. than in most other developed countries.\(^2\) Reducing these rates has been identified as a national priority by the Department of Health and Human Services (HHS).\(^3\)

On January 1, 2016, the State of Oregon took an unprecedented step to reduce unintended pregnancy rates within its borders. The state enacted a statute that authorized pharmacists to prescribe oral and transdermal contraceptives to women aged eighteen years or older.\(^4\) This law also allowed pharmacists to prescribe to women younger than eighteen years of age who have a previous prescription from a primary care provider.\(^5\)

Oregon’s new law has raised concerns in the legal and medical communities. This law is giving pharmacists an authority to prescribe, a power that pharmacists have never exercised before in providing health care. The legal community’s concern is whether states, instead of the Food and Drug Administration (FDA), have and should be allowed to have the power to expand and regulate the practice of health care professionals.\(^6\) Through this law, pharmacists will be prescribing to millions of women and exercising

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2. See Gilda Sedgh et al., Intended and Unintended Pregnancies Worldwide in 2012 and Recent Trends, 45 STUD. FAM. PLAN. 301, 306 (2014) (stating that the rates of unintended pregnancy have remained significantly higher in the U.S. than in other developed countries for many years); see also Wm. Robert Johnston, Abortion Rates by Country (Countries Listed by Name), JOHNSTON’S ARCHIVE (Feb. 25, 2017), http://www.johnstonsarchive.net/policy/abortion/wrjp336abrate2.html; GUTTMACHER INST., FACT SHEET: UNINTENDED PREGNANCY IN THE UNITED STATES 1 (2019), https://www.guttmacher.org/fact-sheet/unintended-pregnancy-united-states.


6. See generally Patricia J. Zettler, Pharmaceutical Federalism, 92 IND. L.J. 845, 892 (2017); Jesse C. Vivian, Pharmacists Prescribing Birth Control, US PHARMACIST 48, 50 (2016) (stating that Oregon is the first state to enact such law and other states are following Oregon, where legality of such laws is uncertain).
independent treatment judgment that will directly affect women’s health and use of hormonal contraceptives in the state. The medical community’s concern is that allowing pharmacists to prescribe might not increase access to hormonal contraceptives, because women may not be willing to receive prescriptions from pharmacists as pharmacists are not used to making independent treatment decisions. The medical community is also concerned that this law might jeopardize safety, because pharmacists are not accustomed to evaluating patients’ conditions and treating them with prescription-only drugs. This raises an additional concern that costs for patients and for the health care system might increase.

However, Oregon’s model offers strong solutions that likely resolve all concerns of the legal and medical communities. This article describes these solutions by evaluating legal, scientific, and scholarly literature via an interdisciplinary approach. Regarding the legal community’s concern, this Article proposes that states have the authority to regulate the practice of health care professionals, because this power has been granted to them by the Fourteenth Amendment and has been acknowledged by the Supreme Court of the United States. Moreover, this Article advocates three major reasons that demonstrate Oregon, and states in general, is in a better position than the FDA to regulate the practice of health care professionals. First, Oregon will be able to respond to local access needs of its citizens more effectively and quickly than the FDA. Second, Oregon can enact laws that will allow health care professionals to address clinical needs of individual patients. Third, Oregon can enforce regulations and supervise the practice of health care professionals more closely and effectively than the FDA.

Regarding the medical community’s concerns, this Article proposes that Oregon’s model will increase access to hormonal contraceptives. Clinical studies have shown that allowing pharmacists to prescribe hormonal contraceptives actually increases access, because women are willing and feel safe to receive hormonal contraceptive prescriptions from pharmacists. Also, this was evident by an increase in sales of hormonal contraceptives in those studies. Oregon’s model will not jeopardize safety of women’s health; rather it will improve their health. The clinical studies have also proved that pharmacists can prescribe medications more safely, in fact, than physicians. Oregon’s model


will not increase costs for patients or for the health care system. Finally, the studies have shown that increasing access to hormonal contraceptives reduces unintended pregnancy and abortion rates, which decreases overall health care cost. Also, with Oregon’s model, the cost for patients will not increase, because prescriptions from pharmacists will be covered by insurance and patients will pay nothing or reduced costs for their prescriptions.

Part II of this Article is divided into two sections. Section A will discuss the FDA’s authority in regulating public health. This section will describe the FDA’s role and involvement specifically in the drug approval process. Section B will discuss congruent authority of states in regulating public health. This section will describe states’ roles in supervising the practice of health care professionals and also draw a distinction from the FDA’s authority.

Part III of this Article also is divided into two sections. Section A will discuss the history and development of hormonal contraceptives. This section will describe the characteristics that led to their prescription-only status. Section B will discuss the authority of the FDA to switch a drug from prescription-only to non-prescription status and the scientific data it analyzes in making a switch. This section will describe the switch of one hormonal contraceptive drug, levonorgestrel (Plan B), to non-prescription status and how that impacts the public’s access to the drug.

Part IV of this Article is divided into four sections. Section A will analyze Oregon’s new law and its scope pursuant to a state’s power recognized by the federal courts. This section will examine whether Oregon, compared to the FDA, is in a better position to regulate the practice of health care professionals. Section B will discuss the legislative intent behind Oregon’s new law and whether there is a need to increase access to hormonal contraceptives. This section will investigate whether women are willing to receive hormonal contraceptive prescriptions from pharmacists and whether allowing pharmacists to prescribe hormonal contraceptives can actually increase access. Section C will analyze the impact of Oregon’s new law on safety of women’s health. This section will examine whether women feel safe in receiving hormonal contraceptive prescriptions from pharmacists and whether pharmacists can prescribe them safely. Section D will analyze the impact of Oregon’s new law on costs for patients and for the health care system. This section will also discuss whether Oregon has taken any measures to reduce the financial burden on patients.

Part V of this Article will provide an overview of solutions to the legal and medical communities’ concerns addressed in Part IV. This section will also summarize the authority of states and the FDA in regulating public health and will assess whether Oregon is in a better position to regulate the practice of health care professionals. This section further will conclude on impact of Oregon’s new law on access, safety, and cost of hormonal contraceptive use in the state.
II. BACKGROUND REGULATION

This Part will discuss the congruent power of the FDA and states in regulating public health. This Part also will draw a distinction between these powers and describe how regulating drugs is reserved to the FDA and regulating the practice of health care professionals is reserved to states.

A. The Food and Drug Administration’s Power to Regulate Drugs

The FDA is a federal regulatory agency that protects the public by regulating the safety, efficacy, and quality of drugs marketed in the country. The FDA also assures that all necessary information is available to the public for safe use of drugs. The FDA is well-known for its “gatekeeping” authority for entry of new drugs in the market. As per 21 U.S.C. § 355(a), “[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application [by the FDA].” Thus the FDA is a gatekeeper to new drugs, because they cannot be sold or marketed in the U.S. without its approval.

In addition to the authority to supervise entry of new drugs, the FDA also has the authority to further restrict their access. The Food, Drug, and Cosmetic Act authorizes the FDA to assign ‘prescription-only’ status to drugs upon finding that “[the drug’s] toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer [it].” Thus, the FDA can restrict access of certain drugs, making them available only via prescription from a licensed practitioner.

Moreover, the FDA’s authority covers the “entire lifecycle of a drug,” from the early stages of research to its approval. To approve a drug for sale in the U.S., the FDA must determine that the drug is safe and effective for its proposed indication by the manufacturer. The safety and effectiveness must be shown via “substantial evidence,” which includes data from “adequate and well-controlled” clinical trials. After a manufacturer applies for approval of a drug, the FDA and the manufacturer are constantly in communication throughout the approval process of the drug. The FDA also conducts advisory committee meetings, where drug experts can raise concerns regarding the drug.

10. Id.
11. Zettler, supra note 6, at 857.
13. Id. § 353(b)(1).
14. Id. § 355(d).
15. Id.
16. See 21 C.F.R. § 314.102(a) (2016) (stating that the “FDA shall communicate with applicants about scientific, medical, and procedural issues that arise during the review process”).
17. Id. § 314.103(c)(3).
also assures that the proposed labeling is not false or misleading and “good manufacturing practice” was used during the development of the drug.\textsuperscript{18} When the FDA decides to approve a new drug, it provides the public with comprehensive scientific data that supports its approval decision.\textsuperscript{19} Thus, the FDA’s collaborative and extremely comprehensive new drug approval process covers the entire lifecycle of a drug.\textsuperscript{20}

Despite the intense effort involved in the FDA approval process, the FDA’s approval is limited as it does not determine that the drug is “generally” safe and effective. Instead, the FDA determines that a drug is safe and effective only for a particular use proposed by the manufacturer, that is, to treat a specific condition at a particular dose in a certain patient population.\textsuperscript{21} However, once the FDA approves a drug, physicians may prescribe the drug for any other conditions, including unapproved uses, known as “off-label” uses.\textsuperscript{22}

Thus, the FDA is not only a gatekeeper to new drugs, but it also has the authority to further restrict access to them. The laws also allow the FDA to be actively involved in every step of the drug development and approval process. This expansive power of the FDA enables it to regulate public health via its supervision at every stage of a drug’s lifecycle.

B. The States’ Power to Regulate the Practice of Health Care Professionals

It is a well-established principle, arising from the Supreme Court’s decision, that states have the power to regulate the practice of health care professionals. In \textit{Graves v. State of Minnesota}, the Supreme Court stated that “a state may, consistently with the Fourteenth Amendment, prescribe that only persons possessing the reasonably necessary qualifications of learning and skill shall practise [sic] medicine[.]”\textsuperscript{23} This recognition is based on the rationale that for the general welfare of its citizens, a state, in its judgment, is allowed to enact laws to regulate the practice of health care professionals to protect its citizens from harm caused by the incompetent and unethical practice of health care.\textsuperscript{24}

In addition, federal courts have distinguished between the congruent authority of states and the FDA regarding protecting the public. In \textit{United States v. Evers}, the Fifth Circuit clarified that the FDA was not intended and does not have the authority to regulate the practice of health care professionals.\textsuperscript{25} The circuit court further stated that the FDA was only intended to “control the

\begin{itemize}
\item \textsuperscript{18} \textit{Id.} § 314.125(b)(6), (13).
\item \textsuperscript{19} \textit{Id.} § 314.430(e).
\item \textsuperscript{20} Zettler, \textit{supra} note 6, at 858.
\item \textsuperscript{22} \textit{Id.} at 476, 477.
\item \textsuperscript{23} Graves v. State of Minn., 272 U.S. 425, 427 (1926).
\item \textsuperscript{24} \textit{Id.}
\item \textsuperscript{25} \textit{United States v. Evers}, 643 F.2d 1043, 1048 (5th Cir. 1981).
\end{itemize}
availability of drugs” that practitioners could prescribe. Similarly, in *United States v. Regenerative Sciences, LLC*, the FDA stated that Congress did not intend for the FDA to regulate the practice of health care professionals. Moreover, the court, supporting the FDA’s view, also noted that Congress left the practice of health care professionals for states to regulate. Thus, the federal courts have distinguished between regulation of products and regulation of practice.

This distinction between practice and products serves as the dividing line between state and federal regulation. In October 2013, the FDA approved Zohydro ER, a new, high-dose opioid medication. The State of Massachusetts, in an attempt to address opioid addiction problems, prohibited “prescribing and dispensing” of Zohydro ER by practitioners within its borders, because this new medication lacked abuse-resistant formulation. Here, the state’s regulation contradicted the FDA’s approval of Zohydro ER to be widely available for practitioners throughout the country. The court considered whether Congress intended FDA oversight to preempt state regulation and whether Massachusetts intended to regulate drugs. The court reasoned that FDA’s approval of country-wide availability of Zohydro ER preempted state regulations. The court further reasoned that Massachusetts intended to regulate Zohydro ER even though the prohibition in the statute technically applied only to practitioners. The court concluded that the state cannot indirectly regulate medical products via medical practice regulations. Hence, the federal courts have acknowledged medical practice regulation pursuant to states’ police powers and medical product regulations pursuant to the FDA’s power.

However, there are some examples where state regulations have extended their reach and entered into the federal drug regulation arena. Over thirty states have passed “right-to-try” laws that permit terminally-ill patients access to drugs that are unapproved by the FDA. At least thirty-four states have enacted laws that allow use of marijuana for medical purposes, regardless of whether the FDA has approved marijuana for medical purposes or whether such laws are

26. Id.
28. Id. at 1319.
30. Id. at *2.
31. Id. at *2.
32. Id.
33. Id.
consistent with the federal Controlled Substances Act. The constitutionality of these state regulations still remains uncertain.

Hence, states have the authority to regulate the practice of health care professionals. The federal courts have distinguished and acknowledged medical practice regulation as a power reserved to states and medical product regulation as a power reserved to the FDA.

III. HORMONAL CONTRACEPTIVES

This part will describe why hormonal contraceptives are assigned prescription-only status. This part will also address why the FDA decided to assign non-prescription status to Plan B and how that affects the public’s access to the drug.

A. History and Nature of Hormonal Contraceptives

A hormonal contraceptive, also known as birth control drug, is any pill, injection, or device that uses hormones to prevent pregnancy. In 1960, the FDA approved the first oral contraceptive: a pill containing mestranol and norethynodrel. This medication became quite popular upon its approval, but its high-dose formulation caused blood-clotting problems (like venous thromboembolism and arterial vascular events) that led to the increase in mortality risk among its users. With significant research and development in hormone therapy, low-dose, low-risk formulations with estrogen and progestin were developed. In the 1970s, a progestin-only pill containing norethindrone, also known as the mini pill, became widely available in the country. The mini pill was less effective than previous formulations, because it only contained progestin; yet it was considered comparatively safe. In the 1990s, hormone combination formulations containing estrogen and progestin were developed.

40 W. H. W. Inman et al., Thromboembolic Disease and the Steroidal Content of Oral Contraceptives: A Report to the Committee on Safety of Drugs, 2 B RIT. MED. J. 203, 204, 207 (1970) (describing how combined regimens of estrogen and progestogen were developed).
42 See James Trussell, Contraceptive Failure in the United States, 83 CONTRACEPTION 397, 399, 401 (2011).
Most hormonal contraceptives now contain both progestin and estrogen. Progestin suppresses ovulation by prohibiting the surge of follicle-stimulating hormone and luteinizing hormone, thickening cervical mucus, and keeping the endometrium lining thin. Estrogen also suppresses ovulation in the ovaries and prevents breakdown of the endometrium lining in the uterus. Thus, progestin and estrogen together in hormonal contraceptives work to make the uterus inhospitable for implantation of a fertilized egg, and thereby prevent pregnancy.

Hormonal contraceptives come in various formulations: pills, patches, vaginal rings, injections, implants, and intrauterine devices (IUDs). Selection of the appropriate formulation for a particular patient requires medical judgment, as each of these formulations has different dosing schedules and mechanisms of function. With oral pills, practitioners recommend women take a pill every day; women who prefer not to get a period are recommended to skip the hormone-free pills in the pack and take a hormone pill every day instead. With skin patches, practitioners recommend women wear the patch on the upper arm, shoulder, back, or hip for three weeks (a new patch each week), and then leave the patch off during week four when they have their period. With vaginal rings, practitioners recommend women put the hormonal ring in the vagina for three weeks at a time and remove the ring during week four. With injections, practitioners give a hormone shot to women in the arm or buttocks every four months. With implants, practitioners inject a tiny rod in the arm that releases hormones, and the rod can stay in the arm for up to three years. With IUDs, practitioners place a device inside the uterus that releases hormones. Thus, selection and use of hormonal contraceptives is done under direct supervision and direction of health care practitioners.

Hormonal contraceptives interact with many common medications, and practitioners will check such interactions before prescribing particular contraceptives. Hormonal contraceptives interact with rifamycin-class antibiotics like rifampin, rifabutin, rifapentine; anti-seizure medications like

43. Petitti & Sidney, supra note 41, at 32.
44. Hormonal Birth Control, supra note 37.
46. Id.
47. Hormonal Birth Control, supra note 37.
48. See Martin & Barbieri, supra note 45.
49. Hormonal Birth Control, supra note 37.
50. Id.
51. Id.
52. Id.
53. Id.
barbiturates, carbamazepine, phenytoin; antiviral medications containing ritonavir; and herbal remedies such as St. John’s wort.\textsuperscript{54} These interactions can reduce the efficacy of either the hormonal contraceptives or of the additional medication.\textsuperscript{55} The interactions are significant enough to warrant intervention by a practitioner of either a different approach to contraception or a different medication for the underlying condition.\textsuperscript{56} Thus, interactions of hormonal contraceptives with numerous drugs require them to be prescribed under the supervision of an experienced health care practitioner.

Moreover, hormonal contraceptives require careful assessment of medical history of a patient. Before prescribing, practitioners generally measure the patient’s blood pressure and also calculate the patient’s body mass index, because obese patients are at greater risk for blood-clotting side-effects (venous thromboembolism) of hormonal contraceptives.\textsuperscript{57} Practitioners also assess for symptoms of blood-clotting diseases like chest pain, shortness of breath, and cough.\textsuperscript{58} They also look for new or worsened migraines or headaches associated with neurologic signs like confusion, dizziness, and visual disturbances, which prohibit use of hormonal contraceptives and warrant evaluation of the underlying condition.\textsuperscript{59} While breast exams, Pap smears, and screening for sexually transmitted diseases are important, many professional medical groups, including the American College of Obstetricians and Gynecologists and the World Health Organization, suggest that these procedures are unnecessary before the first prescription.\textsuperscript{60} Hence, prescription of hormonal contraceptives requires appropriate evaluation of medical history and health of a patient by a practitioner.

Therefore, research in hormonal contraceptives has been moving toward development of low-risk, low-dose formulations. Hormonal contraceptives must be prescribed and dispensed under the supervision of a health care provider, because professional medical judgment is warranted for selection of formulation, evaluation of drug-interactions, and assessment of patients’ medical and contraceptive history.

\textsuperscript{54} See Martin & Barbieri, supra note 45.
\textsuperscript{55} Id.
\textsuperscript{58} Id.
\textsuperscript{60} US Selected Practice Recommendations for Contraceptive Use, 2016, supra note 57.
B. Plan B: From Prescription-Only to Non-Prescription

The FDA has authority to assign “non-prescription” status to a drug. As per 21 U.S.C. § 353(b)(3), the FDA can “remove drugs subject to [prescription-only requirements] . . . when such requirements are not necessary for the protection of the public health.” The FDA can switch only where the evidence demonstrates that the drug’s dispensing requirements are no longer “necessary for the protection to public health” due to its toxicity or its potential side effects and that the drug is safe and effective for the proposed self-use, without supervision of a practitioner. Thus, the FDA can switch a drug from prescription-only to non-prescription status.

Levonorgestrol, currently marketed as Plan B, is an emergency contraceptive that was recently switched to non-prescription status by the FDA, increasing women’s access to it. Emergency contraceptives are hormonal contraceptives that are used to prevent pregnancy when taken within seventy-two hours after unprotected sex. Many professional medical groups, including the American Medical Association and the Association of Reproductive Health Professionals, advocated for making levonorgestrel available as a non-prescription drug. Levonorgestrel was well tolerated and safe based on the extensive safety data from clinical studies where more than 15,000 women took various doses of it for emergency contraception. Moreover, the data collected from comprehensive research in literature and unpublished study reports did not uncover any major side effects. There were no serious adverse events reported during the ongoing studies or from introductory trials that were related to the use of levonorgestrel. Also, no major side effects, such as thromboembolic events or ectopic pregnancies, were reported with these studies, a concern that exists with all prescription-only hormonal contraceptives. Therefore, based on scientific data from clinical trials, there was no medical reason to restrict levonorgestrel to prescription-only status.

66. Id. at 1.
67. Id. at 40 (noting “miscarrage is a common outcome of pregnancy and the relationship of this event to [levonorgestrel] could not be definitely established.”).
68. Id. at 59.
Levonorgestrol’s switch to non-prescription status was achieved in a quite controversial manner, signifying the FDA’s difficulty in regulating hormonal contraceptives and the public’s interest in availability of these drugs.69 In February 2011, Teva Pharmaceuticals submitted an application to make levonorgestrel available as non-prescription.70 In December 2011, the FDA was set to approve non-prescription status with no age restriction based on the studies submitted by Teva.71 However, this action was overruled by the Secretary of HHS.72 Teva then filed an amended application with additional substantial data.73 The Center for Reproductive Rights filed a lawsuit against the Secretary in the federal district court of New York for overruling on the FDA’s decision.74 In April 2013, the court ordered the FDA to allow over-the-counter sales of levonorgestrel with no age restriction.75 The court stated that “the secretary’s action was politically motivated, scientifically unjustified, and contrary to agency precedent.”76 In June 2013, levonorgestrel became available as a non-prescription drug without age restriction and is marketed as Plan B throughout the country.77 In most pharmacies, it is located on the shelf in the family planning aisle; some pharmacies may choose to keep it in a locked cabinet.78

Hence, the FDA has authority to switch a drug to non-prescription status. Plan B is an example of a hormonal contraceptive that was recently switched to non-prescription status by the FDA, making it available as an over-the-counter medication for women.

IV. OREGON MODEL’S IMPLICATIONS

This Part will analyze the scope of Oregon’s new law and describe whether Oregon, and states in general, is in a better position to regulate practice of health care professionals compared to the FDA. This Part further will examine whether allowing pharmacists to prescribe hormonal contraceptives can actually increase access to such drugs. Moreover, this Part will investigate whether women feel safe in receiving hormonal contraceptive prescriptions from pharmacists and whether pharmacists can prescribe them safely. Finally, this Part will assess

70. See CTR. FOR DRUG EVALUATION & RESEARCH, *supra* note 65; Sifferlin, *supra* note 69.
72. Id.
73. See id.
75. Id. at 197.
76. See id. at 192.
77. See Sifferlin, *supra* note 69.
whether Oregon’s new law increases costs for patients and for the health care system.

A. Oregon’s Power to Regulate the Practice of Health Care Professionals

Oregon enacted a statute, section 689.683(1) of the Oregon Revised Statute, which went into effect on January 1, 2016 and expanded the scope of the practice of pharmacists. The statute provides that pharmacists can prescribe and dispense self-administered hormonal contraceptives.79 The statute authorizes pharmacists to prescribe two formulations of hormonal contraceptives: oral pills and patches. A pharmacist cannot prescribe other formulations such as injections, IUDs, and implants, as discussed in Part II, Section A. The statute further states that “a pharmacist may prescribe . . . hormonal contraceptive patches and self-administered oral hormonal contraceptives to a person who is: (a) [a]t least 18 years of age . . .; or (b) [u]nder 18 years of age, only if the person has evidence of a [such] previous prescription from a primary care practitioner . . . .”80 Essentially, the statute poses age requirements where patients younger than eighteen years of age cannot receive a prescription from a pharmacist without a previous prescription from a primary care provider. “This caveat ensures that women will still receive the recommended screenings,” like a Pap test for their first prescription from primary care providers.81 However, patients who are younger than eighteen years of age are not completely deprived of receiving hormonal contraceptives. They still can receive their first prescription from a primary care provider. Primary care providers also have the authority to prescribe hormonal contraceptives, and Oregon’s practice of medicine statute does not pose any age limitations on hormonal contraceptives.82 Interestingly, this expanded scope of the practice of pharmacy overlaps with the scope of the practice of medicine at least on the part of prescribing oral and transdermal hormonal contraceptives.

Oregon’s new law only regulates the practice of pharmacy, a role for states that the Supreme Court has acknowledged as constitutional. The Court has determined that states are granted power to regulate the practice of health care professionals through the Fourteenth Amendment.83 The expanded scope of the practice of pharmacists in Oregon does not contradict the FDA’s approval of hormonal contraceptives. This lies in contrast to Zogenix, Inc. v. Patrick, discussed in Part II, Section B, where Massachusetts attempted to prohibit the

80. Id.
use of an FDA-approved drug in the state and made the drug completely unavailable for its citizens. The court held Massachusetts’s law invalid, because it was regulating drugs contrary to FDA’s decision, that is, what physicians can or cannot prescribe. Here, Oregon is not prohibiting or disapproving the use of FDA-approved hormonal contraceptives within its borders. It is only regulating who can prescribe them, particularly providing pharmacists with such authority, and not what practitioners can or cannot prescribe. Hence, this regulation does not regulate drugs and clearly falls within regulating the practice of health care professionals. Also, the FDA’s determination that hormonal contraceptives be prescribed under supervision of a practitioner is not contradicted by Oregon’s new law, because hormonal contraceptives are still required to be prescribed under the supervision of a pharmacist.

In fact, there are some examples where states have expanded the scope of the practice of pharmacists. In Florida, a pharmacist can prescribe otic analgesics, anti-nausea preparations, and topical antibacterials from a formulary defined in the statute. In California, a pharmacist can prescribe emergency contraception drugs, nicotine replacement products, and “medications not requiring a diagnosis . . . for individuals traveling outside of the United States.” Thus, some states have expanded the scope of the practice of pharmacists where they can prescribe medications from approved formularies.

Oregon, and states in general, is in better position than the FDA to expand and regulate the practice of health care professionals for three major reasons. First, Oregon will be able to serve its citizens more effectively than the FDA, because Oregon has the expertise to understand local needs of its citizens and can quickly respond to challenges with new laws if need be. Even though it is suggested that such state experimentation may threaten public health, the needs of the citizens might worsen with the FDA regulation of pharmacists, because it would be too expansive in scope, missing specific details required to address local needs, and be oppressive and binding on other states.

85. See id. at *2–3 (emphasis added).
87. FLA. STAT. § 465.186 (2018); FLA. ADMIN. CODE ANN. r. 64B16-27.220 (2007).
Second, allowing the FDA to govern the practice of pharmacists may restrict pharmacists’ flexibility in successfully carrying out their duties and obligations to their patients. The FDA regulation may force pharmacists to provide care not based on their judgment of an individual patient’s best interests, but instead based on overall public health objectives. For instance, the federal Drug Enforcement Agency’s current restrictions on the use of certain opioid drugs, aimed at reducing opioid drug abuse nationally, make it challenging for practitioners to treat patients that have genuine medical needs.

Third, because the FDA lacks state-specific focus and maintains general nationwide presence, the FDA’s enforcement of pharmacists’ practice in Oregon specifically would become challenging. There is evidence that federally regulating the practice of health care professionals has been unsuccessful. For example, an estimated thirty percent of human growth hormone drugs prescribed by physicians is for off-label uses that are not approved by the FDA. On the other hand, there is an argument that federal supervision is required in many cases. For instance, in April 2011, Colorado identified adulterated drugs compounded by a Massachusetts’s pharmacy and blocked their sales in the state. Even though Colorado had promptly notified Massachusetts, Massachusetts was unable to stop the adulterated drugs from reaching and harming patients in other states. In this case, it is likely that the FDA’s supervision over compounding practices could have prevented the production of adulterated drugs.

It is true that for certain problems uniform policy and federal supervision is necessary; however, in cases where patient-specific and local needs are considered, like women’s access to certain federally-approved drugs, states should have the authority to regulate. Federal regulation is generally warranted when health care practice within states contributes to a national public health concern that the states are unable to address. When the states have already established coherent measures to regulate the practice of health care professionals effectively, then there should be no need for federal agencies to intervene.

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90. See Patricia J. Zettler, Toward Coherent Federal Oversight of Medicine, 52 SAN DIEGO L. REV. 427, 487 (2015).
94. Id.
95. Zettler, supra note 90, at 481.
96. Id. at 482.
97. Id.
B. Impact on Access to Hormonal Contraceptives

In a news release on May 27, 2015, the Chair of Oregon Legislature Rules Committee, Val Hoyle, stated that “[i]creasing access to birth control is one of the most important things we can do to improve the lives and health of women from all walks of life.”98 She further stated that “[w]e all share the goal of reducing the number of unwanted pregnancies, and one of the most effective ways we can do that is to increase access and availability of contraceptives for women across the state from every background.”99 The legislative intent behind Oregon’s new law is to increase access for women to hormonal contraceptives in the state in order to reduce unintended pregnancies. Oregon’s new law attempts to achieve this goal by making it easier for women to obtain hormonal contraceptive prescriptions directly from pharmacy stores as compared to scheduling an appointment and waiting to receive a prescription from a primary care provider.

A qualitative study was conducted with twenty reproductive health practitioners, including physicians and advanced practice clinicians, in California from 2008 to 2009.100 The study concluded that most providers considered prescription-only access to hormonal contraceptives to be too restrictive.101 The providers suggested that the rates of unintended pregnancies can be reduced by increasing access to hormonal contraceptives through pharmacists via education and training.102

With Oregon’s new law, based on the increase in the number of prescribers, it is clear that more health care professionals will now be able to prescribe hormonal contraceptives, because along with primary care providers, pharmacists can also now prescribe them. However, research data needs to be analyzed to determine whether women are willing to receive prescriptions from pharmacists and whether allowing pharmacists to prescribe can actually increase access to hormonal contraceptives.

A survey was conducted across the country to better understand women’s experiences with hormonal contraceptives and their interest in gaining direct access to them. In this study, a telephone survey was conducted in the U.S. on

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101. Id. at 689.
102. Id. at 692.
811 women aged 18–44 years who were at risk for unintended pregnancy.\textsuperscript{103} The survey looked at women’s readiness and comfort with obtaining hormonal contraceptives from pharmacists without first visiting a clinic or a physician.\textsuperscript{104} The results showed that sixty-eight percent of women in the U.S. said they will use a pharmacy to access hormonal contraceptives.\textsuperscript{105} Likely users included women not using contraception who would begin using hormonal contraceptives (forty-one percent) if they were available directly in pharmacies, and oral pills, patch, or ring users (sixty-six percent) were interested in obtaining their method from pharmacies.\textsuperscript{106} Thus, most women are willing to receive hormonal contraceptive prescriptions from pharmacists.

The result of the above survey was evident in a pilot study conducted in Washington state. Five organizations—Program for Appropriate Technology in Health, the Washington State Pharmacists Association, the University of Washington Department of Pharmacy, the Washington State Board of Pharmacy, and DDB World-wide Communications Group, Inc.—conducted a pilot project from February 1998 to June 1999 that allowed pharmacists to prescribe hormonal contraceptives.\textsuperscript{107} The study measured the number of prescriptions sold and demand for hormonal contraceptives.\textsuperscript{108} During this period, emergency contraceptives held prescription-only status. In this project, a total of 11,969 prescriptions for emergency contraceptive medications were prescribed and dispensed by pharmacists at 130 pharmacies.\textsuperscript{109} From February 1998 through December 2000, Washington state pharmacists reported having served 28,649 women and more than 1,000 new emergency contraceptive prescriptions were initiated by pharmacists \textit{per month}.\textsuperscript{110} Hence, this study proved that allowing pharmacists to prescribe contraceptives significantly increased women’s access to hormonal contraceptives.

Thus, research data has shown that women are willing to receive prescriptions from pharmacists and that allowing pharmacists to prescribe hormonal contraceptives has actually increased women’s access to the drugs.

\begin{footnotesize}
\begin{enumerate}
\item[103.] Sharon Cohen Landau et al., \textit{Birth Control Within Reach: A National Survey on Women’s Attitudes Toward and Interest in Pharmacy Access to Hormonal Contraception}, 74 CONTRACEPTION 463, 464 (2006).
\item[104.] Id.
\item[105.] Id. at 467.
\item[106.] Id.
\item[108.] Id.
\item[109.] Id.
\item[110.] Id. at 174 (emphasis added).
\end{enumerate}
\end{footnotesize}
C. Impact on Safety of Prescribed Hormonal Contraceptives

Many people place substantial trust in pharmacists because of their expertise in counseling on proper drug use and knowledge on drug interactions. Pharmacists are also trained in optimizing drug therapy for patients suffering from chronic conditions. In fact, the FDA proposed to establish a new category of drugs that would allow pharmacists to dispense prescription-only drugs without a prescription after pharmacists’ intervention as a condition for safe use. The rationale was that since pharmacists counsel patients on proper use of prescription-only drugs, they should also be allowed to dispense them for certain chronic medical conditions such as asthma, high blood pressure, and high cholesterol, as these conditions are highly undertreated.

Even though pharmacists’ image and education seem promising, an inquiry needs to be made whether women feel safe in receiving prescriptions from pharmacists and whether pharmacists can prescribe hormonal contraceptives safely. A community-based intervention study was conducted from 2003 to 2005 in Seattle, Washington that assessed whether women consider it safe to receive hormonal contraceptive prescriptions from pharmacists. In this study, 214 women and 26 community pharmacists participated. The participating women provided their medical and contraceptive history, and the participating pharmacists identified women at risk of unintended pregnancies, measured their weight and blood pressure, and prescribed them hormonal contraceptives. The results showed that 195 women (ninety-one percent) were prescribed hormonal contraceptives by pharmacists, and 136 women (seventy percent) reported continuing use of hormonal contraceptives. Nearly all women expressed willingness to continue to see pharmacists for prescriptions and felt safe in receiving prescriptions from pharmacists. The study also concluded that pharmacists can effectively prescribe hormonal contraceptives to women.

114. Glatter, supra note 111.
116. Id.
117. Id.
118. Id.
119. Id.
120. Gardner et al., supra note 107, at 174, 175.
Thus, there is evidence that women feel safe in receiving prescriptions from pharmacists.

Moreover, a fourteen-month study was conducted in California that compared prescribing abilities of pharmacists and physicians. The patients were assigned one of two groups, one treated by pharmacists and the other by physicians. There was no significant difference between the two patient populations. The study assessed prescribing abilities in six different measures: (1) was the chosen drug appropriate for diagnosis; (2) are drug interactions properly checked; (3) was quantity appropriately prescribed; (4) was the dose proper; (5) were patient directions clear and safe; and (6) will the prescription have a positive effect on the patient’s health. Pharmacists and physicians prescribed from a formulary containing more than 300 drugs like antihypertensives, antidiabetics, and thyroid medications. The results revealed that in measure one, pharmacists scored better than the physicians in choosing drugs most appropriate for the diagnosis, with the difference being statistically significant (p<0.01, t=−2.61). In measures two, three, four, and five, although the difference was not statistically significant, pharmacists had better scores than physicians. In fact, in measure six, which assessed whether the prescription would have a positive effect on the patient’s health, pharmacists received better scores than physicians with the difference being statistically significant (p<0.05, t=−2.51). The study concluded that because of pharmacists’ expertise in pharmacology and rational drug use, pharmacists can prescribe at least as well as, and on some measures, more appropriate than physicians. Thus, there is evidence that pharmacists can prescribe medications safely.

When it comes to hormonal contraceptives, there is less complication involved in making prescribing decisions than with other prescription-only drugs. Other prescription-only drugs, such as antihypertensives, antidiabetics, thyroid medications, etc., require complex clinical tests like electrolyte levels, blood sugar levels, blood hormone levels, and complete blood counts before they are prescribed. In comparison, hormonal contraceptives only require

122. Id. at 439.
123. Id. at 441.
124. Id.
125. Id. at 438–39.
126. McGhan et al., supra note 121, at 442–44.
127. Id.
128. Id.
129. Id.
130. AM. C. OF CARDIOLOGY, 2017 GUIDELINE FOR THE PREVENTION, DETECTION, EVALUATION, AND MANAGEMENT OF HIGH BLOOD PRESSURE IN ADULTS 1, 13 (2017); AM. DIABETES ASS’N, Standards of Medical Care in Diabetes–2017, 40 Diabetes Care 1, S66–69.
measurement of weight, BMI, and blood pressure before prescribing.\textsuperscript{131} Other prescription-only drugs are required to be dose-adjusted based on fluctuating blood pressure, electrolyte levels, and hormone levels.\textsuperscript{132} In contrast, hormonal contraceptives do not require daily monitoring of clinical health status and are not dose-adjusted.\textsuperscript{133} Also, hormonal contraceptives do not have more drug interactions or a more severe side effect profile compared to most other prescription-only drugs.\textsuperscript{134} As shown in the study mentioned previously and also corroborated by other studies, pharmacists have safely prescribed more-intense and less-safe prescription-only drugs to patients.\textsuperscript{135} Thus, pharmacists are professionally competent to prescribe hormonal contraceptives safely.

In addition to the expertise pharmacists already possess, Oregon has established training requirements for pharmacists to ensure safe prescribing of hormonal contraceptives. Pharmacists throughout the state are required to complete a certification course before they are allowed to prescribe hormonal contraceptives.\textsuperscript{136} This course is developed under the guidance of the Oregon Board of Pharmacy and accredited by the Accreditation Council for Pharmacy Education.\textsuperscript{137} The program provides a stronger foundation on formulations and risks of hormonal contraceptives, educates pharmacists on counseling patients in missed pill situations, and teaches pharmacists to assess patients’ eligibility for a prescription.\textsuperscript{138} Moreover, a questionnaire and an algorithm, drafted by the Oregon Board of Pharmacy, can be used by pharmacists to obtain adequate medical and contraceptive history. The questionnaire asks a patient to state her name, health care provider, date of birth, date of last health clinic visit, and

\textsuperscript{131} US Selected Practice Recommendations for Contraceptive Use, 2016, supra note 57.
\textsuperscript{132} AM. C. Of Cardiology, supra note 130, at 13; AM. Diabetes Ass’n, supra note 130, at S66–69; AM. Thyroid Ass’n, supra note 130, at 1355–57.
\textsuperscript{133} US Selected Practice Recommendations for Contraceptive Use, 2016, supra note 57.
\textsuperscript{134} Martin & Barbieri, supra note 45, at 6.
\textsuperscript{135} McGhan et al., supra note 121, at 442–44 (describing other studies that proved that pharmacists can prescribe prescription-only medications safely).
\textsuperscript{137} Id.
\textsuperscript{138} Id.
health insurance status.\textsuperscript{139} There are also questions related to the patient’s medical and family history.\textsuperscript{140}

Following the prescribing and dispensing of the hormonal contraceptive, the pharmacist must give the patient a “Pharmacist Referral and Visit Summary” form.\textsuperscript{141} When the patient is prescribed a medication, the form will state “Today you were prescribed the following hormonal contraceptive” and name the medication.\textsuperscript{142} If the patient is not eligible for a prescription, the form will state that “I am not able to prescribe hormonal contraception to you today,” and list three possible reasons: (1) the patient has a health condition that requires further evaluation, (2) the patient takes medications that may interfere with hormonal contraceptives, or (3) the patient’s blood pressure is greater than 140/90 mmHg.\textsuperscript{143} Thus, Oregon has developed effective training and procedural measures to ensure that hormonal contraceptives are prescribed safely.

The results of clinical studies show that women feel safe in receiving prescriptions from pharmacists. Pharmacists can prescribe at least as safely, and in some aspects, more appropriately than physicians. Also, the training and procedural requirements established by Oregon further strengthen the safety measures.

D. Impact on Costs for Patients and for the Health Care System

The cost of unintended pregnancies on the health care system is extremely high. Births from unintended pregnancies resulted in approximately twenty-one billion dollars in government expenditures in 2010.\textsuperscript{144} Women with unintended pregnancy must either choose to deliver the baby, undergo abortion, or plan for adoption; each of these choices involves significant cost for a woman and for the health care system. As a result, it is proposed that increasing access to contraceptives could reduce the cost for the health care system. Based on recent estimates, each dollar spent on publicly-funded contraceptive services will likely save $5.68 for the health care system.\textsuperscript{145}

\begin{itemize}
\item \textsuperscript{141} Vivian, supra note 6.
\item \textsuperscript{142} Id.
\item \textsuperscript{143} Id.
\end{itemize}
A sixteen-month pilot project was conducted in Washington, D.C., that assessed the cost for patients and for the health care system from increased availability of hormonal contraceptives. In this study, pharmacists prescribed hormonal contraceptives to patients.\textsuperscript{146} The cost per visit averaged between thirty and forty dollars, which included contraceptive pills, a medication to prevent nausea and vomiting, and the pharmacist’s time in assessing, counseling, and documenting interventions.\textsuperscript{147} With this study, however, there was no third-party payment service for contraceptive prescriptions.\textsuperscript{148} Despite no third-party financial support, thousands of women paid out-of-pocket to use pharmacists’ services.\textsuperscript{149} This study concluded that provision of hormonal contraceptive prescriptions by pharmacists was a cost-saving measure under all assumptions for prospective public and private payers.\textsuperscript{150} This study also reported a decline in unintended pregnancies in Washington, D.C., as abortions rates had reached the lowest level in two decades, dropping by five percent, and teenage pregnancy rates were seven percent lower during the study period.\textsuperscript{151} Thus, there is evidence that increasing access to hormonal contraceptives through pharmacists reduces unintended pregnancies.

Oregon has taken several measures to ensure that excessive financial burden on patients is avoided. In Oregon, under the new law, hormonal contraceptive prescriptions from pharmacists are covered by insurance.\textsuperscript{152} Under a separate law, health plans must pay for up to a three-month supply for the first fill and up to a twelve-month supply for these prescriptions.\textsuperscript{153} Moreover, Oregon has also passed the “pharmacist provider status” law that recognizes pharmacists as providers for billing purposes.\textsuperscript{154} Most Oregon pharmacists have a National Provider Identification number to bill for immunizations, and the state has also established a billing pathway for them to get reimbursed for hormonal contraceptives.\textsuperscript{155} They will be reimbursed at the same rate as other prescribers.\textsuperscript{156} Patients with valid insurance will pay nothing or at least a reduced cost for their prescriptions, depending on their insurance coverage. If a patient is determined not eligible for hormonal contraceptive prescription and is referred to a physician, then the pharmacist will not charge insurance for the services.\textsuperscript{157}

\begin{itemize}
\item \textsuperscript{146} Gardner et al., \textit{supra} note 107, at 172.
\item \textsuperscript{147} \textit{Id.} at 174.
\item \textsuperscript{148} \textit{Id.}
\item \textsuperscript{149} \textit{Id.}
\item \textsuperscript{150} \textit{Id.}
\item \textsuperscript{151} Gardner et al., \textit{supra} note 107, at 174.
\item \textsuperscript{152} Loren Bonner, \textit{Oregon Pharmacists Begin Prescribing Hormonal Contraceptives}, \textsl{Pharmacy Today}, Mar. 2016, at 64.
\item \textsuperscript{153} \textit{Id.}
\item \textsuperscript{154} \textit{Id.}
\item \textsuperscript{155} \textit{Id.}
\item \textsuperscript{156} \textit{Id.}
\item \textsuperscript{157} Bonner, \textit{supra} note 152.
\end{itemize}
Thus, patients likely will not have excessive financial burden when obtaining hormonal contraceptives prescribed by pharmacists. Therefore, there is evidence that increasing access to hormonal contraceptives reduces unintended pregnancies, and thereby, costs for the health care system. In Oregon, since hormonal contraceptive prescriptions from pharmacists will be covered by insurance, patients with valid insurance will pay nothing or a reduced cost for their prescriptions.

V. CONCLUSION

There is a distinction between the power of the FDA and states regarding protection of the public. The FDA has authority to regulate medical products, which allows it to be actively involved at every step of their approval process. The states have the authority to regulate the practice of health care professionals, because this power has been granted to them by the Fourteenth Amendment and has been acknowledged by the Supreme Court of the United States.

Oregon, and states in general, is in a better position than the FDA to regulate the practice of health care professionals. First, Oregon will be able to respond to local access needs of its citizens more quickly than the FDA. Second, Oregon can enact laws that will allow health care professionals to address clinical needs of individual patients better than the FDA. Third, Oregon can enforce regulations and supervise the practice of health care professionals more closely and effectively than the FDA.

This Article has shown that Oregon’s model offers strong solutions that likely resolves all concerns of the legal and medical communities. Oregon’s law will increase access to hormonal contraceptives. The clinical studies have shown that allowing pharmacists to prescribe hormonal contraceptives actually increases access to them, because women are willing and feel safe to receive hormonal contraceptive prescriptions from pharmacists. Oregon’s law will not jeopardize safety of women’s health; rather it will improve their health. The clinical studies have proved that pharmacists can prescribe medications safely, in fact, better than physicians can. Oregon’s law will not increase costs for patients and for the health care system. The studies have shown that increasing access to hormonal contraceptives reduces unintended pregnancy and abortion rates, which decreases overall health care costs. Also, with Oregon’s model, the cost for patients will not increase, because prescriptions from pharmacists will be covered by insurance and patients will pay nothing or receive a reduced cost for their prescriptions.

Oregon’s model will serve as a prime example of a state’s effort in regulating the practice of health care professionals. Oregon’s efforts likely will
inspire other states to expand the scope of the practice of pharmacists and empower pharmacists to enhance health care in the country.

MADHAV Y. BHATT*