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No Way FDA, Let States Lead the Way on Expanding the Prescriptive Authority of Pharmacists

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CONTENTS

I. INTRODUCTION

States have long controlled the regulation of prescriptive authority.[1] Traditionally, states limited prescriptive authority to physicians.[2] More recently, states have expanded prescriptive authority to more health care professionals, including physician assistants and nurse practitioners, to help address access issues.[3] As access issues and other

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1. Phillip Zhang & Preeti Patel, *Practitioners and Prescriptive Authority*, *in* STATPEARLS (2023).

2. *Id.*

3. *Id.*

barriers to health care remain a problem in most of the United States, states have sought to allow health care professionals to practice at the top of their licenses to fill these gaps.[4] This push to increase access to health care has led many states to expand prescriptive authority to pharmacists.[5] States have started to utilize pharmacists to meet the individual needs of their constituents, causing the scope of practice amongst pharmacists to vary widely by the state in which they practice.[6] In July 2022, the Food and Drug Administration (FDA) revised its Emergency Use Authorization for Paxlovid in its continued response to the COVID-19 pandemic to give pharmacists prescriptive authority for Paxlovid, a drug used in the treatment of COVID-19.[7] The FDA's revision was the first time the agency regulated the prescriptive authority of pharmacists.[8] This paper argues that the FDA's revision of the Emergency Use Authorization for Paxlovid granting prescriptive authority to pharmacists is an encroachment on states' rights and a bad precedent to set. States should reject the FDA's recent invasion into the regulation of the prescriptive authority of pharmacists to prevent further federal overreach, as states are in a better position to regulate the practice of pharmacy than the FDA.

The first part of this paper will focus mainly on the FDA's history of regulating drugs and devices, starting with the passing of the Pure Food and Drug Act of 1906. The next portion of this paper outlines the history of the regulation of the pharmacy practice beginning when pharmacists first decided to self-regulate to the utilization of pharmacy boards today. Following this brief history, the paper will redirect to the history of the FDA's Emergency Use Authorization Power, reviewing

4. Kristen Engelen, *3 Questions About Pharmacist Prescribing Authority*, RxLive (Oct. 13, 2021), https://rxlive.com/blog/mapping-u-s-statewide-protocols-for-pharmacist-prescriptive-authority/ [https://perma.cc/R5UQ-JKWJ].

5. *Id.*

6. Alex Evans, *Prescribing Authority for Pharmacists: Rules and Regulations by State*, GoodRx Health (July 22, 2022), https://www.goodrx.com/hcp/pharmacists/prescriber-authority-for-pharmacists [https://perma.cc/NJR2-4LRP].

7. *FDA Authorizes Pharmacists to Prescribe Paxlovid with Certain Limitations*, U.S. Dep't Health & Hum. Serv. (July 6, 2022), https://aspr.hhs.gov/COVID-19/Therapeutics/updates/Pages/important-update-06July2022.aspx [https://perma.cc/HK2F-Y2DH].

8. David Pope, *Expert: FDA Announcement of Pharmacists' Prescribing Authority for COVID-19 Antiviral Paxlovid 'Is Pharmacy's Moment' to Seize the Path to Provider Status*, Pharmacy Times (July 8, 2022), https://www.pharmacytimes.com/view/expert-fda-announcement-of-pharmacists-prescribing-authority-for-covid-19-antiviral-paxlovid-is-pharmacy-s-moment-to-seize-the-path-to-provider-status [https://perma.cc/3R5X-A2M6].

its origination and increased use during the country's COVID-19 pandemic response.

The second portion of this paper examines the history of pharmacist prescriptive authority and how states have enacted legislation to grant pharmacists this power. After this section, the paper reviews the FDA's revision of its Emergency Use Authorization for Paxlovid, which led to pharmacists gaining prescriptive authority over the drug in July 2022. The subsequent section discusses why the FDA lacks the authority to regulate the prescriptive authority of pharmacists. Following this section, the paper analyzes why states are better suited than the FDA to oversee the prescriptive authority of pharmacists. After this analysis, the paper explores ways the FDA can increase patient access to medications without intruding on the states' long history of regulating this area. Lastly, the paper considers how states should respond to the FDA's July 2022 revision to its Emergency Use Authorization for Paxlovid.

II. LITERATURE REVIEW

There is not much academic writing related to the effect of the FDA's revision of the Emergency Use Authorization for Paxlovid on July 6, 2022, which gave state-licensed pharmacists the authority to prescribe Paxlovid. This lack of scholarship may be because it is a relatively recent occurrence. Others have written on pharmacist prescriptive authority, how certain states have tackled the issue, and its relatedness to FDA authority.

One law review article discussing Oregon's law allowing pharmacists to prescribe birth control concludes that the state of Oregon was "in a better position than the FDA to regulate the practice of health care providers."[9] The author states that Oregon is better suited to regulate the practice of health care providers because it can "respond to local access needs" more quickly, enact laws to address the "needs of individual patients," and "enforce regulations and supervise the practice of health care professionals more closely and effectively."[10] The author of that article chose to approach the topic of the regulation of pharmacist prescriptive authority from a state-specific statute.[11]

Another article focuses on how states have attempted to regulate pharmaceuticals that conflict with the FDA's oversight of these types of products.[12] That paper has a section that looks at plausible

9. Madhav Y. Bhatt, *A State's Effort to Enhance Health Care: Empowering Pharmacists with Prescribing Authority*, 12 ST. LOUIS U. J. HEALTH L. & POL'Y 367, 367 (2019).

10. *Id.* at 369.

11. *Id.* at 367.

12. Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L. J. 845, 845 (2017).

arguments for how the FDA's authority could preempt state law when regulating medical practice.[13] The author notes that a preemption argument is "nebulous" but also points to some examples, including Maine's drug importation law and Massachusetts's ban of Zohydro, that have the potential to make the line of what is considered medical practice regulation and what is not to become more blurred.[14] None of the examples listed are like the FDA's July 2022 revision of the Emergency Use Authorization for Paxlovid.[15]

There are articles related to the impacts of pharmacist prescriptive authority and how states have expanded this authority to pharmacists. One paper discusses some of the older ways, specifically North Carolina's Clinical Pharmacist Practitioner Act and New Mexico's Pharmacist Prescriptive Authority Act of 1993, in which certain states tried to increase the prescriptive authority of pharmacists and the resistance that they faced.[16] Another article examines the potential benefits and hazards of expanding prescriptive authority while comparing Washington's Collaborative Drug Therapy Agreements and California's Advanced Practice Pharmacist license.[17] There is also literature on how some states have created decentralized models to determine which drugs pharmacists have the authority to prescribe.[18] This paper incorporates background information on several ways states have approached the expansion of prescriptive authority to pharmacists and the opportunities and obstacles in its passing. Additionally, it argues that the individual states – not the FDA – are the ones that should expand pharmacist prescriptive authority.

13. *Id.* at 885.

14. *Id.* at 886–88.

15. Richard H. Hughes IV & Kala K. Shankle, *FDA Greenlights Pharmacists to Prescribe COVID-19 Drug Paxlovid*, EPSTEIN BECKER GREEN (July 15, 2022), https://www.ebglaw.com/insights/publications/fda-greenlights-pharmacists-to-prescribe-covid-19-drug-paxlovid [https://perma.cc/T3RZ-AE99] (noting that the FDA's revision to its Emergency Use Authorization for Paxlovid "is unique because it explicitly authorizes a specific health care provider type to prescribe a product.").

16. Leighanne Root, *Closing the Primary Care Gap: Is Pharmacist Prescriptive Authority the Answer?*, 23 ANNALS HEALTH L. 66, 67 (2013).

17. Olivia Plinio, *Your Pharmacist Will See You Now: The Expansion of Prescribing Rights Reaches the Pharmacist*, 44 SETON HALL LEGIS. J. 399, 399–400 (2020).

18. Alex J. Adams & Timothy P. Frost, *Pathways to Pharmacist Prescriptive Authority: Do Decentralized Models for Expanded Prescribing Work?*, 18 RSCH. SOC. & ADMIN. PHARMACY 2695, 2695 (2022).

III. HISTORY OF THE FDA & ITS SCOPE OF REGULATION

After the passing of the Pure Food and Drug Act in 1906, the FDA was founded.[19] The original goal of this act was to prohibit the misbranding of foods and drugs, which, at the time, meant ensuring that a manufacturer was not misleadingly labeling its products.[20] In 1938, the Food, Drug, and Cosmetic Act replaced the Pure Food and Drug Act, strengthening the safety and quality aspects of those products under the FDA's supervision.[21] More specifically, the Food, Drug, and Cosmetic Act of 1938 required makers of new drugs to show that they were safe, expanded the FDA's control to include cosmetics and therapeutic devices, and authorized the FDA to conduct factory inspections.[22] By 1951, when Congress passed the Durham-Humphrey Amendment, the FDA was given the power, which the drug manufacturers once held, to categorize drugs as either prescription or nonprescription (over-the-counter [OTC]).[23] Congress passed the Kefauver-Harris Amendment in 1962, following the thalidomide tragedy, which required drug manufacturers to prove to the FDA that its products were efficacious for the first time before they could be sold to the public.[24] Over the last sixty years, other prominent pieces of legislation that have shaped the landscape and role of the current FDA include the Orphan Drug Act of 1983, the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act), the Prescription Drug User Fee Act, and the Food and Drug Administration Modernization Act of 1997.[25]

Today, the FDA regulates prescription and nonprescription drugs; foods like dietary supplements, bottled water, infant formulas, and other food products not regulated by the United States Department of Agriculture; biologics including vaccines and blood products; medical devices including tongue depressors, heart pacemakers, and surgical implants; electronic products that give off radiation including microwave ovens, x-ray equipment, and laser products; cosmetics including skin moisturizers, nail polish, and color additives used in makeup; veterinary products including livestock feeds, veterinary drugs, and veterinary devices; and tobacco products including cigarettes,

19. Sant Leelamanthep & Shane R. Sergent, *Pharmacy Federal Rules and Regulations*, *in* STATPEARLS (2023).

20. *Id.*

21. *Id.*

22. *Milestones of Drug Regulation in the United States*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/109482/download [https://perma.cc/75JA-VCUH].

23. Leelamanthep & Sergent, *supra* note 19.

24. *Milestones of Drug Regulation in the United States*, *supra* note 22.

25. *Id.*

smokeless tobacco, and e-cigarettes.[26] When looking at the regulation of pharmacies, the FDA approves and regulates the prescription and nonprescription drugs, along with any other products from the above list or included within the category, sold in pharmacies.[27] In addition, if the pharmacy compounds drugs, the FDA publishes rules and policies that apply to those pharmacies.[28]

IV. HISTORY OF REGULATING THE PRACTICE OF PHARMACY

In the late nineteenth century, American pharmacists chose to self-regulate the profession to distinguish themselves as health care professionals and not merchants of pharmaceuticals.[29] Pharmacists primarily did this self-regulation at the state level.[30] In 1804, Louisiana became the first state to require pharmacists to be licensed.[31] When the federal government started to pass drug laws in the early part of the twentieth century, this early organization by pharmacists and the creation of a self-governance system allowed for the enforcement of these newly passed laws.[32]

In addition to the early organization of the profession being at the state level, the Supreme Court has found the regulation of health care providers to be a state power.[33] In *Dent v. West Virginia*, the Supreme Court deemed a state law constitutional that required a person to obtain a certificate from the state Board of Health before practicing in the state.[34] The Supreme Court found that the statute was not void under the Fourteenth Amendment and reasoned that West Virginia had the right to exclude those not having the necessary qualifications to practice medicine to protect its citizens.[35] Before this case, in 1895,

26. *What Does FDA Regulate?*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate [https://perma.cc/CA9G-TXBV].

27. *What FDA Does and Does Not Regulate*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/animal-veterinary/animal-health-literacy/what-fda-does-and-does-not-regulate [https://perma.cc/6KWP-UGWM].

28. *Id.*

29. RICHARD R. ABOOD & KIMBERLY A. BURNS, PHARMACY PRACTICE AND THE LAW 302 (9th ed. 2020).

30. *Id.*

31. Karen Schwartz, *The Craft That Cured a City*, HISTORY, https://www.history.com/the-promised-land/new-orleans-pharmacy.html [https://perma.cc/KF7W-6FGC].

32. ABOOD & BURNS, *supra* note 29, at 302.

33. *See* Dent v. West Virginia, 129 U.S. 114, 122–23 (1889); Graves v. Minnesota, 272 U.S. 425, 428–29 (1926).

34. *Dent*, 129 U.S. at 122–23.

35. *Id.* at 121–23.

the Supreme Court mentioned that a state could grant licenses to pursue particular occupations in a case about using "spiritous liquors" in medicinal products created by a pharmacist.[36]

Today, state laws or pharmacy practice acts regulate the practice of pharmacy.[37] These laws provide for a state administrative agency, most often the state's board of pharmacy, to oversee the enforcement of these laws and regulations.[38] The governor of the state usually appoints the members of the board.[39] Practicing pharmacists make up the majority of members on state boards of pharmacy.[40] However, the composition of a board of pharmacy depends on the state, as some states allocate a certain number of seats for consumer members or members from other health care professions.[41] Additionally, some states require pharmacists from different practice settings, like community pharmacies and hospital pharmacies, to fill the pharmacist member positions on the board.[42]

The board of pharmacy ensures that the entire profession follows these laws and regulations.[43] Pharmacies, pharmacists, student pharmacists, pharmacy technicians, and ancillary personnel working within a pharmacy can all be subject to the board's control.[44] The board of pharmacy licenses those practicing pharmacy and the business entities operating pharmacies.[45] In addition, the board is responsible for handling disciplinary issues that may arise if a licensed individual or pharmacy is not complying with a specific law or regulation.[46] The board is occasionally criticized by members of the profession when it enforces certain rules or imposes disciplinary action.[47] However, it is important to remember that the board of pharmacy does not serve the profession's interests but protects the public's interests.[48]

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36. Gray v. Connecticut, 159 U.S. 74, 76–77 (1895).
37. ABOOD & BURNS, *supra* note 29, at 303.
38. *Id.*
39. *Id.* at 304.
40. *Id.*
41. *Id.*
42. *Id.*
43. *Id.* at 303–04.
44. Ned Milenkovich, *State Boards of Pharmacy Wield Control and Power*, 86 PHARMACY TIMES (2020).
45. ABOOD & BURNS, *supra* note 29, at 304–05.
46. Milenkovich, *supra* note 44.
47. ABOOD & BURNS, *supra* note 29, at 303.
48. *Id.*

V. THE FDA'S EMERGENCY USE AUTHORIZATION AUTHORITY

The Emergency Use Authorization authority permits the FDA to utilize medical countermeasures to protect the nation during public health emergencies.[49] Medical countermeasures are any FDA-regulated products that can be "used to diagnose, prevent, protect from, or treat" diseases or conditions during a public health emergency.[50] Section 564 of the Federal Food, Drug, and Cosmetic Act allows the FDA to authorize the use of unapproved medical products or approved medical products for unapproved uses during emergencies when no other approved alternatives are available.[51] Before the FDA can authorize the use of an unapproved medical product or an approved medical product for an unapproved use, the Secretary of Health and Human Services (HHS) must first declare that there is a public health emergency and that an emergency use authorization is appropriate.[52] The Secretary of HHS can support their declaration of use by pointing to one of the four types of determinants of threats:

> 1. A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a CBRN[53] agent(s);
>
> 2. A determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a CBRN agent(s);
>
> 3. A determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents,

49. *Emergency Use Authorization*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization [https://perma.cc/6WGQ-474A].

50. *What Are Medical Countermeasures?*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/emergency-preparedness-and-response/about-mcmi/what-are-medical-countermeasures [https://perma.cc/F2Q2-5YFP].

51. *Emergency Use Authorization*, *supra* note 49.

52. *Id.*

53. Chemical, biological, radiological, or nuclear. *Id.*

> or a disease or condition that may be attributable to such agent(s); or
>
> 4. The identification of a material threat, by the Secretary of Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act, that is sufficient to affect national security or the health and security of United States citizens living abroad.[54]

One can trace the FDA's Emergency Use Authorization authority back to the passing of the Project BioShield Act of 2004 following the September 11 terrorist attacks and the ensuing anthrax mail attacks.[55] It was Congress's intent for the FDA to authorize unapproved products that the FDA controls for emergency use following an emergency declaration by the Secretary of HHS.[56] The FDA rarely used its Emergency Use Authorization authority before the COVID-19 pandemic.[57] Its most prominent use, pre-COVID-19, was during the 2009 Swine Flu Pandemic when the FDA authorized the use of antivirals, personal respiratory protection devices, and diagnostic devices to aid in the fight against the H1N1 virus.[58] The FDA also used this power in anticipation of the Middle East Respiratory Syndrome (MERS), Ebola, and Zika epidemics.[59]

Most recently, the FDA has issued hundreds of Emergency Use Authorizations to help end the COVID-19 pandemic.[60] Since February 2020, following Secretary of HHS Alex Azar's declaration of a public health emergency, personal protective equipment, medical devices, in vitro diagnostic products, drugs, and vaccines have been a part of Emergency Use Authorizations.[61] This was the first time the FDA authorized a new vaccine via its Emergency Use Authorization power.[62] For comparison, the FDA issued twenty-two Emergency Use

54. *Emergency Use Authorization of Medical Products and Related Authorities*, U.S. FOOD & DRUG ADMIN. (Jan. 2017), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities [https://perma.cc/32NE-2H5E].

55. Jonathan Iwry, *From 9/11 to COVID-19: A Brief History of FDA Emergency Use Authorization*, HARV. L. PETRIE-FLOM CTR. (Jan. 28, 2021), https://blog.petrieflom.law.harvard.edu/2021/01/28/fda-emergency-use-authorization-history/ [https://perma.cc/MDQ4-SU9N].

56. *Id.*

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.*

61. *Id.*

62. *Id.*

Authorizations during the 2009 Swine Flu Pandemic and almost four hundred during its response to the COVID-19 pandemic.[63] Certain groups criticized the FDA's increased issuance of Emergency Use Authorizations,[64] but it is also important to note that the FDA was dealing with an unprecedented pandemic.

VI. THE HISTORY OF PHARMACIST PRESCRIPTIVE AUTHORITY

Pharmacists in some states have been able to prescribe through collaborative practice agreements for decades.[65] In 1979, Washington became the first state to pass legislation allowing pharmacists to prescribe following the creation of a collaborative practice agreement.[66] Under collaborative practice agreements, pharmacists and physicians create guidelines that enable the pharmacist to start or change prescription regimens in particular situations.[67] Forty-nine states have laws authorizing pharmacists to prescribe when acting under a collaborative practice agreement, but there is a growing trend to allow pharmacists to prescribe without a collaborative practice agreement.[68] However, not all states have granted pharmacists prescriptive authority, and the ones that permit pharmacists to prescribe vary in which medications pharmacists can prescribe and how they can do so.[69]

Depending on the state, pharmacists may have prescriptive authority for hormonal contraceptives, tobacco cessation aids, naloxone, HIV Pre-Exposure Prophylaxis (PrEP) medication, epinephrine, travel medicines, or immunizations.[70] Pharmacists can prescribe hormonal contraceptives in twenty-one states, as of September 2022, without a collaborative practice agreement.[71] As of

63. *Id.; see also* Itay Moshkovits & Daniel Shepshelovich, *Emergency Use Authorizations of COVID-19-Related Medical Products*, 182 JAMA INTERNAL MED. 228, 228 (2022) (finding that 393 products were issued Emergency Use Authorizations during the COVID-19 pandemic as of January 22, 2021).

64. Iwry, *supra* note 55.

65. Alex J. Adams, *Pharmacist Prescriptive Authority: Lessons from Idaho*, 8 PHARMACY 112, 112 (2020).

66. Matthew Murawski et al., *Advanced-Practice Pharmacists: Practice Characteristics and Reimbursement of Pharmacists Certified for Collaborative Clinical Practice in New Mexico and North Carolina*, 68 AM. J. HEALTH SYS. PHARMACY 2341, 2342 (2011).

67. Adams, *supra* note 65, at 112.

68. *Id.*

69. Engelen**,** *supra* note 4.

70. *Id.*

71. *Pharmacist Prescribing: Hormonal Contraceptives*, NAT'L ALL. STATE PHARMACY ASS'NS (Sept. 1, 2022), https://naspa.us/resource/contraceptives/ [https://perma.cc/5LV6-URR4].

March 2022, seventeen states have permitted pharmacists to prescribe tobacco cessation aids.[72] Some states permit a pharmacist to prescribe all FDA-approved tobacco cessation products (including varenicline and bupropion), while others may limit it to all nicotine replacement products.[73] All fifty states allow pharmacists to prescribe naloxone in some manner, whether through a standing order, without a prescription, or under a statewide protocol.[74] Naloxone is an opioid antagonist that reverses an opioid overdose by restoring the person's normal breathing.[75] Regarding PrEP, six states have expanded pharmacist prescriptive authority to include these drugs.[76]

States have approached pharmacist prescriptive authority in a variety of different ways. State legislatures have granted prescriptive authority for one medication at a time through legislation, authorized parameters or situations in which the state board of pharmacy may authorize pharmacists to prescribe certain medications, and passed legislation that allows pharmacists to prescribe medications in particular categories.[77] A few states require pharmacists to gain additional credentials or undergo specific training to prescribe once the state legislature has authorized pharmacist prescriptive authority.[78]

Some states, like Virginia and Arkansas, have passed legislation for granting or expanding pharmacist prescriptive authority one medication at a time.[79] This process requires the state legislature to pass a law each time to change the practice of pharmacy within that

72. *Pharmacist Prescribing: Tobacco Cessation Aids*, NAT'L ALL. STATE PHARMACY ASS'NS (Feb. 10, 2021), https://naspa.us/resource/tobacco-cessation/ [https://perma.cc/W8K6-SBK4].

73. *Id.*

74. *Pharmacist Prescribing: Naloxone*, NAT'L ALL. STATE PHARMACY ASS'NS (Jan. 17, 2019), https://naspa.us/resource/naloxone-access-community-pharmacies/ [https://perma.cc/HH4K-98KL].

75. *Naloxone DrugFacts*, NAT'L INST. ON DRUG ABUSE (Jan. 2022), https://nida.nih.gov/publications/drugfacts/naloxone [https://perma.cc/7ML9-CH3N].

76. Anna Wells & Amanda Nguyen, *Greater Pharmacist Prescribing Authority Improves Patient Access: A Case Study on PrEP for HIV*, GOODRX HEALTH (Nov. 2, 2022), https://www.goodrx.com/healthcare-access/research/pharmacist-prescriber-authority-hiv-prep [https://perma.cc/P2FV-CDE6].

77. James Broughel & Elise Amez-Droz, Expanding Pharmacists' Prescriptive Authority: Options for Reform, MERCATUS CTR. GEO. MASON UNIV. (Dec. 15, 2021), https://www.mercatus.org/research/policy-briefs/expanding-pharmacists-prescriptive-authority-options-reform [https://perma.cc/24GC-HPQ8].

78. Evans, *supra* note 6.

79. Broughel & Amez-Droz, *supra* note 77.

state to include the prescribing of the specific medication.[80] One advantage of expanding prescriptive authority this way is that it allows legislators and other stakeholders to monitor implementation, leading to greater transparency.[81] The potential downsides include that this process is slow for those wanting to expand access to care to meet unmet patient needs and that it can be time-consuming and burdensome for legislators.[82] Further, expanding prescriptive authority in this manner opens up each subsequent expansion to criticism and lobbying efforts of those against pharmacists performing this task, extending the time that some patient needs may go unmet.[83]

Other states, like Oregon and Utah, took a different route in granting pharmacist prescriptive authority by passing legislation that sets parameters for the state board of pharmacy to decide which medications pharmacists can prescribe that meet the legislature's broad criteria.[84] Proponents of expanding prescriptive authority this way emphasize that it allows those with the expertise – the board of pharmacy members – to make the decisions that yield the best result for patients.[85] Additionally, some find that this option for expansion shields the decision-making process from political motives and special interest groups.[86] Opponents of this expansion option bring up that the board of pharmacy may not move any faster at promulgating regulations than the legislature would at passing laws.[87] Further, they criticize the process as giving power to an unelected board that constituents cannot hold to the same accountability standards as those elected to enact laws.[88]

States like Idaho decided to grant pharmacists prescriptive authority by allowing pharmacists to prescribe medications from broad categories established by the state legislature and the board of pharmacy unless the statute prohibits a particular drug or the act of prescribing in a specific situation.[89] Supporters of this expansion process often point to the idea that allowing prescriptive authority in this way authorizes pharmacists to intervene more easily in patient care.[90] In

80. *Id.*
81. *Id.*
82. *Id.*
83. *Id.*
84. *Id.*
85. *Id.*
86. *Id.*
87. *Id.*
88. *Id.*
89. *Id.*
90. *Id.*

addition, some say that permitting prescriptive authority in this manner enables the pharmacist-patient interaction to determine the prescribing decision rather than the agenda of the state legislature or board of pharmacy.[91] The increased access to care and prescriptive authority will depend on the breadth of the categories created.[92] Critics of this type of expansion stress the budgetary problems this could put on insurers or government-funded health care programs.[93] However, the pharmacists' ability to solve patient issues without the patient seeking more expensive outpatient or inpatient care may offset this increased spending.[94]

New Mexico, California, Montana, and North Carolina require pharmacists to obtain additional credentials before prescribing certain medications or performing specific functions.[95] In 1993, New Mexico was the first state to do this, requiring pharmacists to obtain a Pharmacist Clinician Certification before prescribing drugs to treat chronic and nonchronic conditions.[96] Today, the New Mexico Board of Pharmacy calls a pharmacist completing these additional requirements a Pharmacist Clinician.[97] In California, pharmacists can obtain an Advanced Practice Pharmacist license to deliver complex health care services after completing more requirements than a standard licensed pharmacist.[98] North Carolina and Montana offer pharmacists expanded prescriptive authority by obtaining a Clinical Pharmacist Practitioner license.[99]

VII. The FDA's Emergency Use Authorization for Paxlovid

Pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act, the FDA issued an Emergency Use Authorization for Paxlovid in response to the COVID-19 pandemic.[100] Paxlovid is an antiviral drug

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.*

95. Evans, *supra* note 6.

96. *Id.*

97. *Id.*

98. *Id.*

99. *Id.*

100. Letter from Patrizia Cavazzoni, Dir., Ctr. for Drug Evaluation & Rsch. U.S. Food & Drug Admin. to Karen Baker, Glob. Regul. Affairs Dir., Pfizer, Inc. (Oct. 27, 2022).

that consists of nirmatrelvir and ritonavir.[101] Nirmatrelvir is a SARS-CoV-2 main protease inhibitor, which would theoretically inhibit SARS-CoV-2 replication.[102] Ritonavir is an HIV-1 protease inhibitor and CYP3A4 inhibitor, which could allow for the nirmatrelvir plasma levels to increase to more opportunistic levels for SARS-CoV-2 replication inhibition by inhibiting the CYP3A4-mediated metabolism of nirmatrelvir.[103] With this mechanism of action in mind, along with the totality of the evidence available to the FDA and the lack of available alternatives, the FDA determined it was reasonable to believe that Paxlovid may be effective at treating mild-to-moderate COVID-19 in those patients meeting all the criteria.[104] The initial Emergency Use Authorization for Paxlovid allowed physicians, advanced practice registered nurses, and physician assistants to prescribe Paxlovid to eligible patients.[105]

On July 6, 2022, the FDA revised its Emergency Use Authorization for Paxlovid to allow state-licensed pharmacists to prescribe Paxlovid to patients meeting the appropriate criteria.[106] In the FDA's news release of the revised Emergency Use Authorization for Paxlovid, Patrizia Cavazzoni, Director of the FDA's Center for Drug Evaluation and Research, reasoned that since patients must start Paxlovid within the first five days of the onset of symptoms, allowing pharmacists to prescribe the drug would expand access to care.[107] In 2015, 90% of Americans lived within two miles of a pharmacy.[108] As a result of this

101. *Fact Sheet for Healthcare Providers: Emergency Use Authorization for Paxlovid*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/155050/download [https://perma.cc/T2YM-QRXP].

102. *Id.*

103. *Id.*

104. *Id.*

105. Lea Gulotta James et al., *FDA Allows Pharmacists to Prescribe the COVID-19 Antiviral Paxlovid*, FOLEY & LARDNER LLP (Aug. 3, 2022), https://www.foley.com/en/insights/publications/2022/08/fda-pharmacists-prescribe-covid-antiviral-paxlovid [https://perma.cc/F2A3-K6E3].

106. *FDA Authorizes Pharmacists to Prescribe Paxlovid with Certain Limitations*, *supra* note 7.

107. *Id.* (noting that Patrizia Cavazzoni said "[t]he FDA recognizes the important role pharmacists have played and continue to play in combatting this pandemic," and that "[s]ince Paxlovid must be taken within five days after symptoms begin, authorizing state-licensed pharmacists to prescribe Paxlovid could expand access to timely treatment for some patients who are eligible to receive this drug for the treatment of COVID-19.").

108. Dima Mazen Qato et al., *The Availability of Pharmacies in the United States: 2007-2015*, 12 PLOS ONE 1 (2017).

revision, the FDA authorized state-licensed pharmacists to prescribe Paxlovid to adults and pediatric patients meeting the following criteria:

> Positive SARS-CoV-2 test (Confirmation of a positive home rapid SARS-CoV-2 test result with additional direct SARS-CoV-2 viral testing is not required.)
>
> Age ≥ to 18 years or ≥ to 12 years of age and weighing at least 40 kg
>
> Has one or more risk factors for progression to severe COVID-19 (Healthcare providers should consider the benefit-risk for an individual patient.)
>
> Symptoms consistent with mild to moderate COVID-19[109]
>
> Symptom onset within 5 days (Prescriber is encouraged to include a note to the pharmacist in the prescription stating: Please fill prescription by [insert date]. The prescription fill by date is within 5 days from symptom onset and complies with the patient eligibility criteria under the EUA.)
>
> Not requiring hospitalization due to severe or critical COVID-19 at treatment initiation
>
> No known or suspected severe renal impairment (eGFR ≤ 30 mL/min)
>
> > Note that a dose reduction is required for patients with moderate renal impairment (eGFR ≥ 30 < 60 mL/min); see the Fact Sheet for Healthcare Providers.
> >
> > To assess renal function:
> >
> > > Physicians, advanced practice registered nurses, and physician assistants who are licensed or authorized under state law to prescribe drugs may rely on patient history and access to the patient's health records to make an assessment regarding the likelihood of renal impairment. Providers may consider ordering a serum creatinine or

109. *Clinical Spectrum of SARS-CoV-2 Infection*, NAT'L INST. OF HEALTH, https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum [https://perma.cc/ETB9-CH2U] (defining those with mild to moderate illness as those "who have any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell) but who do not have shortness of breath, dyspnea, or abnormal chest imaging," and those with moderate illness as those "who show evidence of lower respiratory disease during clinical assessment or imaging and who have an oxygen saturation measured by pulse oximetry (SpO2) ≥94% on room air at sea level.").

> calculating the estimated glomerular filtration rate (eGFR) for certain patients after assessment on a case-by-case basis based on history or exam.
>
> State-licensed pharmacists must have sufficient information available, such as through access to health records less than 12 months old or consultation with a health care provider in an established provider-patient relationship with the individual patient; see the Fact Sheet for Healthcare Providers.[110]

No known or suspected severe hepatic impairment (Child-Pugh Class C)

> To assess hepatic impairment:
>
> Physicians, advanced practice registered nurses, and physician assistants who are licensed or authorized under state law to prescribe drugs may rely on patient history and access to the patient's health records to make an assessment regarding the likelihood of hepatic impairment.
>
> State-licensed pharmacists must have sufficient information available, such as through access to health records less than 12 months old or consultation with a health care provider in an established provider-patient relationship with the individual patient; see the Fact Sheet for Healthcare Providers.[111]

No history of clinically significant hypersensitivity reactions [e.g., toxic epidermal necrolysis (TEN) or Stevens-Johnson syndrome] to the active ingredients (nirmatrelvir or ritonavir) or other components of the product.[112]

Under the above criteria, if a pharmacist cannot assess a patient's renal or hepatic function, they cannot prescribe Paxlovid to the patient.[113] Pharmacists must also confirm no contraindications or interactions with the patient's concomitant medications.[114] When a pharmacist cannot assess the patient for potential drug interactions or a modification of one of the patient's concomitant medications is needed

110. *Fact Sheet for Healthcare Providers: Emergency Use Authorization for Paxlovid*, *supra* note 101.

111. *Id.*

112. *Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers*, U.S. FOOD & DRUG ADMIN. (Mar. 13, 2024), https://www.fda.gov/media/158165/download [https://perma.cc/K5EC-HQWP].

113. *Id.*

114. *Id.*

to take Paxlovid, the pharmacist must refer the patient to a physician, advanced practice registered nurse, or physician assistant for clinical evaluation.[115] Only after ensuring the patient meets the above criteria is a pharmacist permitted to prescribe Paxlovid to a patient.[116]

VIII. THE FDA LACKS THE AUTHORITY TO REGULATE PRESCRIPTIVE AUTHORITY

A. The Supreme Court Has Settled That States Regulate the Practice of Health Care Providers, While the FDA Regulates Products

The Supreme Court has long held that states have the power to regulate the practice of health care providers by setting the required educational qualifications and skills needed to receive a certificate or license to practice within that state.[117] In 1899, the Supreme Court found that states can place these licensure requirements on health care providers because the state's power to provide for the general welfare of its people allows it to put in place such regulations.[118] By implementing these qualifications for licensure, the state is acting in a way that it believes "will secure or tend to secure them against the consequences of ignorance and incapacity as well of deception and fraud."[119] Further, the Supreme Court ruled that states can put in place requirements that they deem necessary as long as they are "appropriate to the calling or profession, and attainable by reasonable study or application," finding that unless the requirement contradicts these points, it does not deprive one of the right to pursue a lawful vocation.[120]

Almost forty years later, Minnesota passed a statute prohibiting persons from practicing dentistry whom the state board of dental examiners had not licensed.[121] An unlicensed person practicing dentistry challenged the law's constitutionality, focusing on the requirement that an applicant for licensure must show that they have a diploma from an approved dental college before being examined by the board.[122] The Supreme Court in *Graves v. Minnesota* maintained its position that states have the power to regulate the practice of health care providers to protect the general welfare of its people under the Fourteenth Amendment and found that the state was not acting in an arbitrary or

115. *Id.*

116. *FDA Authorizes Pharmacists to Prescribe Paxlovid with Certain Limitations*, *supra* note 7.

117. Dent v. West Virginia, 129 U.S. 114, 122–23 (1889).

118. *Id.*

119. *Id.* at 122.

120. *Id.*

121. Graves v. Minnesota, 272 U.S. 425, 426 (1926).

122. *Id.* at 426–27.

unreasonable manner by having this requirement for licensure in place.[123] Thus, the statute was constitutional.[124]

A few years before the *Graves* decision, the Supreme Court heard another case about the licensing and practice of dentistry.[125] In *Douglas v. Noble*, a person who had not passed the examination required by the state licensing board but had an appropriate degree and was of good moral character was denied a license by the board.[126] The person continued to practice dentistry without a license.[127] When the state brought criminal proceedings against him, he argued that the state licensing statute was void and the board arbitrarily exercised its power when it refused to grant him a license.[128] The unlicensed person argued that the state statute did not "state in terms what the scope and character of the examination shall be," and as such, it was arbitrary for the board to grant or deny licenses.[129] Citing *Mutual Film Corporation v. Ohio Industrial Commission*, the Supreme Court ruled that it was appropriate for state boards to "[t]o determine the subjects of which one must have knowledge in order to be fit to practice dentistry; the extent of knowledge in each subject; the degree of skill requisite; and the procedure to be followed in conducting the examination."[130] Further, the Supreme Court found that states could delegate these functions to the state boards and that this delegation complies with the Constitution.[131]

In *United States v. Evers*, the Fifth Circuit Court of Appeals decided a case relating to a physician's ability to prescribe any lawful drug for any purpose, even those indications that were not FDA-approved.[132] The Fifth Circuit found that the Federal Food, Drug, and Cosmetic Act did not prevent a physician from prescribing FDA-approved drugs for uses that were not FDA-approved.[133] The opinion also highlighted that Congress did not intend for the Federal Food, Drug, and Cosmetic Act to regulate the practice of medicine, noting that instead, the Act's purpose was to control which drugs were

123. *Id.* at 428–29.

124. *Id.* at 429.

125. Douglas v. Noble, 261 U.S. 165, 166 (1923).

126. *Id.* at 167.

127. *Id.* at 166.

128. *Id.*

129. *Id.* at 167.

130. *Id.* at 169–70.

131. *Id.* at 170.

132. United States v. Evers, 643 F.2d 1043, 1044 (5th Cir. 1981).

133. *Id.* at 1048.

available for practitioners to prescribe.[134] More recently, in *United States v. Regenerative Sciences, LLC*, the United States Court of Appeals for the District of Columbia Circuit Court cited *Evers* and noted that Congress did not intend for the Federal Food, Drug, and Cosmetic Act to regulate the practice of medicine.[135] This case concerned the distribution of a drug mixture of a patient's stem cells and doxycycline manufactured by a doctor.[136] The circuit court determined that this was not considered the practice of medicine and was within the powers given to the FDA under the Federal Food, Drug, and Cosmetic Act because the case was about the safety of the product, not about the administration of the product.[137]

Based on the Supreme Court decisions above, there is a long-standing precedent that states have the power to regulate the practice of health care providers.[138] That power includes allowing the states to determine the requirements for licensure and delegating to the boards the function of determining if a candidate met all the requirements for licensure.[139]

It is difficult to construe the FDA's July 2022 revision of its Emergency Use Authorization for Paxlovid without reading it in a way that would alter the practice of state-licensed pharmacists in numerous states. As discussed in Section VI, pharmacist prescriptive authority is a relatively recent development and is inconsistent amongst the states.[140] Pharmacist prescriptive authority varies significantly from state to state, with states differing on which drugs pharmacists can prescribe and the mechanism or process in place for the pharmacist to prescribe.[141] Further, some states require additional credentials on one's pharmacist license to participate in the state's expanded prescriptive authority.[142]

When the FDA released its July 6, 2022, revision of its Emergency Use Authorization for Paxlovid, the revision's blanket inclusion of all

134. *Id.*

135. United States v. Regenerative Scis., LLC, 408 U.S. App. D.C. 259, 264–65 (2014).

136. *Id.* at 262.

137. *Id.* at 264–65.

138. *See* Dent v. West Virginia, 129 U.S. 114, 122–23 (1889); Graves v. Minnesota, 272 U.S. 425, 428–29 (1926); Douglas v. Noble, 261 U.S. 165, 167–68 (1923).

139. *Douglas*, 261 U.S. at 170.

140. Adams, *supra* note 65, at 112.

141. Evans, *supra* note 6.

142. *Id.* (noting that New Mexico, California, Montana, and North Carolina are all states that require additional credentialing to practice with the state's expanded prescriptive authority).

state-licensed pharmacists to prescribe Paxlovid regulated the practice of health care providers and encroached on the state's right to do so. The FDA's revision increased the scope of practice for pharmacists with no regard to the state's current stance on pharmacist prescriptive authority, the state's current regulations in place, or the state's requirement for additional credentialing to be able to prescribe. The FDA lacks this authority, as the courts have ruled that Congress intended the Federal Food, Drug, and Cosmetic Act to regulate which drugs were available to be prescribed, not the practice of medicine.[143] The FDA's revision to its Emergency Use Authorization for Paxlovid as related to pharmacist prescriptive authority does not control which drugs health care providers can prescribe; instead, it controls which health care providers can prescribe drugs. As such, the revision should be deemed void.

B. The Federal Food, Drug, and Cosmetic Act Does Not Explicitly Grant the FDA the Power to Alter Prescriptive Authority

The Director of the FDA's Center for Drug Evaluation and Research, Dr. Patrizia Cavazzoni, cited Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §360bbb-3) for the FDA's authority to expand the prescriptive authority to state-licensed pharmacists in a letter of authorization.[144] Section 564 gives the FDA the power to authorize the use of unapproved medical products or approved medical products for unapproved uses during public health emergencies.[145] This paper does not discuss the Secretary's decision to issue a public health emergency declaration, just whether the FDA has the authority to alter pharmacist prescriptive authority following the Secretary of HHS's determination that there was a public health emergency.[146] Section 564(d) requires the authorization to state the diseases that practitioners can use the product to diagnose, prevent, or treat.[147] Further, the authorization must mention that the Secretary's decision of the known and potential benefits of the product outweigh its risks, and the Secretary's conclusions about the safety and effectiveness of the product are based on the available evidence.[148]

Given that Paxlovid would be classified as an unapproved product, the required conditions of authorization in Section 564(e)(1)(A) would apply. The statute defines an unapproved product as one that "is not

143. United States v. Evers, 643 F.2d 1043, 1048 (5th Cir. 1981); United States v. Regenerative Scis., LLC, 408 U.S. App. D.C. 259, 265 (2014).

144. Letter from Patrizia Cavazzoni, *supra* note 100.

145. Authorization of Emergency Use of a Biological Product During the COVID-19 Pandemic; Availability, 87 Fed. Reg. 52790 (July 13, 2022).

146. Letter from Patrizia Cavazzoni, *supra* note 100.

147. 21 U.S.C. § 360bbb.

148. *Id.*

approved, licensed, or cleared for commercial distribution."[149] Section 564(e) states:

> (e) Conditions of authorization
>
> (1) Unapproved product
>
> (A) Required conditions
>
> With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:
>
> (i) Appropriate conditions designed to ensure that health care professionals administering the product are informed—
>
> (I) that the Secretary has authorized the emergency use of the product;
>
> (II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and
>
> (III) of the alternatives to the product that are available, and of their benefits and risks.[150]

Section 564(e)(1)(A)(i) uses the term "administering" to describe the action in which health care professionals are to utilize unapproved products during emergencies.[151] The term "administer" is not defined within Section 564's definitions or anywhere else in the Federal Food, Drug, and Cosmetic Act.[152] However, Section 360(g)(2) within the Federal Food, Drug, and Cosmetic Act uses the phrase "prescribe or administer" to describe what actions a practitioner can take regarding

149. *Id.*

150. *Id.*

151. *Id.*

152. *Id.*; 21 U.S.C. §§ 301–399i.

drugs and devices.[153] Thus, one could argue that they cannot mean the same thing under the general principles of statutory interpretation. For example, when a statute uses specific language in one section but does not include it in other parts, the reader is to presume that Congress did so intentionally and purposely.[154] Without a definition or explicit statement that the reader should use the words interchangeably, the term "administering" throughout the statute should not be construed in a way that means the same thing as prescribing. It should only pertain to the administration of drugs, which would not give the FDA the authority to regulate prescribing.

Further, the difference between these actions is not unknown to legislators or health care providers. Some state statutes and pharmacy acts differentiate administering from prescribing by defining administering as the direct application of a drug to the patient's body through injection, inhalation, ingestion, or another route.[155] The act of prescribing, on the other hand, usually means ordering or issuing a prescription for a drug or device for a particular patient to use themselves.[156] The FDA's July 2022 revision of the Emergency Use Authorization for Paxlovid permits pharmacists to prescribe Paxlovid – not administer it.[157] Thus, one could argue the FDA went beyond the authority provided to it under Section 564 of the Federal Food, Drug, and Cosmetic Act when it permitted the prescribing of unapproved products instead of administering them.

In addition, past court cases have considered whether specific language granting the FDA authority to regulate certain areas expands its authority beyond what the statute explicitly mentions.[158] In *Judge*

153. 21 U.S.C. § 360.

154. *See* Merck & Co. v. Reynolds, 559 U.S. 633, 656–57 (2010) (Scalia, J., concurring) (finding that using the word "discovery" alone in one part of the statute and the phrase "discovery . . . or after such discovery should have been made" in another part of the statute implies that the use of "discovery" alone does not include the meanings provided within the longer phrase).

155. *See* W. VA CODE § 30-5-4 (2020) (defining administer as "the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion or any other means"); CAL BUS. & PROF. CODE § 4016 (1998) (defining administer as "the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means"); TEX. OCC. CODE § 551.003(1) (1999) (defining administer as "to directly apply a prescription drug to the body of a patient by any means, including injection, inhalation, or ingestion").

156. *Prescribe vs Administer – What's the Difference?*, WIKIDIFF, https://wikidiff.com/administer/prescribe [https://perma.cc/F3SA-XGAU].

157. Letter from Patrizia Cavazzoni, *supra* note 100.

158. *See* Judge Rotenberg Educ. Ctr., Inc. v. United States FDA, 453 U.S. App. D.C. 90, 93 (2021) (finding that the FDA could not ban stimulation

Rotenberg Education Center, Inc. v. United States FDA, the FDA banned using electrical stimulation devices in treating patients with aggressive or self-injurious behavior.[159] The court found that the natural reading of the statute would only allow the FDA to decide whether to ban the product entirely or approve it.[160] The statutory language did not provide for a third option of having an intermediate state where the ban was for only specific uses.[161] The court then reviewed 21 U.S.C.S. § 360f and 21 U.S.C.S. § 396 in its statutory analysis of whether the FDA had the authority to ban a product for certain uses because the FDA also had to assess the device's risks compared to its benefits.[162] Contemplating that a device could have multiple uses and the risk-to-benefit profile could be different based on how the prescriber was using the device, the FDA focused on the word "reasonable" within the statute and argued that 21 U.S.C.S. § 360f permitted its banning of electrical stimulation devices in some circumstances where there is an unreasonable risk.[163] However, 21 U.S.C.S. § 396 explicitly "denies the FDA [the] authority to construe any part of the Federal Food, Drug, and Cosmetic Act," including its powers authorized under 21 U.S.C.S. § 360f, in a way that would allow the FDA to "limit or interfere" with the prescriptive authority of practitioners administering or prescribing legally marketed devices.[164] The court used the ordinary meanings of the terms "limit" and "interfere" to show that the FDA's restriction was not permitted.[165] Banning the use of electrical stimulation devices in treating patients with aggressive or self-injurious behavior both limited and interfered with a practitioner's ability to practice medicine.[166]

The logic behind the court's decision in *Judge Rotenberg Education Center, Inc. v. United States FDA* could apply here when looking at the ordinary meaning of the term "administer." Merriam-Webster's Dictionary defines administer as "to manage or supervise the execution,

devices for certain purposes because the FDA cannot construe 21 U.S.C. § 396 in a way that would allow them to interfere with the practice of medicine).

159. *Id.*

160. *Id.* at 96.

161. *Id.*

162. *Id.*

163. *Id.*

164. *Id.* at 96–97 (noting that "a device is legally marketed if it is lawful for a manufacturer to sell the device or a practitioner to prescribe or administer it.").

165. *Id.* at 96.

166. *Id.*

use, or conduct of" and "to provide or apply."[167] Thus, Section 564's use of the word administer should not equate to the act of prescribing.

IX. WHY STATES ARE BETTER SUITED TO REGULATE PRESCRIPTIVE AUTHORITY

States are in a better position to make decisions about pharmacist prescriptive authority than the FDA for a variety of reasons.

First, a state can more easily assess and then decide what the patients within its borders need, leading to a more individualized approach.[168] A state can evaluate specific unmet needs that patients in its state may be experiencing that those in other states are not experiencing. For example, patients in rural communities may be more likely to forgo HIV PrEP medications because there is a lack of providers, wait times for appointments with other health care providers are long, or travel to available providers is lengthy. If this were the case, a state with predominantly rural areas might expand prescriptive authority to include pharmacists to increase access to care for its constituents. However, how the state goes about the expansion or whether to expand at all should be left up to the individual state and not the FDA. One could apply this same example to various medications or categories of drugs. Thus, after identifying an access to care issue within a particular segment of health, a state can then decide if it wishes to have pharmacists address that need.

Second, pharmacist prescriptive authority expansion will be better controlled and supervised at the state level.[169] State-empowered medical, dentistry, and nursing boards have been tasked with managing the respective prescriptive authority for providers within their control.[170] In addition, the FDA is too far removed to make decisions that directly impact the boards. By increasing the prescriptive authority of pharmacists, the FDA has likely increased the workload of the state boards of pharmacy, especially those that have not granted pharmacists prescriptive authority. However, it is likely that states with pharmacist prescriptive authority still faced an increased workload when the FDA permitted pharmacists to prescribe Paxlovid. At a minimum, this increased workload could be in the form of answering more questions and providing guidance about how this Emergency Use Authorization works within the state.[171] It also could have resulted in

167. *Administer*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/administer [https://perma.cc/Q2S5-9YPY].

168. Bhatt, *supra* note 9, at 389.

169. *Id.*

170. *See* Zhang & Patel, *supra* note 1.

171. *See FDA Emergency Use Authorization for Paxlovid*, TEX. STATE BD. PHARMACY, https://www.pharmacy.texas.gov/news/fda-emergency-use-auth-paxlovid.asp [https://perma.cc/VVJ2-UECT] (showing an example

state boards of pharmacy having to educate pharmacists of this change and making regulations to ensure the necessary equipment to access recent health records with sufficient information to address a patient's renal and hepatic function is on-site.[172]

Third, states can address local needs promptly and sometimes quicker than the federal government.[173] On March 13, 2020, President Donald Trump declared a national emergency in response to growing concerns about the spread of COVID-19.[174] Shortly after the declaration, states started implementing various shutdowns by closing schools, restaurants, and bars.[175] By March 19, 2020, California became the first state to issue a stay-at-home order.[176] By the end of April 2020, forty-three states had issued lockdown or stay-at-home orders to combat the spread of COVID-19.[177] On March 2, 2020, before President Trump's March 13 declaration, New York's governor had already created emergency rules that barred private insurance companies from inflicting cost-sharing on its enrollees if they sought COVID-19 testing.[178] Other states had also imposed similar restrictions before Congress could pass the Families First Coronavirus Response Act containing related provisions on March 18, 2020.[179] Although each

of a state board of pharmacy providing information related to the FDA's Emergency Use Authorization for Paxlovid).

172. *See OPA COVID-19 Vaccines and Therapeutics: July 13, 2022 Update*, OHIO PHARMACY ASS'N (July 13, 2022), https://www.ohiopharmacists.org/aws/OPA/page_template/show_detail/450716?model_name=news_article [https://perma.cc/2HD7-K3NJ] (highlighting an example of an update put out by a board of pharmacy to educate pharmacists about pharmacists prescribing Paxlovid).

173. Bhatt, *supra* note 9, at 389.

174. *CDC Museum COVID-19 Timeline*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/museum/timeline/covid19.html [https://perma.cc/473F-B5U2].

175. *Id.*

176. AJMC Staff, *A Timeline of COVID-19 Developments in 2020*, AM. J. MANAGED CARE (Jan. 1, 2021), https://www.ajmc.com/view/a-timeline-of-covid19-developments-in-2020 [https://perma.cc/N7NX-UZQM].

177. *States That Issued Lockdown and Stay-at-Home Orders in Response to the Coronavirus (COVID-19) Pandemic, 2020*, BALLOTPEDIA, https://ballotpedia.org/States_that_issued_lockdown_and_stay-at-home_orders_in_response_to_the_coronavirus_(COVID-19)_pandemic,_2020 [https://perma.cc/Z7VF-SSVL].

178. Sabrina Corlette et al., *What Are State Officials Doing to Make Private Health Insurance Work Better for Consumers During the Coronavirus Public Health Crisis?*, COMMONWEALTH FUND (Mar. 20, 2020), https://www.commonwealthfund.org/blog/2020/what-are-state-officials-doing-make-private-health-insurance-work-better-consumers-during [https://perma.cc/HX4Z-WLBF].

179. *Id.*

state's actions varied, all fifty states, either through the governor or a state agency, declared active emergencies to combat the COVID-19 pandemic.[180]

Fourth, when the FDA grants prescriptive authority to pharmacists, it takes away the state's right to experiment with applicable law to address the issue for themselves. State legislators should be able to tweak the law to suit the needs of their constituents or alter the statute to address the problems they intend to combat. Eliminating the state's ability to act in this way allows the FDA to restrict what has long been considered a state right – the power to regulate prescriptive authority.

Lastly, the FDA is not an elected body. Therefore, when it changes prescriptive authority, a well-established state right, it takes power away from the state's legislators to listen to constituents who may wish to lobby for the expansion or restriction of pharmacist prescriptive authority. This issue is not one without controversy, as specific groups have spoken out against the FDA's expansion.[181] More specifically, the Association of American Physicians (AAPS) released a policy statement stating that the FDA lacks the "statutory authority to regulate the practice of medicine" and pharmacists lack the training and qualifications to prescribe Paxlovid given its unique circumstances.[182] Additionally, the president of the American Medical Association (AMA), Jack Resneck, Jr., released a statement on the organization's behalf asserting that prescribing Paxlovid requires a knowledge of the patient's medical history and appropriate follow-up of side effects and improvement of symptoms, which he claims a pharmacist's training and

180. *State Emergency Health Orders During the Coronavirus (COVID-19) Pandemic,* 2021-2022, BALLOTPEDIA, https://ballotpedia.org/State_emergency_health_orders_during_the_coronavirus_(COVID-19)_pandemic,_2021-2022 [https://perma.cc/KHW7-ZQM4].

181. *Association of American Physicians (AAPS) Objects to FDA's Dangerous Rule Allowing Pharmacists to Prescribe Paxlovid*, ASS'N OF AM. PHYSICIANS & SURGEONS (July 20, 2022), https://aapsonline.org/association-of-american-physicians-aaps-objects-to-fdas-illegal-and-dangerous-rule-allowing-pharmacists-to-prescribe-paxlovid/ [https://perma.cc/92PW-F7ZC] (noting that the AAPS objects to pharmacists prescribing Paxlovid); Jack Resneck, Jr., *AMA Statement on Paxlovid Prescribing*, AM. MED. ASS'N (July 6, 2022), https://www.ama-assn.org/press-center/press-releases/ama-statement-paxlovid-prescribing [https://perma.cc/4ZD4-8RYY] (noting that the AMA objects to pharmacists prescribing Paxlovid).

182. *Association of American Physicians (AAPS) Objects to FDA's Dangerous Rule Allowing Pharmacists to Prescribe Paxlovid*, *supra* note 181 (noting that the AAPS believes the FDA lacks the authority to alter pharmacist prescriptive authority related to ordering and administering COVID vaccines through Emergency Use Authorizations under the PREP Act).

scope of practice does not include.[183] Pharmacist associations have the exact opposite viewpoint.[184] The CEOs of the American Pharmacists Association (APhA) and National Community Pharmacists Association (NCPA) released statements opposing the AMA's view, arguing that pharmacists are more than capable of prescribing Paxlovid and are an integral part of ensuring that Americans have access to care.[185] Given the differing viewpoints and the questionable authority that the FDA has over the regulation of prescriptive authority, state legislators should be the ones making the decisions so they can be held accountable by those who vote.

X. OTHER WAYS IN WHICH THE FDA COULD HAVE INTERVENED

The FDA can increase patient access to medications without altering the prescriptive authority of health care professionals. As discussed in Section V, during public emergencies, the FDA's Emergency Use Authorization power allows the FDA to authorize unapproved medical products or approved products for unapproved uses.[186] The FDA has used this power to allow patients increased access to medications during past public health emergencies without altering the prescriptive authority of pharmacists.[187] This paper does not argue

183. Resneck, *supra* note 181 (noting that the following statement is credited to Resneck, "Paxlovid is an important treatment and critical tool in the fight against COVID-19. While the majority of COVID-19 positive patients will benefit from Paxlovid, it is not for everyone and prescribing it requires knowledge of a patient's medical history, as well as clinical monitoring for side effects and follow-up care to determine whether a patient is improving—requirements far beyond a pharmacist's scope and training. In the fight against a virus that has killed more than a million people in the United States and is still extremely present and transmissible, patients will get the best, most comprehensive care from physician-led teams—teams that include pharmacists. But, whenever possible, prescribing decisions should be made by a physician with knowledge of a patient's medical history and the ability to follow up. To ensure the best possible care for COVID-19 patients, we urge people who test positive to discuss treatment options with their physician, if they have one.").

184. Christine Blank, *Pharmacy Groups Respond to AMA Criticism on Pharmacists Prescribing Paxlovid,* DRUG TOPICS (July 18, 2022), https://www.drugtopics.com/view/pharmacy-groups-respond-to-ama-criticism-on-pharmacists-prescribing-paxlovid [https://perma.cc/L226-U2RT].

185. *Id.*

186. *Emergency Use Authorization*, *supra* note 49.

187. *See* Kathleen Sebelius, *Declaration of Emergency Pursuant to Section 564 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360bbb-3(b)*, DEPT. HEALTH & HUM. SERVS. (Mar. 26, 2020), http://wayback.archive-it.org/7993/20170723041200/https://www.fda.gov/downloads/Emergenc

that the FDA should not be able to approve unapproved medical products or approved products for unapproved uses during times of emergency; it asserts that the FDA cannot, under its Emergency Use Authorization powers, alter the prescriptive authority of pharmacists.

One way Congress authorized the FDA to impact patient access when a public health emergency is not declared is through its expanded access program.[188] The FDA's expanded access program allows patients with "a serious or immediately life-threatening disease or condition" to utilize investigational medical products for treatment when no satisfactory therapeutic alternatives are available.[189] The FDA defines investigational medical products as drugs, biologics, or devices that the FDA has not approved, lack data for the FDA to determine the effectiveness of a specific treatment, or cause serious side effects.[190] Patients with one of these diseases or conditions who are unable to enroll in a clinical trial and where there is no comparable alternative therapy may utilize the expanded access program when the potential benefits justify the potential risks of the investigational medical product.[191] To participate in the expanded access program, a patient must find a licensed physician to work with the product company to submit the appropriate paperwork to an Institutional Review Board (IRB) and the FDA requesting expanded access.[192] The physician can treat the patient utilizing the investigational medical product if the physician can acquire the product from the company and is willing to submit the required paperwork and the IRB and FDA approve it.[193] The physician filling out the forms must oversee and monitor the patient's treatment.[194] Between 2010 and 2015, the "FDA authorized 99% of single patient expanded access applications."[195]

However, there are still some hindrances that may prevent a patient from utilizing this program. A patient may be unable to locate a

yPreparedness/Counterterrorism/UCM206802.pdf [https://perma.cc/896X-4CL8].

188. *Expanded Access*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/news-events/public-health-focus/expanded-access [https://perma.cc/ZDY2-YVYN].

189. *Id.*

190. *Id.*

191. *Id.*

192. *Expanded Access | Information for Patients*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/news-events/expanded-access/expanded-access-information-patients [https://perma.cc/4NLU-NVQ6].

193. *Id.*

194. *Id.*

195. Jonathan P. Jarow et al., *Overview of FDA's Expanded Access Program for Investigational Drugs*, 51 THERAPEUTIC INNOVATION & REGUL. SCI. 177, 178 (2017).

licensed physician willing to complete the required steps or oversee their treatment.[196] Further, even if a patient does satisfy the law and the FDA regulations, the IRB may not approve the expanded access program, or the investigational medical product company may not be willing to provide the patient with the investigational medical product.[197] No law requires investigational medical product companies to give their drugs to patients meeting eligibility criteria.[198] These companies may choose not to provide the investigational medical product because there is an ongoing clinical trial or if there is a limited supply of the product.[199] Patients utilized the expanded access program during the COVID-19 pandemic for convalescent plasma to treat severe acute respiratory syndrome coronavirus 2.[200] Like with the convalescent plasma, the FDA could have increased patient access to Paxlovid by having physicians complete the required documents through the expanded access program.

Another way the FDA could influence patient access is by issuing guidance documents. The FDA can issue guidance documents that reflect its current viewpoint on a particular topic or one of its policies.[201] Guidance documents typically cover product design, production, labeling, promotion, and manufacturing.[202] These documents do not bind the public or the FDA to follow what the guidance document suggests.[203] However, the guidance documents could influence state legislators or other agency rule-makers to act a certain way. Here, issuing a guidance document about the possible benefits of using Paxlovid could impact state legislative processes, resulting in the FDA proposing the best way for states to combat the COVID-19 pandemic instead of the states themselves. This allows state legislators to review the FDA's thoughts on a matter before deciding if their state would benefit from implementing one of the FDA's proposals, allowing constituents to hold their state politicians accountable for their decisions.

The FDA can expand patient access to medical products through many different mechanisms. The approaches mentioned above only

196. *Expanded Access | Information for Patients*, *supra* note 192.

197. *Id.*

198. *Id.*

199. Jarow et al., *supra* note 195, at 178.

200. Jonathon W. Senefeld et al., *Access to and Safety of COVID-19 Convalescent Plasma in the United States Expanded Access Program: A National Registry Study*, 18 PLOS MEDICINE 1, 2 (2021).

201. *Guidances*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/industry/fda-basics-industry/guidances [https://perma.cc/4YVW-ZQDV].

202. *Id.*

203. *Id.*

comprise a partial list of all the actions the FDA can take to increase patient access to medications.[204] Within this short section alone, this paper offers the FDA several other avenues it could have utilized to allow more patients to acquire Paxlovid that did not interfere with a state's right to regulate the prescriptive authority of pharmacists. As such, the FDA should have chosen a different process for expanding access to Paxlovid and should not increase access to medications through similar means during future public health emergencies.

XI. What States Should Do Moving Forward

States should push back against the FDA's encroachment, as states have the right to regulate the practice of medicine. Being complacent with just one instance of the usurping of states' rights allows the FDA to utilize this action as a precedent. The FDA may use this power in the future during times less dire than the COVID-19 pandemic. In addition, the FDA may implement additional expansions or restrictions on prescriptive authority that trigger much more opposition.

In this case, the FDA likely was acknowledging the seriousness of the COVID-19 pandemic when it decided to revise its original Emergency Use Authorization for Paxlovid to include prescriptive authority for pharmacists. Expanding prescriptive authority to address access issues is a worthy cause, and pharmacists are qualified to prescribe medications.[205] However, these points do not justify the FDA's actions. If access issues exist and patients cannot adequately obtain COVID-19 treatment, states can enact legislation to address this problem. States may seek to expand pharmacist prescriptive authority to increase patient access to COVID-19 treatments or address the access issue differently. Looking specifically at addressing this issue with the expansion of pharmacist prescriptive authority, states hesitant to pass robust legislation can expand pharmacist prescriptive authority one medication at a time – here, just Paxlovid.

204. The FDA can also increase patient access to particular drugs by regulating the switch from prescription to nonprescription or OTC drugs. *See* Agata Bodie, Cong. Rsch. Serv., R46985, FDA Regulation of Over-the-Counter (OTC) Drugs: Overview and Issues for Congress (2021). However, this conversion is inappropriate for Paxlovid. Paxlovid had not yet been FDA-approved and should not be exempt from prescription-dispensing requirements due to its hepatic and liver function assessment requirements and potential for drug use interactions.

205. See George Van Antwerp et al., *The Pharmacist of the Future: Unlocking the Profession's Potential to Improve Patient Care*, Deloitte Insights, https://www2.deloitte.com/us/en/insights/industry/health-care/future-of-pharmacists.html [https://perma.cc/32JJ-GMVP] (discussing how pharmacists can be utilized to improve patient care and noting that pharmacists who have a Doctor of Pharmacy degree "receive as much classroom clinical instruction as medical doctors").

To stop the FDA from doing this again, states not in favor of expanding prescriptive authority to pharmacists should bring forth a case against the FDA. States have been parties to lawsuits against federal agencies regarding whether Congress authorized the agency to act in a particular way.[206] States have also sued the FDA directly.[207] Trade associations have successfully brought forth cases against the FDA, too.[208] To ensure states remain in control of regulating prescriptive authority, the party bringing the suit should base its argument on the potential issues related to how the July 2022 Emergency Use Authorization for Paxlovid revision regulates the practice of medicine and the FDA's lack of statutory power to act in this way as outlined in Section VIII of this paper.

XII. CONCLUSION

One should not view the lack of pushback from states to the FDA's expansion of pharmacist prescriptive authority as a green light for the federal government to advance any agenda on the well-recognized state right of regulating the practice of medicine. A state legislature is better positioned than the FDA to expand prescriptive authority for pharmacists because it can tailor its approach to best fit its constituents' needs and supervise its implementation. States have the power to enact legislation that expands prescriptive authority, and multiple states have successfully implemented these changes using various methods. States should reject the FDA's revision of the Emergency Use Authorization for Paxlovid to ensure that the federal government, specifically the FDA, knows that states have the right to regulate prescriptive authority.

206. *See* West Virginia et al. v. Environmental Protection Agency et al., 597 U.S. ___ (2022).

207. *See* State v. FDA, No. 8:22-cv-1981-TPB-JSS (M.D. Fla. 2022).

208. *See* Big Time Vapes, Inc. v. FDA, 963 F.3d 436 (5th Cir. 2020) (showing that a vaping trade association could sue the FDA); Natural Products Association v. FDA, No. 8:21-cv-03112-GLS (D. Md. Dec. 6, 2021) (indicating that an association representing the manufacturers and retailers of natural products could bring a suit against the FDA); Afr. Am. Tobacco Control Leadership Council et al. v. U.S. HHS et al., No. 4:20-cv-4012-KAW (N.D. Cal. Dec. 3, 2020) (demonstrating that multiple associations including the American Medical Association and the National Medical Association can sue the FDA).