



June 16, 2023

The Honorable Elizabeth Warren  
309 Hart Senate Office Building  
U.S. Senate  
Washington, DC 20510-2105

The Honorable Mazie K. Hirono  
109 Hart Senate Office Building  
U.S. Senate  
Washington, DC 20510-2105

The Honorable Tammy Duckworth  
524 Hart Senate Office Building  
U.S. Senate  
Washington, DC 20510-2105

The Honorable Tina Smith  
720 Hart Senate Office Building  
U.S. Senate  
Washington, DC 20510-2105

Dear Senators Warren, Hirono, Duckworth, and Smith:

On behalf of the American Pharmacists Association (APhA), we would like to thank your offices for meeting with us on June 12, 2023, and appreciate the opportunity to provide additional comments related to the impact on patients' access to healthcare services following the U.S. Supreme Court decision in *Dobbs v Jackson Women's Health Organization*. As highlighted in our letters on September 9, 2022<sup>1</sup>, September 30, 2022<sup>2</sup>, and June 8, 2023<sup>3</sup>, we are concerned due to continued and expanding reports of delayed care and lost access to medications and continued confusion surrounding conflicting state and federal laws and regulations.

APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

As communicated in our June 8, 2023,<sup>4</sup> letter, APhA supports equitable patient access to evidence-based comprehensive reproductive health care, including, but not limited to, the management of pregnancy loss, ectopic pregnancy, infertility, pregnancy termination, contraception, and permanent contraception. Given this position, we continue to share your concerns with the troubling reports of delays in care or lost access to medications following the *Dobbs* decision. Over the last year, these reports have included patients'

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<sup>1</sup> APhA response to Senator Warrant Regarding States' Access to Reproductive Services (September 2022). Available at [https://pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=IuAXtHhcy\\_Y%3d](https://pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=IuAXtHhcy_Y%3d)

<sup>2</sup> APhA Letter to Senator Warren (September 2022). Available at <https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=2nxkWQsGJII%3d>

<sup>3</sup> APhA Comments to Senator Warren on Reproductive Health Care (June 2023). Available at: [https://pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=IW5EIC\\_bVbA%3d](https://pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=IW5EIC_bVbA%3d)

<sup>4</sup> Ibid

impacted access to medications for abortion, management of pregnancy loss, contraception, and for indications unrelated to reproductive health care.

APhA has spoken publicly of these concerns and requested action from policymakers to ensure patients' continuity of care is not interrupted.<sup>5,6,7,8,9</sup> Specifically, APhA's response to the *Dobbs v. Jackson* decision states:

"As the landscape across the country is changing regarding the provision of reproductive health care and abortion, this should not stand in the way of a pharmacist providing FDA-regulated medications and evidence-based patient care services while carrying out their obligation to their patient. Patients' access to certain medications is challenged in parts of the country where state laws prohibit the use of medications that have reproductive health uses but are also FDA-approved for treatment of chronic diseases; for example, methotrexate for rheumatoid arthritis or misoprostol for ulcer prevention. The current lack of clarity between conflicting laws and regulations creates confusion, and it is compromising patient care."<sup>5</sup>

In addition, APhA is also concerned about courts replacing the scientific expertise and experience of FDA scientists by making uninformed and uneducated decisions on the safety and efficacy of drugs. A regulatory and legal responsibility set forth to FDA by Congress. Following the April 2023 decision in *Alliance for Hippocratic Medicine v U.S. Food and Drug Administration*, APhA released the following statement:

"APhA and our nation's pharmacists stand behind the FDA review and approval process that relies on evidence-based expert review to establish the safety and efficacy of marketed drugs," said Ilisa BG Bernstein, PharmD, JD, FAPhA, interim executive vice president and CEO of APhA. "The FDA gold standard for approval has been in place for nearly 120 years and is the basis for pharmacists' trust and confidence in the medicines they recommend and dispense to patients. The Texas decision does not change this gold standard."<sup>10</sup>

We also issued a joint statement with the American Medical Association (AMA), Society of Health-System Pharmacists (ASHP), and National Community Pharmacists Association (NCPA).<sup>11</sup> In the joint statement, the organizations call on state policymakers to ensure through guidance, law, or regulation that patient care is not disrupted and that physicians and pharmacists shall be free to continue to practice medicine and

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<sup>5</sup> Breaking: APhA issues statement in response to Supreme Court's *Dobbs v Jackson* decision. July 25, 2022. Available at <https://www.pharmacist.com/APhA-Press-Releases/breaking-apha-issues-statement-in-response-to-supreme-courts-dobbs-v-jackson-decision>

<sup>6</sup> New Federal Guidance confuses an already complicated landscape for pharmacists. July 13, 2022. Available at <https://www.pharmacist.com/APhA-Press-Releases/new-federal-guidance-confuses-an-already-complicated-landscape-for-pharmacists>

<sup>7</sup> Abortion Restrictions May Be Making It Harder for Patients to Get a Cancer and Arthritis Drug. *Time Magazine*. Available at <https://time.com/6194179/abortion-restrictions-methotrexate-cancer-arthritis/>

<sup>8</sup> Women with chronic conditions struggle to find medications after abortion laws limit access. *CNN*. July 22, 2022. Available at <https://www.cnn.com/2022/07/22/health/abortion-law-medications-methotrexate/index.html>

<sup>9</sup> Post-Roe drug delays weigh on patients, providers. *Axios*. July 26, 2022. Available at <https://www.axios.com/2022/07/26/post-roe-drug-delays-weigh-on-patients-providers>

<sup>10</sup> APhA statement related to Texas District Court decision regarding mifepristone. April 7, 2023. Available at <https://www.pharmacist.com/About/Newsroom/apha-statement-related-to-texas-district-court-decision-regarding-mifepristone>

<sup>11</sup> AMA, APhA, ASHP, NCPA Statement on State Laws Impacting Patient Access to Medically Necessary Medications. September 8, 2022. Available at: <https://www.pharmacist.com/APhA-Press-Releases/ama-apha-ashp-ncpa-statement-on-state-laws-impacting-patient-access-to-medically-necessary-medications>

pharmacy without fear of professional sanction or liability. Through the joint statement, we strongly urge state medical and pharmacy boards, agencies, and policymakers to act to help ensure that our patients retain continuity of care and that our members clearly understand their legal and licensing obligations.

Please see the below answers to questions included in your May 25, 2023, letter:

**1. How has access to medication abortion changed since the Supreme Court issued its decision in *Dobbs v. Jackson Women’s Health Organization* and since the District Court’s ruling in *Alliance for Hippocratic Medicine v. FDA*?**

Both the *Dobbs* and the *Alliance for Hippocratic Medicine vs. FDA* cases have created confusion due to the rapidly changing legal landscape and fear for pharmacists that providing medication abortion could result in legal consequences.

Differences in state laws, in response to these cases, have worsened already existing disparities in healthcare, particularly for marginalized populations. Not every patient has the time, money, and ability to travel far distances to seek comprehensive reproductive healthcare services. These patients are impacted the most, given that states enacting abortion bans already have higher maternal morbidity/mortality, higher rates of uninsurance, and less social support for families.

Patients who are unable to obtain medication abortion in their state are looking for information online. This creates new issues regarding which websites are legitimate, legal, and able to mail medication abortion medications in the time frame needed under safety guidelines.

**2. Have your providers seen an increase in confusion from patients and/or providers regarding the safety, efficacy, and legality of medication abortion?**

There has been consistent confusion amongst patients and providers regarding the legality of medications used for reproductive health care services since the *Dobbs* decision. This is in large part due to contradictory laws, rules, and guidance’s from state and federal policymakers leaving health care providers in a position where they are unable to efficiently provide needed health care services to their patients.

For example, in December 2022, the General Counsel of the United States Postal Service (USPS) issued a slip opinion entitled *Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions*.<sup>12</sup> In this slip opinion, the argument is made that mailing mifepristone and misoprostol to any jurisdiction is not prohibited under the Comstock Act and that due to the variety of uses of mifepristone and misoprostol, “USPS could not reasonably assume that the drugs are nonmailable simply because they are being sent into a jurisdiction that significantly restricts abortion.”<sup>13</sup>

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<sup>12</sup> Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions. Memorandum Opinion for the General Counsel United States Postal Service. Published December 23, 2022. Available at: <https://www.justice.gov/olc/opinion/file/1560596/download>

<sup>13</sup> Ibid

Following the issuance of this slip opinion, a coalition of 20 State Attorneys General sent letters<sup>14,15</sup> to national pharmacy chains directly disagreeing with the USPS interpretation of Comstock Act and stating, “Federal law expressly prohibits using the mail to send or receive any drug that will ‘be used or applied for producing abortion’...And anyone who ‘knowingly takes any such thing from the mails for the purpose of circulating’ is guilty of a federal crime.” Additionally, the letters highlight that “the laws of many states also prohibit using the mail to send or receive abortion drugs...We emphasize that it is our responsibility as State Attorneys General to uphold the law and protect the health, safety, and well-being of women and unborn children in our states.”

Due to direct contradictions from state and federal policymakers and threats of violating federal or state law, providers lack the clarity of whether providing care to their patients will result in professional, civil, or criminal sanction.

### **3. How have state-imposed restrictions on medication abortion affected patients?**

State-imposed restrictions on abortion care have affected patients in multiple ways. Most directly, patient access to elective abortion care services has become illegal or has been severely restricted in many states. Although this impacts the entire population capable of becoming pregnant in the state, these policies disproportionately impact individuals who face issues related to social determinants of health and do not have the ability, or access to travel to a state where they could receive elective abortion care and related health care services.

State-imposed restrictions on abortion care have expanded during the 2023 legislative sessions. Legislation that expands state-imposed restrictions on abortion care was enacted in 11 states (Florida,<sup>16</sup> Idaho,<sup>17</sup> Nebraska,<sup>18</sup> North Carolina,<sup>19</sup> North Dakota,<sup>20</sup> South Carolina,<sup>21</sup> South Dakota,<sup>22</sup> Tennessee,<sup>23</sup> West Virginia,<sup>24</sup> and Wyoming<sup>25</sup>).

Indirectly, state-imposed restrictions on abortion care have impacted pregnancy care, reproductive care, and other forms of health care. Many of these issues have been the result of vaguely worded state policies that could be interpreted as being more broadly applied to patients even if they are not receiving care related to an abortion. For example, see the below definitions of “abortion-inducing drug,” medical abortion, or other comparable terms:

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<sup>14</sup> Letter to Walgreens Boots Alliance, Inc. Available at: [https://ago.mo.gov/docs/default-source/press-releases/2023-02-01-fda-rule---walgreens-letter-danielle-gray.pdf?sfvrsn=ff1e6652\\_2](https://ago.mo.gov/docs/default-source/press-releases/2023-02-01-fda-rule---walgreens-letter-danielle-gray.pdf?sfvrsn=ff1e6652_2)

<sup>15</sup> Letter to CVS Health. Available at: [https://ago.mo.gov/docs/default-source/press-releases/2023-02-01-fda-rule---cvs-letter-tom-moriarty.pdf?sfvrsn=d42cfc2b\\_2](https://ago.mo.gov/docs/default-source/press-releases/2023-02-01-fda-rule---cvs-letter-tom-moriarty.pdf?sfvrsn=d42cfc2b_2)

<sup>16</sup> Florida SB 300. Available at: <https://www.flsenate.gov/Session/Bill/2023/0300/ByVersion>

<sup>17</sup> Idaho HB 374. Available at: <https://legislature.idaho.gov/sessioninfo/2023/legislation/H0374/>

<sup>18</sup> Nebraska LB 574. Available at: [https://www.nebraskalegislature.gov/bills/view\\_bill.php?DocumentID=49961](https://www.nebraskalegislature.gov/bills/view_bill.php?DocumentID=49961)

<sup>19</sup> North Carolina SB 20. Available at: <https://www.ncleg.gov/BillLookup/2023/S20>

<sup>20</sup> North Dakota SB 2150. Available at: <https://www.ndlegis.gov/assembly/68-2023/regular/bill-overview/bo2150.html>

<sup>21</sup> South Carolina S 474. Available at: [https://www.scstatehouse.gov/sess125\\_2023-2024/bills/474.htm](https://www.scstatehouse.gov/sess125_2023-2024/bills/474.htm)

<sup>22</sup> South Dakota HB 1220. Available at: <https://sdlegislature.gov/Session/Bill/24248>

<sup>23</sup> Tennessee HB 883 / SB 745. Available at: <https://wapp.capitol.tn.gov/apps/BillInfo/default.aspx?BillNumber=HB0883&ga=113>

<sup>24</sup> West Virginia HB 3199. Available at:

[http://www.wvlegislature.gov/Bill\\_Status/Bills\\_history.cfm?input=3199&year=2023&sessiontype=RS&btype=bill](http://www.wvlegislature.gov/Bill_Status/Bills_history.cfm?input=3199&year=2023&sessiontype=RS&btype=bill)

<sup>25</sup> Wyoming HB152. Available at: <https://wyoleg.gov/Legislation/2023/HB0152>

**Wisconsin:** “Abortion-inducing drug” means a drug, medicine, oral hormonal compound, mixture, or preparation, when it is prescribed to terminate the pregnancy of a woman known to be pregnant.”<sup>26</sup>

**Idaho:** “Abortifacient” means mifepristone, misoprostol and/or other chemical or drug dispensed with the intent of causing an abortion as defined in section 18-604(1), Idaho Code. Nothing in the definition shall apply when used to treat ectopic pregnancy;”<sup>27</sup>

**Texas:** “Medical abortion--The use of a medication or combination of medications to induce an abortion, with the purpose of terminating the pregnancy of a woman known to be pregnant. Medical abortion does not include forms of birth control.”<sup>28</sup>

The definitions from these three states exemplify the variability in defining these terms which is seen in many more state laws and regulations. This variability adds further confusion to an already complicated situation for health care professionals to navigate.

Without clear guidance from federal and state policymakers, pharmacists in many states are uncertain of the professional, financial, and legal liability they may face when providing care to their patients regardless of if the care is related to abortion care services. One example is a lack of clarity of the federal and state liability for a pharmacist in a state where abortion is legal and may face penalties if they provide care or dispense medication, regardless of if the care or medication is related to abortion care services, to a patient that has traveled from a state where abortion is illegal or severely restricted.

These restrictions have resulted in limited access, delays in care, and confusion for numerous health care professionals and organizations as they attempt to follow obscure and conflicting federal and state laws and regulations.

State-imposed restrictions on abortion care have also significantly impacted pharmacists and their ability to care for their patients in multiple ways, including, an inability to practice evidence-based health care, an increase in administrative burden, and uncertainty about their liability. First and foremost, the issue most concerning to pharmacists is that state-imposed restrictions are limiting or delaying their ability to provide evidence-based therapies to their patients.

For example, take a patient that has been taking methotrexate, referenced in your letter, for an extended period of time for their rheumatoid arthritis (RA). Although methotrexate is commonly used for RA, it is also used off-label for the termination of intrauterine pregnancy. In many states,

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<sup>26</sup> Wis. Stat. § 253.10

<sup>27</sup> Idaho Code § 18-617

<sup>28</sup> 25 TAC § 139.2

such as Alabama<sup>29,30,31</sup>, Arkansas<sup>32,33,34,35,36</sup>, Kansas<sup>37</sup>, Kentucky<sup>38</sup>, Louisiana<sup>39,40</sup>, Montana<sup>41</sup>, Oklahoma<sup>42,43</sup>, South Carolina<sup>44,45</sup>, Tennessee<sup>46</sup>, Texas<sup>47</sup>, and Virginia<sup>48</sup>, methotrexate is specifically mentioned in state laws and regulations related to abortion care services. Due to the lack of guidance in interpreting laws in many states, pharmacists are unsure of the liability they would face in dispensing methotrexate, despite it being used for RA. This limits or delays patients from receiving their needed care and affects pharmacists' ability to independently exercise their professional judgement.

Complicating the current environment following the *Dobbs* decision has been President Biden's Executive Order (EO) on Securing Access to Reproductive and Other Healthcare Services<sup>49</sup> and the guidance<sup>50</sup> from the U.S. Department of Health and Human Services' Office for Civil Rights (OCR) that interprets pharmacists' obligations under federal civil rights laws, conflicting with some state laws, and raising concerns for our nation's pharmacies and pharmacists. The EO perpetuates existing confusion in an already complicated landscape for our patients and profession. While we understand the intent, without consultation with our nation's pharmacists the OCR's guidance, as written, has language in conflict with a pharmacist's professional judgment to make "determinations regarding the suitability of a prescribed medication for a patient; or advising patients about medications and how to take them."

The OCR's guidance lists potential examples when a pharmacist's refusal to dispense a drug to a patient "may be" a violation of federal law. As you know, the practice of pharmacy is regulated by the states and State Boards of Pharmacy, which provide and oversee pharmacy and pharmacist licenses. In addition, OCR's guidance does not address all federal conscience protections for health

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<sup>29</sup> Ala. Admin. Code r. 420-5-1-.01

<sup>30</sup> Code of Ala. § 22-9A-13

<sup>31</sup> Code of Ala. § 26-23E-3

<sup>32</sup> 060 00 CARR 001

<sup>33</sup> 007 05 CARR 004

<sup>34</sup> A.C.A. § 20-16-1503

<sup>35</sup> A.C.A. § 20-16-1702

<sup>36</sup> A.C.A. § 20-16-2502

<sup>37</sup> K.A.R. § 28-56-2

<sup>38</sup> KRS § 311.7731

<sup>39</sup> La. R.S. § 14:87.1

<sup>40</sup> La. R.S. § 14:87.1

<sup>41</sup> 50-20-703, MCA

<sup>42</sup> 63 Okl. St. § 1-756.2

<sup>43</sup> 63 Okl. St. § 1-757.2

<sup>44</sup> S.C. Code Ann. § 40-47-37

<sup>45</sup> S.C. Code Ann. § 44-41-460

<sup>46</sup> Tenn. Code Ann. § 63-6-1102

<sup>47</sup> Tex. Health & Safety Code § 171.061

<sup>48</sup> 18 VAC 110-30-20

<sup>49</sup> Executive Order on Securing Access to Reproductive and Other Healthcare Services. Available at <https://www.whitehouse.gov/briefing-room/presidential-actions/2022/08/03/executive-order-on-securing-access-to-reproductive-and-other-healthcare-services/>

<sup>50</sup> U.S. Department of Health and Human Services. Office for Civil Rights. Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services. Available at <https://www.hhs.gov/sites/default/files/pharmacies-guidance.pdf>

care professionals.<sup>51</sup> More than just the Church Amendments applies because the scope and impact of this federal guidance goes beyond health care services only related to abortion. Pharmacists cannot ignore state law if a pharmacy and pharmacist licenses would be in jeopardy, even with OCR's interpretation of a limited number of existing federal statutes. The implications of OCR's federal guidance also has the potential to cause widespread unintended consequences beyond reproductive health care services which could force pharmacists to dispense any medication that could impact the safety of our patients. For example, if there is a drug-drug interaction, drug allergy, drug-condition interaction, or other clinical concern that may impact patient safety.

Additionally, state-imposed restrictions have increased the administrative burden on pharmacists and other health care professionals. Due to the obscurities and conflicts in state and federal law, pharmacists must take additional steps to ensure they are not violating any laws when providing care to their patients. This increase in administrative burden has the potential to delay care for multiple patients as it interrupts the workflow of the pharmacist.

State-imposed restrictions on abortion care and the response from the federal government are both contributing to legal confusion and impacting health care professionals, including pharmacists, ability to independently exercise their professional judgment.

**5. What guidance have you provided to your members, if any, about how to administer medication abortion in light of increased misinformation and the ongoing litigation in *Alliance for Hippocratic Medicine v. FDA* and *Washington v. FDA*?**

We have provided information<sup>52</sup> to our members on relevant terminology differences related to reproductive health care services, guidance to assist in navigating conflicting interpretations of federal and state laws, state and federal<sup>53</sup> conscience protections for health care professionals along with APhA policy on the topic,<sup>54</sup> and resources to guide their practice following the *Dobbs* decision.

Unfortunately, due to the 1) Lack of clarity in state laws and rules, 2) Lack of clarity in federal laws, rules, and guidances, and 3) Conflicts between state and federal law, additional guidance to our members has been limited to educating pharmacists to follow state and federal laws - while urging action from policymakers to ensure patients' continuity of care is not interrupted. As more laws, rules, and guidances are published in the future we plan to interpret and update our members.

We deeply appreciate your focus on these important and urgent issues. We hope that this correspondence can continue to foster collaboration with your office, APhA, and the pharmacy community to address the many issues impacting patients' continuity of care and provide helpful guidance from state and federal policymakers to assist our nation's pharmacists. We welcome and encourage Senators Warren, Hirono, Duckworth, and Smith to meet with us to discuss these and many other issues facing our nation's

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<sup>51</sup> HHS. Conscience Protections for Health Care Providers. Content last reviewed September 14, 2021. Available at:

<https://www.hhs.gov/conscience/conscience-protections/index.html#:~:text=Federal%20statutes%20protect%20health%20care,moral%20objections%20or%20religious%20beliefs>

<sup>52</sup> Reproductive Health Care: Navigating The Dobbs Decision. Available at

<https://www.pharmacist.com/Advocacy/Issues/Reproductive-Health>

<sup>53</sup> Conscience Protections for Health Care Providers. Content last reviewed September 14, 2021. Available at

<https://www.hhs.gov/conscience/conscience-protections/index.html>

<sup>54</sup> Pharmacist Conscience Clause. Available at <https://aphanet.pharmacist.com/policy-manual?key=Pharmacist+Conscience+Clause&op=Search>

pharmacists and our patients. Please contact Michael Baxter, Acting Head of Government Affairs at [mbaxter@aphanet.org](mailto:mbaxter@aphanet.org) with any additional questions.

Sincerely,

A handwritten signature in black ink, reading "Ilisa BG Bernstein". The signature is fluid and cursive, with the first name "Ilisa" being the most prominent.

**Ilisa BG Bernstein, PharmD, JD, FAPhA**  
Interim Executive Vice President and CEO

cc: Valerie Prince, PharmD, BCPS, FAPHA, APhA President