

Written-Only Opponent Testimony for HB 324

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Stephanie L. Ash, MSW, LSW, Esq. (she/her)

steph@stephanieash.net

Chair Schmidt, Vice Chair Deeter, Ranking Member Somani, and members of the House Health Committee, thank you for the opportunity to provide written testimony. My name is Stephanie Ash (she/her) and I am a licensed attorney and social worker in Ohio. I serve as the Region 3 (Cleveland area) Co-Director on the National Association of Social Workers (NASW) Ohio Chapter Board. I am also a member of the NASW Ohio Social Work Criminalization Task Force. I write to voice my opposition to HB 324 because it proposes a redundant process that will burden the Ohio Department of Health and places unnecessary and cumbersome barriers to accessing mental health care and medications on Ohioans.

To begin, HB 324 creates redundancy as the United States Food and Drug Administration (“FDA”) already has a robust review process both to approve medications available to consumers and to withdraw such approval if needed. According to the FDA, the following rigorous process must be completed before a drug is approved:

1. Preclinical (animal) testing.
2. An investigational new drug application (IND) outlines what the sponsor of a new drug proposes for human testing in clinical trials.
3. Phase 1 studies (typically involve 20 to 80 people).
4. Phase 2 studies (typically involve a few dozen to about 300 people).
5. Phase 3 studies (typically involve several hundred to about 3,000 people).
6. The pre-NDA period, just before a new drug application (NDA) is submitted. A common time for the FDA and drug sponsors to meet.
7. Submission of an NDA is the formal step asking the FDA to consider a drug for marketing approval.
8. After an NDA is received, the FDA has 60 days to decide whether to file it so it can be reviewed.
9. If the FDA files the NDA, an FDA review team is assigned to evaluate the sponsor's research on the drug's safety and effectiveness.
10. The FDA reviews information that goes on a drug's professional labeling (information on how to use the drug).
11. The FDA inspects the facilities where the drug will be manufactured as part of the approval process.
12. FDA reviewers will approve the application or issue a complete response letter [1].

This entire process takes several years to complete, unless accelerated approval is sought for “serious and life-threatening illnesses that lack satisfactory treatments” [2]. Moreover, the FDA is authorized to withdraw approval of previously approved drugs for a variety of reasons including new scientific data showing the drug is unsafe for what it was approved to treat [3]. The creation of an Ohio-specific process to determine which drugs have “severe adverse effects of greater than five per cent of the drug’s users” outside of the robust FDA review and approval process which already governs drug approval and availability creates redundancy and will burden the Ohio Department of Health without cause. I also have deep concerns whether our State agency will have the same staff, reporting data, and research resources available as the FDA to make a thorough determination on a medication’s rate of “severe adverse effects.” I believe this process traditionally focused on science and evidence will become politically motivated and will reflect partisan politics instead of actual patient protection.

Second, HB 324 erects unnecessary and burdensome barriers to accessing mental health medications on patients. The American Psychiatric Association explains that the “safety and efficacy of

traditional antidepressants, antipsychotics, and mood stabilizers (such as lithium and some anticonvulsants) and stimulant medications have been established through decades of rigorous research, randomized clinical trials, peer-reviewed studies, meta-analyses, national registry studies of thousands of people, post-marketing pharmacovigilance monitoring, and FDA oversight” [4]. However, despite the known safety, some individuals may still have “severe adverse effects,” even with frequent and consistent monitoring by prescribers. There are serious considerations and professional medical judgment that goes into prescribing these medications which HB 324 does not permit.

Every medication is not appropriate for each person diagnosed with the same mental illness. For example, a doctor may not want to prescribe certain antidepressants depending on an individual patient’s chronic kidney disease progression [5]. Further, drug-induced liver injury is the 4th leading cause of liver disease in Western countries with anti-infectious agents, psychiatric medications, and neurology medications as the top drugs causing hypertoxicity [6]. Does this mean we should outright ban anti-infectious agents, psychiatric medications, and neurology drugs for Ohioans? Did the Committee know that acetaminophen toxicity is the most common cause of liver failure in the U.S., causing 50% of all reported cases [7]? With little effort, I can craft a strong argument that any medication, prescription or over-the-counter, is subject to regulation by HB 324.

Further, the prohibition on mailing drugs that cause “one or more severe adverse effects in greater than five per cent of the drug’s users” adds an unnecessary and cumbersome burden to patients with mental illness trying to access their medications. Many health insurance companies require beneficiaries to order medication through mail order pharmacies as these reduce costs to both the patient and insurance company. If the State of Ohio determines a medication falls under the regulations proposed by HB 324, patients may not be able to access their medications at an affordable rate (or at all) depending on their insurance coverage and access to a retail pharmacy in their community. This could also have interstate commerce and constitutional implications as HB 324 places limits on mailed consumer goods.

Lastly, HB 324’s insistence on meeting a prescriber in person before being prescribed “a drug that causes one or more severe adverse effects in greater than five per cent of the drug’s users” is another unnecessary barrier to those taking mental health medications. Many Ohioans rely on telehealth services to access behavioral health. The Ohio Department of Mental Health and Addiction Services estimates there are 2.4 million Ohioans who cannot access mental health care due to a critical shortage of behavioral health professionals and there has been more than a 350% increase in demand for mental health services [8]. If the State of Ohio determines that a mental health medication falls under what HB 324 proposes, Ohioans will not easily be able to access the care they need if in-person care is required, especially in rural areas. Furthermore, it is unknown how HB 324 will interact with Ohio Administrative Code Rule 4731-11-09(E)(3), which expressly allows mental health medications that are controlled substances to be prescribed via telehealth visits. If a controlled substance is deemed to fall under HB 324, will patients be able to access their prescription via telehealth per Rule 4731-11-09(E)(3) or will patients have to find an in-person prescriber?

I urge the Committee to vote NO on HB 324 in its entirety as it does not actually protect patients and instead creates redundancy and unnecessary barriers to accessing care. Instead of trying to politicize medications and recreate drug review and approval processes which have existed for decades, our time would be better spent providing access to mental health care through greater appropriations for Medicaid in the State budget; increased grant funding to nonprofit behavioral health agencies; more financial support for Ohio researchers studying these medications; and greater incentives for future behavioral health practitioners to join our profession and stay in Ohio. Thank you.

References

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- [3] 21 CFR § 314.150 (1999). <https://www.law.cornell.edu/cfr/text/21/314.150>
- [4] American Psychiatric Association. (2025). *Joint statement on federal concerns about psychotropic medication safety*. <https://www.psychiatry.org/news-room/news-releases/joint-statement-on-federal-concerns-about-psychotr>
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- [8] Ohio Department of Mental Health and Addiction Services. (2025, July 17). *New statewide initiative further combats critical shortages in behavioral health workforce* [Press Release]. <https://dbh.ohio.gov/about-us/media-center/news/pressrelease-2025.07.17>