Chairperson Schimidt, Vice-Chair Deeter, and Ranking Member Dr. Somani, thank you for accepting my testimony in opposition to House Bill 324. My name is Ellena Privitera and I am a fourth-year medical student in Columbus. I am grateful for the opportunity to speak on behalf of myself today, thanks to the graciousness of my preceptors who have allowed me to leave so that I might be able to talk with you about the harms of this bill.

I am here because I care deeply for patient care and safety. I am especially concerned that H.B. 324 disregards the expertise of medical professionals in Ohio and will place unnecessary burdens on patients, providers, and Ohio government agencies. I do not think there is evidence to say that the provisions of House Bill 324 will meaningfully address issues of patient safety.

This bill tasks the Ohio Department of Health to come up with a list of medications which have a greater than 5% risk of a specific list of adverse events. When I think of medications commonly prescribed via telemedicine that might require additional monitoring by a clinician, I think of anti-coagulants, psychiatric medications, controlled substances, and those which cause Qt prolongation (of which there are many – like Zofran or antibiotics). However, I struggled to find evidence that any of these common prescriptions meet the specifications of this bill.

The only medication regimen that I could find as a potential fit was an anticoagulant triple therapy which is so uncommon and specialized that it has never come up in my training and is unlikely to be something I would ever manage independently as a future primary care provider. Requiring burdensome in-person visits for initiation and follow-up does not have merit without evidence that it will improve patient safety. Furthermore, the percentage cut off and adverse effects listed in House Bill 324 appear to be arbitrary. They do not encapsulate the range of potential adverse effects of commonly prescribed medications, nor do they acknowledge the nuance of care that happens via telemedicine.

When discussing which medications are appropriate to offer and in what modality, my mentors and I consider things like patient history, demographics, their monitoring needs, and their access to services and support, as well as what recommendations or guidelines exist from regulatory authorities and specialty organizations.

House Bill 324 has the potential to cause harm. Mandates from the legislature on how medical care is provided interferes with the doctor-patient relationship, stopping medical professionals like me from providing individualized care based on patients' needs. It will cause delays and increased costs for care.

Furthermore, directing the ODH to come up with a list of medications to restrict based on insurance claims data surrounding arbitrary parameters represents a significant, unnecessary logistical and financial burden. It could lead to biased conclusions which don't account for the real risks patients and providers weigh when making decisions about prescriptions.

For example, proponents of this bill have almost exclusively mentioned mifepristone as a dangerous medication that should be restricted. They reference a self-published document from The Ethics and Public Policy Center which used insurance claims data as part of its methodology. It was not peer-reviewed and has a variety of flaws that make any conclusions

drawn by the authors highly questionable and not reliable. There is a lack of transparency on the data source, meaning the study lacks reproducibility. The analysis does not account for confounding variables, meaning that the adverse events authors attributed to mifepristone could have been from other medical problems patients were having.

Under the supervision of licensed professionals, I have provided telemedicine abortion counseling services to several patients during a rotation in another state. Like any other medication or procedure, I facilitated informed consent conversations which involve the risks, benefits, and alternatives.

Peer-reviewed research published in well-known scientific journals has consistently shown that mifepristone is safe and effective, whether in-person or via telemedicine. There is no evidence that requiring a patient to have an in-person appointment with a physician increases the safety of the medication.

The alternative to medication abortion with mifepristone is to continue a pregnancy, or to use a less-effective regimen to induce an abortion or to manage a spontaneous abortion. The risks associated with these alternatives are significant. Pregnancy transforms a person's body, causing changes to several organ systems. Being pregnant increases a person's risk of bleeding, life-threatening infections, sepsis, and death. All these potential adverse events are also included on the list of events this bill seeks to address. The chances of these negative events happening to a pregnant person are much higher without access to abortion care through regimens like medication abortion with mifepristone.

This brings me to several important questions I have for you.

- If the bills' proponents are basing their claims on reports which lack scientific rigor and are ignoring overwhelming evidence that contradicts them, what evidence do legislators have to take away important resources from the ODH, State Medical Board, and other agencies to implement this law?
- How will the ODH collect data to determine which medications need to be on this list, and how will we be sure that the evaluation is genuinely reflective of risk?
- When new evidence comes out regarding the listed medications, how will that evidence be evaluated?
- What is the process for this list be updated and addended?
- How will clinicians like me be made aware to changes in rules?
- What penalties will exist if physicians or our patients don't follow them?
- Mail-order pharmacies and telehealth make it convenient for patients to get care – imagine the burden on PCP's and psychiatrists (who we already have a shortage of) trying to book more appointments to evaluate and follow up with patients. What will this mean for elderly and disabled patients who rely on these systems to get care, if their medications show up on the list? How will we support patients and practices to manage the burden of additional visits/examinations and cover the increased costs?

My concerns should make you question the utility of a blanket restriction such as this one. Politicians are not well-suited to make medical decisions. This law presents a significant

challenge for ODH and for future physicians like me, who simply want to provide quality care to patients without interference from the government.

Ultimately, the people bearing the consequences is our patients, who deserve access to timely care and nuanced recommendations from their doctors. Having worked at an abortion clinic prior to the passage of the Ohio Reproductive Freedom Amendment, I have seen firsthand how restrictions on mifepristone have caused unnecessary delays on patients' care, causing them to go through unwanted procedures and even unwanted pregnancies.

As a medical student, I've also seen firsthand the amazing impact of telemedicine to improve peoples' access to preventative care as well as adherence to treatment for chronic diseases.

I don't think our legislators should be dictating physicians' scope of practice on the basis of junk science being pushed by anti-abortion extremists. It is wasteful to ask our government agencies to be spending potentially **millions of dollars** trying to meet the demands of this bill, especially without any evidence that it will meaningfully improve peoples' lives. I urge you to vote no on this bill.

Thank you for your time and consideration.

Annotated Bibliography

Information about medication harms/adverse drug events

Shehab N, Lovegrove MC, Geller AI, Rose KO, Weidle NJ, Budnitz DS. US Emergency Department Visits for Outpatient Adverse Drug Events, 2013-2014. JAMA. 2016;316(20):2115–2125. doi:10.1001/jama.2016.16201

Used nationally representative surveillance data to estimate amount of ED visits for drug events annually and associated medications. Estimated of 4 adverse drug events per 1000 individuals, found that antibiotics, antipsychotics, anticoagulants, diabetes agents and opioid analgesics as most common causes.

Budnitz DS, Shehab N, Lovegrove MC, Geller AI, Lind JN, Pollock DA. US Emergency Department Visits Attributed to Medication Harms, 2017-2019. JAMA. 2021;326(13):1299–1309. doi:10.1001/jama.2021.13844

Cross-sectional study of 60 Eds between 2017-2019 review of medication harms (adverse events) estimating most frequent medication types and intent to use. Found that anticoagulants, diabetes agents, nontherapeutic use of benzodiazepines, prescription opioids were most common in adults (incidence for each varies based on age, see study for details). For children younger than 5, unsupervised medication exposures and therapeutic use of antibiotics was most common.

Information about DOAC triple therapy

A point of nuance: anticoagulant therapy is important to prevent the occurrence of life-threatening cardiovascular accidents (CVA), like a heart attack or a stroke, in patients with demonstrated risk or history. The studies listed compare the risk of hemorrhage with varying anticoagulation regimens. Clinicians who prescribe these medications weigh the risk of death from CVA with the risk of hemorrhage when having informed consent conversations with their patients about anticoagulation.

Sridharan K, Sivaramakrishnan G. Hemorrhage risk associated with triple antithrombotic therapy: a focused real-world pharmacovigilance disproportional analysis study. BMC Cardiovasc Disord. 2025 Mar 14;25(1):180. doi: 10.1186/s12872-025-04510-4. PMID: 40087557; PMCID: PMC11908036.

Reviews reports to the USFDA Adverse Event Reporting System (AERS) from 2004-2024 to compare hemorrhage risk in patients using triple antithrombotic therapy (TAT) versus dual antiplatelet therapy (DAPT) in patients with long term anticoagulation needs. Highlights the elevated hemorrhage risk associated with TAT in comparison with DAPT, authors suggest further trials for validation of their findings.

Sun X, Ze B, Zhang LJ, BaiMa YZ, Zuo W, Zhao B, GeSang LB. Hemorrhage Risk Profiles among Different Antithrombotic Regimens: Evidence from a Real-World Analysis of Postmarketing Surveillance Data. Cardiovasc Drugs Ther. 2022 Feb;36(1):103-112. doi: 10.1007/s10557-020-07110-w. Epub 2020 Nov 23. PMID: 33226545.

Reviews ~85,000 reports made to the USFDA AERS regarding hemorrhage-related adverse events with antithrombotic drugs, identifying which combinations and medications were most associated with hemorrhage complications and fatalities.

<u>Information about the safety, efficacy, and acceptability of telemedicine abortion with mifepristone</u>

First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review Raymond, Elizabeth G. et al. Contraception, Volume 87, Issue 1, 26 – 37

A meta-analysis of 87 clinical trials showing that medication abortion is safe, with serious complications requiring hospitalization (for vaginal bleeding, pelvic pain, or infection) occurring in less than .3% of patients. Approximately 0.1% of patients required a blood transfusion.

Chong E, Shochet T, Raymond E, Platais I, Anger HA, Raidoo S, Soon R, Grant MS, Haskell S, Tocce K, Baldwin MK, Boraas CM, Bednarek PH, Banks J, Coplon L, Thompson F, Priegue E, Winikoff B. Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic. Contraception. 2021 Jul;104(1):43-48. doi: 10.1016/j.contraception.2021.03.019. Epub 2021 Mar 27. PMID: 33781762; PMCID: PMC9748604.

Study across multiple sites in the US demonstrating that telemedicine abortion/medication abortion by mail is no less effective than in-person visits with pre-treatment ultrasounds,

demonstrates benefits of the telemedicine/mail-order model and demonstrates that in person visits not requisite for providing effective abortion care.

Aiken ARA, Lohr PA, Lord J, Ghosh N, Starling J. Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: a national cohort study. BJOG 2021; 128: 1464–1474.

Study of 52,142 medical abortions in the UK demonstrating that incorporating no-test telemedicine into the care pathway is not inferior to the traditional pathway where all patients are seen in person and have an ultrasound scan. There was no evidence of worse outcomes in failure rate, hemorrhage, need for surgery or failure to detect ectopic pregnancy.

Mark A, Foster AM, Grossman D, Prager SW, Reeves M, Velásquez CV, Winikoff B. Foregoing Rh testing and anti-D immunoglobulin for women presenting for early abortion: a recommendation from the National Abortion Federation's Clinical Policies Committee. Contraception. 2019 May;99(5):265-266. doi: 10.1016/j.contraception.2019.02.008. Epub 2019 Mar 10. PMID: 30867121.

Review of evidence that suggest there is no need for Rh testing in early abortion care, meaning that that in-person laboratory tests are unnecessary prior to initiating medication abortion. See also: Society for Family Planning Consensus Statement on Rh allo-immunization in early pregnancy: https://societyfp.org/wp-content/uploads/2024/03/Society-of-Family-Planning-Statement-of-Rh-testing-in-early-pregnancy-.pdf

*Upadhyay, U.D., Koenig, L.R., Meckstroth, K. et al. Effectiveness and safety of telehealth medication abortion in the USA. Nat Med **30**, 1191–1198 (2024). https://doi.org/10.1038/s41591-024-02834-w*

Study of >6,000 patients from 3 virtual clinics across the US receiving telehealth abortions between 2021-2022, demonstrated that 99.8% (99.6-99.9%) of abortions were not followed by serious adverse events. There was no differences in effectiveness or safety between synchronous or asynchronous models of care.

Srinivasulu S, Nyandak D, Fiastro AE, MacNaughton H, Tressan A, Godfrey EM. Telehealth Medication Abortion in Primary Care: A Comparison to Usual in-Clinic Care. J Am Board Fam Med. 2024 Mar-Apr;37(2):295-302. doi: 10.3122/jabfm.2023.230178R1. PMID: 38740468.

Demonstrates the benefits of telehealth for medication abortion in primary care settings.

Tressan A, Nyandak D, Srinivasulu S, Fiastro AE, MacNaughton H, Godfrey EM. Telemedicine Abortion in Primary Care: An Exploration of Patient Experiences. Ann Fam Med. 2024 Jan-Feb;22(1):19-25. doi: 10.1370/afm.3058. PMID: 38253506; PMCID: PMC11233084.

Demonstrates the acceptability of telehealth for medication abortion from patient perspective.

Upadhyay UD, Johns NE, Combellick SL, Kohn JE, Keder LM, Roberts SC. Comparison of Outcomes before and after Ohio's Law Mandating Use of the FDA-Approved Protocol for Medication Abortion: A Retrospective Cohort Study. PLoS Med. 2016 Aug 30;13(8):e1002110. doi: 10.1371/journal.pmed.1002110. PMID: 27575488; PMCID: PMC5004901.

Investigates impacts of mifepristone restrictions in Ohio, demonstrating the financial and logistical burden Ohioans face when such restrictions exist in our state.

Brief of over 300 Reproductive Health Researchers as Amici Curiai in Support of Petitioners. Case Nos 23-235 and 23-236, Supreme Court of the United States. Jan 30, 2024 https://www.supremecourt.gov/DocketPDF/23/23-235/299159/20240220110531937_23-235%2023-236%20tsac%20Over%20300%20Reproductive%20Health%20Researchers.pdf

Discusses data around FDA approval and restrictions of mifepristone.

Gerdts C, Bell SO, Shankar M, Jayaweera RT, Owolabi O. Beyond safety: the 2022 WHO abortion guidelines and the future of abortion safety measurement. BMJ Glob Health. 2022 Jun;7(6):e009557. doi: 10.1136/bmjgh-2022-009557. PMID: 35725242; PMCID: PMC9214389.

2022 WHO Guidelines around self-managed abortion.