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Senate Bill 260 Opponent Testimony
Senate Health, Human Services, and Aging Committee
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Chairman Burke, Ranking Member Antonio, and members of the Senate Health, Human Services, and Aging Committee, my name is Jaime Miracle and I am the Deputy Director of NARAL Pro-Choice Ohio. I am here to testify on behalf of our more than 50,000 members and activists against Senate Bill 260.

Here we are again, listening to testimony on the eighth bill this session using misinformation, stigma, and lies to restrict access to abortion care in Ohio. All while Ohio's infant mortality and maternal mortality rates remain at crisis levels. The Ohio Legislature's obsession with restricting access to reproductive health care is harming our state. Critically important issues fall by the wayside — missed budget deadlines, missed deadlines to fix the school voucher program and protect our local schools. Ohio's school funding scheme has been unconstitutional for decades. But, instead of dealing with any of those issues, here we are again discussing yet another unconstitutional attack on abortion access.

Last week proponents of SB 260 testified that this bill is necessary because the medication is just too dangerous to allow it to be dispensed via telemedicine. What did they use to back up that assertion? Data from the U.S. Food and Drug Administration (FDA) "Post-Marketing Adverse Events Summary"¹. The FDA keeps these "adverse event" reports for all kinds of medications. In fact, if you go into the database you find that in the same time period the number of deaths reported from Viagra is 1,510 (Figure One); from Tylenol 1,172 (Figure Two).

Without context, data is meaningless. What does this data mean? When you go into the FDA adverse events database, you get a pop-up window with a disclaimer you have to agree to before accessing the information. In this disclaimer, the FDA states "FAERS data alone cannot be used to establish rates of events. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity or frequency of problems associated with drug products, and confirming whether a drug product actually caused a specific even can be difficult based solely on information provided in a given report" (Figure Three). In the FAQ document associated with the database it states, "For any given report, there is no certainty that a suspected drug caused the reaction. While consumers and healthcare professionals are encouraged to report adverse events, the reaction may have been related to the underlying disease being treated, or caused by some other drug being taken concurrently, or occurred for other reasons. The information in these reports reflects only the reporter's observations and opinions."²

In fact, the very document proponents used to argue against the safety of mifepristone last week includes this statement, "These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use, and other possible medical or surgical treatments and conditions." In the footnote under the "death" category it explains that two of the deaths were homicides, which have

¹ Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018
<https://www.fda.gov/media/112118/download>

² Questions and Answers on FDA's Adverse Event Reporting System (FAERS)
<https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers>

nothing to do with the safety of mifepristone, and several deaths were unassociated drug overdoses or other causes that cannot directly be linked to the patient taking mifepristone. The fact that Ohio Right to Life and others so dangerously threw around misinformation to this committee should give each and every one of you pause. You are sent here by your constituents to look at facts and determine what is best for the citizens of the state of Ohio.

Luckily this “data” from the FDA is not the only data we have on this subject. In April 2019, researchers did a systematic review of the data on the use of telemedicine for medication abortion care³. This research found that the patient outcomes from telemedicine-based care were similar to those for patients that received in-person care.

Additional research published in *Obstetrics and Gynecology* in 2019⁴ compared 8,765 patients who accessed medication abortion via telemedicine to 10,405 patients who received in-person care. In both groups only 49 clinically significant adverse events were reported (no deaths or surgical intervention needed), which resulted in 0.18% rate for telemedicine patients compared to a 0.32% rate for in-person care patients. The researchers surveyed 42 area emergency departments and none reported treating a woman with an adverse event after a medication abortion.

The American College of Obstetrics and Gynecology (ACOG) recognizes that medication abortion “can be provided safely and effectively via telemedicine with a high level of patient satisfaction.”⁵

In Ohio there are nine abortion providers, all in the urban centers of Akron (Cuyahoga Falls), Cincinnati, Cleveland (Cleveland and Bedford Heights), Columbus, Dayton (Kettering), and Toledo. This leaves wide areas of the state without access to abortion care in their community.

Telemedicine is a safe and effective way to provide this care without burdening the patient with multiple hour drives to the closest clinic twice, as required by Ohio law. Proponents of SB 260 have provided no evidence that limiting access to abortion care through telemedicine improves patient safety. The only thing this bill would achieve is creating additional hurdles and limitations for abortion care.

Telemedicine has been used by multiple health care sectors for over four decades⁶. Patients have greatly benefited from the use of telemedicine for a variety of health care needs, including management of chronic disease⁷, psychiatry⁸, and even neurology⁹. Multiple studies have shown that telemedicine improves both patient outcomes and patient satisfaction and reduces the cost of medicine.¹⁰

SB 260 has one goal: to again limit access to abortion care in our state. It is not about protecting people’s health; it is not about keeping people safe. It is about using misinformation and stigma to once again limit access to abortion. Abortion is healthcare. The use of telemedicine for medication abortion care increases access to this care closer to people’s homes and helps to alleviate the

³ Endler, M., Lavelanet, A., Cleeve, A., Ganatra, B., Gomperts, R., and Gemzell-Danielsson, K. “Telemedicine for medical abortion: a systematic review.” *BJOG* 2019; 126:1094-1102.

⁴ Upadhyay, U., Grossman, D. “Telemedicine for medication abortion.” *Contraception* 100 (2019) 351-353.

⁵ ACOG, *Practice Bulletin No. 143: Medical Management of First-Trimester Abortion* 11 (Mar. 2014), <http://www.acog.org/Resources-And-Publications/Practice-Bulletins/Committee-on-Practice-Bulletins-Gynecology/Medical-Management-of-First-Trimester-Abortion>.

⁶ AM. MED. ASS’N., *AMA Adopts New Guidance for Ethical Practice in Telemedicine* (June 13, 2016), <https://www.ama-assn.org/ama-adopts-new-guidance-ethical-practice-telemedicine>.

⁷ R.L. Bashshur et al., *Telemedicine Interventions for Chronic Disease Management*, CTRS. FOR DISEASE CONTROL (CDC) (Oct. 2014), http://www.cdc.gov/dhdsp/pubs/docs/sib_oct2014.pdf.

⁸ Kristine Crane, *Telepsychiatry: the New Frontier in Mental Health*, U.S. NEWS & WORLD REPORTS, Jan. 15, 2015, <http://health.usnews.com/health-news/patient-advice/articles/2015/01/15/telepsychiatry-the-new-frontier-in-mental-health>.

⁹ Benjamin P. George, et al., *Telemedicine in Leading US Neurology Departments*, 2 NEUROHOSPITALIST 123 (2012) <http://www.ncbi.nlm.nih.gov/pubmed/23983876>.

¹⁰ AM. TELEMEDICINE ASS’N, *Telemedicine Benefits*, <http://legacy.americantelemed.org/main/about/about-telemedicine/telemedicine-benefits> (last accessed January16, 2020).

obstacles patients face in getting the care they need. The Ohio Legislature should be in the practice of expanding access to health care, not limiting it. I urge a NO vote on SB 260.

Thank you. I'm happy to answer any questions the committee might have.

Figure One: Number of Adverse Event Cases and Deaths – Viagra 2000-2019



Figure Two: Number of Adverse Event Cases and Deaths – Tylenol 2000-2019



Figure Three: Disclaimer on FDA FAERS Database Public Search Query

fis.fda.gov/sense/app/d10be6bb-494e-4cd2-82e4-0135608ddc13/sheet/33a0f68e-845c-48e2-bc81-8141c6aa772/state/analysis

No selection

Adverse Events

Search

Disclaimer

Each year, the FDA receives over one million adverse event and medication error reports associated with the use of drug or biologic products. The FDA uses these reports to monitor the safety of drug and biological products. The FDA Adverse Event Reporting System (FAERS) database houses reports submitted to the FDA by drug manufacturers (who are required to submit these reports to FDA) and others such as health care professionals and consumers. Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

Although these reports are a valuable source of information, this surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified information. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of use. Because of this, FAERS data comprise only one part of the FDA's important post-market surveillance data and the information on this website does not confirm a causal relationship between the drug product and the reported adverse event(s).

- Consumers should not stop or change medication without first consulting with a health care professional.
- The FAERS web search feature is limited to adverse event reports between 1969 and the most recent quarter for which data are available.
- Data submitted to the FAERS system will be made available through the new querying tool on a quarterly basis.
- FAERS data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between drug products. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with drug products.
- Confirming whether a drug product actually caused a specific event can be difficult based solely on information provided in a given report.
- FAERS data do not represent all known safety information for a reported drug product and should be interpreted in the context of other available information when making drug-related or treatment decisions.
- Variations in trade, product, and company names affect search results. Searches only retrieve records that contain the search term(s) provided by the requester.

Importantly, safety reports submitted to FDA do not necessarily reflect a conclusion by FDA that the information in the reports constitutes an admission that the drug caused or contributed to an adverse event. Individual FAERS reports for a given product can be requested by submitting a Freedom of Information Act (FOIA) request at:

<https://www.fda.gov/regulatoryinformation/foi/howtomakeafoiarequest/default.htm>

I have read and understand the disclaimer.