### HB 705 Declaration of Rights-Right to Reproductive Freedom Health and Government Operations Unfavorable

I'm Dr. Sandy Christiansen, a board-certified ob/gyn licensed in the state of Maryland. I am opposed to the passage of HB 705. I stand in solidarity with a majority (80%) of obstetricians who are not in favor of abortion on demand and who do not perform abortions.

### Maryland doesn't need stronger abortion laws

With the Food and Drug Administration decision to permanently remove the in-person requirement from the mifepristone label, every woman in Maryland has ready access to abortion services via telemedicine. Maryland ranks third in the Nation for best reproductive rights and abortion access with an A- rating.

The fall of Roe has had zero impact on access to abortion in Maryland. In fact, we are now an "abortion destination" state.

### The deregulation of abortion will harm women: FDA & REMS

The impetus for the passage of Roe v. Wade was to make abortion "safe, legal, and rare." It was supposed to end "coat hanger" abortions. The abortion industry's push to make abortion available everywhere has led to the removal of nearly all the safeguards surrounding the distribution of the abortion pill. Women are now faced with a "chemical coat hanger" abortion.

The FDA's Risk Evaluation & Mitigation Strategy (REMS) is reserved for drugs where the risks may outweigh the benefits if certain safety measures aren't followed to reduce the risk of complications. Out of the 19,000 current FDA approved drugs, only 62 have a REMS requirement and mifepristone is one of them.

The abortion pill, mifepristone, didn't have REMS at first, it took women dying before it was added. And now, the FDA is dismantling it. In the case of mifepristone, the FDA required the following for physicians who wished to dispense mifepristone:

- 1. Prescribers to be trained and certified by Danco Labs
- 2. Must follow FDA approved use guidelines: which originally included 3 visits, drugs directly handed to the patient
- 3. Patient must be counseled about the risks, must sign Agreement Form, and be given a copy

When mifepristone was first approved by the FDA, three in-person visits were required:

1. First visit:

- a. Confirm/diagnose an intrauterine pregnancy: this is a critical step. Without performing an ultrasound exam, there is no way to know for sure if:
  - i. Is she even pregnant? Pregnancy tests can be wrong
  - ii. Does she have a living pregnancy? If she's miscarrying, she doesn't need an abortion, nor does she need to live with the falsehood that she ended her baby's life.
  - iii. Does she have an intrauterine pregnancy? If she has a pregnancy outside the uterus (termed "ectopic", usually in the Fallopian tube), she is at risk for life-threatening internal bleeding. Ectopic pregnancies are not ended by the abortion pill.
  - iv. Is she expecting twins? The abortion pill regimen is for a single pregnancy. With multiple gestations, the risk of abortion failure is increased, as is the risk of hemorrhage.
- b. Abortion provider collects a health history, checks vital signs, screens for contraindications to the abortion pill regimen
- c. Abortion provider hands her the first drug, mifepristone, and observes her swallowing it.
  - i. Mifepristone is a potent progesterone blocking drug. Progesterone is necessary for the embryo to remain attached to the uterus, receiving nutrients. Mifepristone causes breakdown of the embryo's attachment to the uterus, eventually resulting in the embryo's death.
- 2. Second visit: she returns two days later and is assessed for complications. Then, she is given the second drug, misoprostol, in the abortion pill regimen. This causes the uterus to contract, resulting in cramping and bleeding and expulsion of the embryo and pregnancy tissues.
- 3. Third visit: return two weeks from the first visit to make sure the procedure was complete and to check for complications.

As of December 2021, the FDA succumbed to pressure from abortion lobbyists and made the following changes to the mifepristone label:

- Eliminated the in-person requirement. This is a HUGE change. Not only did it pave the way for "telehealth" abortions, but it required the involvement of pharmacists and pharmacies to dispense the drug.
- There are **ZERO** required in-person visits!

How is less care better for women? It isn't. There are no shortcuts in the delivery of good medical care.

## What's so bad about no in-person requirement to get the abortion pill?

Now, the woman seeking an abortion can schedule a telemedicine visit, which is either a video visit, a phone call, a text or via email. Think about it. No face to face interaction is required. When I went to medical school, the cornerstone of diagnosis was observation, followed by the

medical interview. Next, the physical exam to add clues. A monitor screen is not a substitute for a direct examination where nuances may be observed such as pallor, weakness and hands-on evaluation of well-being may be properly assessed. But in many cases, there is not even a visual visit—just a phone call, or chat room online. If you had told me when I began my residency in Ob/Gyn that doctors would give people they've never met in person advice over the phone, much less prescribing and inducing abortion, it would have hands down been considered malpractice. Here's the reality: **it still is malpractice. The "self managed abortion" is the modern day chemical coat hanger abortion and it will be the women of Maryland (and those who cross state lines) who will suffer.** 

How does the telemedicine abortion work?

- Proof of positive pregnancy test not required. Over the counter pregnancy tests can be wrong. She may not even be pregnant, but will pay hundreds of dollars to be exposed to risky drugs and spend her life believing she aborted a living pregnancy. No in person visit means no easy opportunity to perform a physical exam—a pelvic exam which can provide an estimate of gestational age, no testing for STIs and if there are risk factors for ectopic pregnancy. These telemed clinics don't require proof of a positive PT!
- 2. <u>Incorrect Dates:</u> Gestational age based on LMP: When the abortion provider interviews the patient on the phone, they will determine her pregnancy dating based on her last menstrual period (LMP) which may be wrong, she may be further along. Ordering an ultrasound exam is optional and will cost the patient more. Abortion providers are going off-label and offering the Abortion Pill past 10 weeks LMP, women will be taking these abortive drugs further in pregnancy. There is a greater risk of complications due to incorrect dates: the risk of incomplete abortion, failed abortion , more surgeries and death increases with increasing gestational age.
- 3. <u>Missed ectopic pregnancy</u>: Further, if an ultrasound is not done, than there is no definitive assessment for ectopic pregnancy. Verbally screening for an ectopic pregnancy is inadequate...plus, patients may not reveal symptoms such as pain or bleeding for fear that they won't be given the pill. The abortion pill won't abort an ectopic pregnancy. A missed ectopic could be life-threatening if it burst and caused internal bleeding.
- 4. <u>Missed twins or other unusual ultrasound finding:</u> if the patient had a pelvic exam done and the uterus is larger than expected, any reputable obstetrician would perform an ultrasound to determine if the baby is further along or if the mother is carrying twins or a molar pregnancy. If she has undiagnosed twins or a molar pregnancy and takes abortive pills, she is more likely to suffer complications like severe hemorrhage, incomplete abortion and infection.
- 5. <u>Missed nonviable pregnancy (miscarriage)</u>: Women will undergo abortions for nonviable pregnancies and spend the rest of their lives believing they had aborted their baby.
- 6. <u>Increased risk of future pregnancy complications</u>: without blood testing for the Rh factor, women face potential complications with future pregnancies.

- 7. No exam to verify completion of the procedure or assess for complications. The abortion kits contain a urine PT with instructions to test 4 weeks after taking mifepristone, That's a long time to wait to know if it's done.
- 8. Complications? She's essentially on her own—will likely be instructed to go to the ER. Abortion providers are telling women to lie to the ER doctors and not disclose they have taken the abortion pill. This is shocking to me that a "healthcare" person would care so little for the safety of their patient that they would not want the treating physician to have all the facts in order to take the best care possible of their patient.

In summary, if the woman has regular menses, knows her LMP and has never had an IUD or pelvic infection, she will be prescribed the abortive pills without a physical exam or ultrasound exam, assuming the risk of missed ectopic, nonviable pregnancy, and more.

I can't stress enough how the practice of medicine is being eroded to the detriment of the patient. Less care, worse care. Women receive substandard care in the name of unrestricted access to abortion.

Direct medical oversight is critical when going through a procedure that involves significant risks-hemorrhage, severe infection, and pain. Telemedicine has its application, but abortion should not be one of them.

#### Analysis of Adverse Event Reports for Mifepristone

Induced abortion is associated with very real risks. But, in the U.S. we have incomplete data on abortion complications. The CDC collects voluntary reports with no enforcement arm. A recent study analyzed the adverse event reports to the FDA about mifepristone abortions between 2000-2019. From data of previous studies of complications following mifepristone abortions, there should have been over 180,000 adverse event reports—there were only 3000. Clearly the FDA is only receiving the tip of the iceberg.

From the year that mifepristone was FDA approved in 2000, until 2016, the FDA collected all adverse event reports: blood transfusions, hospitalizations, surgeries for—incomplete or failed abortion, hemorrhage, ectopic pregnancy; infections, and death. In 2016 the FDA stopped collecting data on the morbidity associated with mifepristone, and only collects maternal mortality. Wow. If you had to take your teenage daughter to the ER because she was hemorrhaging from a mifepristone abortion, wouldn't you expect our government to be concerned about that? Abortion harms women, men, and families, and ends the life of an individual who does not have representation.

#### Medication abortion riskier than surgical abortion

In a population-based study in Finland from 2000-2006, 42,619 women at 63 days or less of gestation underwent medication or surgical abortions and were followed up for 42 days. 20% of women who underwent medication abortion suffered complications, while only 5.6% of women

who underwent surgical abortion suffered complications (p value of < 0.001, unlikely to be attributable to chance and statistically significant). In the words of the authors: "The overall incidence of adverse events was <u>fourfold higher</u> in the medical compared with the surgical abortion cohort."<sup>1</sup>

Simply put, medication abortion is higher risk in every category:

- The risk of hemorrhage is 15.6% (1 in 6) in medication abortion and 2.1% (1 in 50) for surgical abortion.
- The risk of incomplete abortion is 6.7% (1 in 15) in medication abortion and 1.6% (1 in 60) for surgical abortion.
- The risk of emergency surgery is 5.9% (1 in 15) in medication abortion and 1.8% (1 in 60) for surgical abortion.

Putting these statistics in perspective 20% of women who undergo medication abortion have a serious adverse event, including hemorrhage (15%), incomplete abortion (tissue left inside, 7%), and need for repeat procedure (6%, overlaps with incomplete abortion for total 20%). In the second trimester, after 13 weeks, the rate of surgical evacuation in one study was as high as 30.8%, meaning that one-third of women who underwent medication abortion required surgical completion.<sup>[9]</sup>

#### Induced abortion is not health "care"

If abortion is necessary for women's health and well-being, how have the nearly 63 million abortions performed since the passage of Roe v. Wade advanced and improved women's lives? The answer: they haven't. There is no proven health benefit to induced abortion. However there is a lot of data pointing to negative health outcomes.

Abortion is not healthcare, it is the taking of an innocent life in the name of privacy. It should not be a right codified into the constitution. Please don't let this be the legacy you leave your grandchildren.

Laws like this one tramples on the physician's right to practice medicine according to their conscience. It is a breach of a physician's oath to first do no harm and to do what is in her patient's best interest.

# Maryland taxpayers would choose reducing maternal mortality over unleashed access to abortion

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The maternal mortality rate in the U.S. (in 2018- 17.4 for every 100,000) ranks the highest compared to nations such as the U.K. (6.5), Canada (8.6), Sweden (4.3), and France (8.7). The U.S. maternal mortality ratio is comparable with Romania, the Russian Federation and Tajikistan and worse than Iran's (16). The maternal mortality ratio in Maryland is 14. This is where the state of Maryland should be investing time, effort and taxpayer's money, not on advancing abortion.

Finally, how comfortable will you be telling your grandchildren and great-grandchildren that you helped put Maryland on the map---for being one of the top per capita abortion producers in the Nation? Is that the legacy you want for your work and for the citizens of Maryland? I pray not.

I ask for an unfavorable report on HB 1171.

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#### References

- 1. Status of Women Maryland <a href="https://statusofwomendata.org/explore-the-data/state-data/maryland/#reproductive-rights">https://statusofwomendata.org/explore-the-data/state-data/maryland/#reproductive-rights</a>
- Aultman K, Cirucci CA, Harrison DJ, Beran BD, Lockwood MD, Seiler S. Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019. Issues Law Med. 2021 Spring;36(1):3-26. PMID: 33939340.
- Food & Drug Administration. (2016, March). Mifeprex clinical studies. Retrieved from <u>http://www.accessdata.fda.gov/drugsatfda\_docs/label/2016/020687s020lbl.pdf</u>
- Center for Drug Evaluation and Research. (2019, April 12). Questions and Answers on Mifeprex. Retrieved from <u>https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-andanswers-mifeprex</u>
- 5. U.S. Food and Drug Administration, Postmarket Drug Safety Information for Patients and Providers. (2011). *Mifeprex TM questions and answers:* Retrieved from website: <u>https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex</u>
- 6. U.S. Food and Drug Administration, (2016). *Mifeprex TM medication guide*. Retrieved from <u>https://www.fda.gov/media/72923/download</u>
- 7. American College of Obstetricians and Gynecologists. (2006). *Practice Bulletin: Management of alloimmunization during pregnancy* (075).
- 8. <u>https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information</u>
- 9. https://www.fda.gov/drugs/besaferx-your-source-online-pharmacy-information/considering-online-pharmacy
- Mentula MJ, Niinimäki M, Suhonen S, Hemminki E, Gissler M, Heikinheimo O. Immediate adverse events after second trimester medical termination of pregnancy: results of a nationwide registry study. Hum Reprod. 2011 Apr;26(4):927-32. doi: 10.1093/humrep/der016. Epub 2011 Feb 11. PMID: 21317416.
- Niinimäki, Maarit MD<sup>1,2</sup>; Pouta, Anneli MD, PhD<sup>1</sup>; Bloigu, Aini<sup>3</sup>; Gissler, Mika BSc, PhD<sup>4,5</sup>; Hemminki, Elina MD, PhD<sup>4</sup>; Suhonen, Satu MD, PhD<sup>5</sup>; Heikinheimo, Oskari MD, PhD<sup>5</sup> Immediate Complications After Medical Compared With Surgical Termination of Pregnancy, Obstetrics & Gynecology: October 2009 - Volume 114 - Issue 4 - p 795-804 doi: 10.1097/AOG.0b013e3181b5ccf9
- Delgado G, Condly SJ, Davenport M, Tinnakornsrisuphap T, Mack J, Khauv V, Zhou PS. A case series detailing the successful reversal of the effects of mifepristone using progesterone. Issues Law Med. 2018 Spring;33(1):21-31. PMID: 30831017.
- 13. AAPLOG-<u>The Reversal of the Effects of Mifepristone by Progesterone</u>

- 14. CDC abortion reporting system voluntary <u>https://www.cdc.gov/reproductivehealth/data\_stats/abortion.htm</u>
- 15. https://www.guttmacher.org/report/pregnancies-births-abortions-in-united-states-1973-2017
- Daniel S, Schulkin J, Grossman D. Abortion Referral Practices among a National Sample of Obstetrician-Gynecologists. Womens Health Issues. 2020 Nov-Dec;30(6):446-452. doi: 10.1016/j.whi.2020.08.002. Epub 2020 Sep 19. PMID: 32962875.
- 17. Stulberg DB, Dude AM, Dahlquist I, Curlin FA. Abortion provision among practicing obstetrician-gynecologists. Obstet Gynecol. 2011 Sep;118(3):609-614. doi: 10.1097/AOG.0b013e31822ad973. PMID: 21860290; PMCID: PMC3170127.
- 18. <u>https://www.cdc.gov/nchs/data/hestat/maternal-mortality-2021/maternal-mortality-2021.htm</u>
- 19. <u>https://www.commonwealthfund.org/publications/issue-briefs/2020/nov/maternal-mortality-maternity-care-us-compared-10-countries</u>
- 20. https://data.worldbank.org/indicator/SH.STA.MMRT?locations=IQ
- 21. <u>https://www.marchofdimes.org/peristats/data?reg=99&top=6&stop=370&lev=1&slev=4&obj=35&sreg=24</u>
- 22. https://www.prochoiceamerica.org/state-law/maryland/
- Desai S, Jones RK, Castle K. Estimating abortion provision and abortion referrals among United States obstetrician-gynecologists in private practice. Contraception. 2018 Apr;97(4):297-302. doi: 10.1016/j.contraception.2017.11.004. Epub 2017 Nov 21. PMID: 29174883; PMCID: PMC5942890
- 24. http://www.prochoiceamerica.org/wp-content/uploads/2021/03/Who-Decides-2021-Maryland.pdf
- 25. https://iwpr.org/wp-content/uploads/2020/08/Maryland-Fact-Sheet.pdf
- 26. https://www.marchofdimes.org/peristats/ViewTopic.aspx?reg=24&top=5&lev=0&slev=4