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Overlooked Dangers of Mifepristone, the FDA's Reduced REMS, and Self-Managed Abortion Policies: Unwanted Abortions, Unnecessary Abortions, Unsafe Abortions

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Introduction

It has been argued that abortions induced with mifepristone and misoprostol (or even misoprostol alone) are so safe and efficacious that they can be self-prescribed and self-managed[1–3]. As a step toward this goal, some have advocated for elimination of the FDA requirements which limit the ability to prescribe mifepristone to any healthcare provider prepared to: (a) accurately assess the gestational age of the pregnancy, (b) diagnose ectopic pregnancies, and (c) provide referrals for surgical intervention in cases of severe bleeding or incomplete abortion[4,5].

These arguments for reducing or eliminating physician oversight of chemical abortions are based on four premises. First, abortion is a human right that advances the equality, wellbeing, and self-determination of women. Second, the risks of mifepristone/misoprostol abortions are negligible. Third, self-managed abortions are an effective means by which women can control their reproductive lives and achieve their goals. Fourth, physician oversight is unnecessary and counterproductive. If these four premises are true, they present a strong basis for allowing the purchase of mifepristone/misoprostol as an over-the-counter drug.

In the discussion which follows, we will show that the four premises above are, in fact, contradicted by real world experience and the best available medical evidence. The first premise is ideological and not supported by data. As a counterargument, we will show that that chemical abortion is often used contrary to women's self-determination and best interests. The second premise is based primarily on research performed by authors with significant ideological and financial conflicts of interest and entanglement with the manufacturer of mifepristone. Moreover, the FDA has failed to require any systematic investigation of complications associated with mifepristone. Our counterargument will summarize a substantial body of studies documenting detailed evidence of physical and psychological complications associated with chemical abortions, which have simply been ignored, not disproven, by mifepristone advocates. The third premise, that chemical abortions are efficacious, is also ideological and unsupported by any meaningful data. Our counterargument will demonstrate that the actual objectives of women undergoing abortions are not being met, much less reliably quantified. The fourth premise, asserting that physician oversight of chemical abortions is unnecessary is also ideologically driven and unsupported by reliable evidence. Our counterargument will demonstrate that the role of physicians in pre-abortion screening, medical administration, and follow-up should be increased, not eliminated. We conclude with recommendations for modifying FDA's current Risk Evaluation and Mitigation Strategy [REMS] applicable to mifepristone in order to provide better data.

Abortion is Frequently Used Contrary to Women's Preferences and Is Often a Threat to Women's Liberty

Pregnancy and the prospect of bringing a child into the world affect not only the pregnant woman, but also male partners, parents, relatives, employers, health care providers and society at large. Conflicting interests from one or several of these quarters can lead to women being pressured into abortions that are contrary to their own maternal desires or moral beliefs.[6,7]

As a result, it is not uncommon for women to undergo forced abortions.[8–12] This injustice is especially common among women enslaved in sex trafficking.[13,14] Similarly, abortions are frequently forced on victims of incest.[15] Since many incest victims see their pregnancies as an opportunity to both escape abuse and to perhaps finally have a true loving relationship in their lives, being forced into an abortion merely prolongs and deepens their experiences of trauma.[15] Clearly, over-the-counter access to mifepristone would make it easier for sex traffickers and sexual predators to instigate and oversee the coerced abortions of their victims while eliminating any risk that crimes might be revealed and reported by health care providers.

Even when there is no criminal conduct, as many as 64% of American women acknowledging a history of abortion report having felt pressured to abort by others.[16] This pressure typically comes from their male partners, parents, employers and social services officials.[10] The degree of pressure can vary from simply withholding support for having the child to threats of abandonment to violent verbal and physical abuse. In some cases, women have been surreptitiously given abortion-inducing drugs by their male partners.[17,18] Mifepristone available as an over-the-counter medication would clearly increase the likelihood of engaging in this crime.

The problem of women feeling pressured to consent to abortions is amplified by the fact that 40-65% of women undergoing abortion feel great ambivalence about their decisions.[6] This ambivalence can arise from either emotional attachment to the child, desires to be a mother, moral reservations about abortion, or any number of similar concerns. The presence of ambivalence about the abortion decision is itself a risk factor for feelings of regret, loss, grief and guilt following an abortion.[6,19]

The idea that women only choose to abort "unwanted" pregnancies is a pernicious myth. Indeed, a recent study of women seeking abortion found that only 42% were willing to describe the pregnancy as "unwanted."[20] The best evidence indicates that the majority of women considering abortion have mixed feelings of attachment, including desires to keep the pregnancy "if only" circumstances or others' attitudes toward the pregnancy could be improved.[6,16,21,22]

This helps to explain why many, if not most, women want more, not less, pre-abortion counseling.[16,23] Their minds are not necessarily settled on abortion as their best choice. In one survey of women who had negative abortion experiences, 40% reported they were still

undecided at the time they went to the abortion clinic for counseling.[24] In the same survey, 83% reported they would have chosen to keep the child if they had received encouragement to do so from the male partner, parents, their abortion counselor, or others, and 61% felt their lives at that time were "controlled by others."

The high incidence rates of ambivalence and pressure from others are just two of many reasons why pre-abortion screening and counseling are essential parts of abortion.[7,25,26] Many women entering abortion centers sincerely hope the counselor will help them find a way to avoid an unwanted abortion. Unfortunately, many abortion clinic counselors complain that given the time pressures of the day, they simply are unable to give their clients the time they need.[27] These problems will not be corrected by eliminating physician oversight of chemical abortions.

Pressures Surrounding Abortion Contribute to Defective Decision Making

In light of the above facts, Uta Landy, a former executive director of the National Abortion Federation, encourages abortion counselors to be aware of the fact that: "Some women's feelings about their pregnancy are not simply ambivalent but deeply confused. This confusion is not necessarily expressed in a straightforward manner, but can hide behind such outward behavior as: (1) being uncommunicative, (2) being extremely self-assured, (3) being impatient (how long is this going to take, I have other important things to do), (4) being hostile (this is an awful place; you are an awful doctor, counselor, nurse; I hate being here)."[25]

According to other leading experts on abortion counseling, "When [abortion] patients feel overwhelmed by emotions such as fright or shame, their ability to think, act, and even respond to the clinician is impaired."[28] These crisis-related pressures may contribute to defective decision-making. Landy describes four types of defective decision-making that are often observed in abortion clinics.[25] She calls the first defective process the "spontaneous approach," in which the decision is made too quickly, without taking sufficient time to resolve internal conflicts or explore options. A second defective decision-making process is the "rational-analytical approach," which focuses on the practical reasons for terminating the pregnancy (financial problems, single parenthood, etc.) without consideration of emotional needs (attachment to the pregnancy, maternal desires, etc.). A third defective process is the "denying-procrastinating" approach, which is typical of women who have delayed deciding precisely because of the many conflicting feelings they have about keeping the baby. When such a "denying-procrastinator" finally agrees to an abortion, it is likely that she has still not resolved her internal conflicts but is submitting to the abortion only because she has "run out of time." Fourth, there is the "no-decision-making approach" in which a woman refuses to make her own decision but allows others, such as her male partner, parents, counselors, or physician, to decide for her.[25]

Related to the defective-decision making traps described by Landy, experts in crisis counseling report that people in crisis often feel trapped by their crisis, doubtful of their own

judgment, and therefore tend to be more easily swayed by the influence of others.[7,29,30] This is especially dangerous when advisors are influenced by their own biases.

All the risks associated with defective decision-making are increased further when abortion counselors are denied sufficient time to interview and counsel their patients.[27] Even when counselors do have sufficient time, the emotional pressures surrounding an abortion patient may lead some to pretend they are understanding the information being disclosed while they are in fact distracted or confused, which is why experts in abortion counseling advise that the only way they can "know that a client has understood something is to have her explain it back to the counselor."[31]

In short, the fact that a woman is considering an abortion does not mean she has all the information she needs or has settled on abortion as her best choice. It is common for women to feel unprepared for the decision and to report that their pre-abortion counseling was inadequate.[16,32] Women considering abortion want more information and decision-making counseling than is typically available for other elective surgeries.[23] The lack of sufficient time for pre-abortion counseling now[27] does not justify the elimination of in-person pre-abortion screening and counseling advocated by proponents of self-managed abortions.

The Pressures to Undergo Unwanted Abortion May Be Exploited and Inflamed by Racial, Class and Population Control Biases

The autonomy of women to make informed decisions to further their own best interests is also endangered by biased abortion counseling, inaccurate disclosure of risks, negligent pre-abortion screening, and insufficient time and resources dedicated to risk and benefits analyses and decision counseling.[7]

Many of these problems stem from institutional biases toward increasing abortion rates to serve social engineering goals, including reducing the number of children born into poverty, advancing toward zero or negative population growth, eliminating genetic disabilities, and/or delaying or preventing the shift in political and economic power that follows population growth in developing countries.[7,33–38] For example, the Population Council[1] was founded by eugenicists John D. Rockefeller III and Frederick Osborn, a founding member of the American Eugenics Society, specifically to rebrand eugenic objectives under the umbrella of population control efforts "leading to the development of government policies and programs…that will encourage lower fertility."[2] The Population Council and the foundations funding its activities subsequently set up Danco exclusively for the manufacturing and distribution of mifepristone.

These social engineering tendencies are apparent in the common complaint from women that their abortion clinic counselors were biased toward encouraging abortion over other options.[16,24,39,40] Former abortion clinic employees have also reported a bias toward encouraging women to abort even when women report coercion, ambivalence, or moral conflict.[33,41,42] These reports appear to be confirmed by an annual report of Planned

Parenthood which reveals that 95% of its pregnancy resolution services resulted in induced abortions, while only 2.7% resulted in prenatal services, 1.2 percent in adoption referrals, and a mere 0.6% in miscarriage management.[43] In addition to the institutional biases outlined above, individual counselors may also be biased toward abortion because of financial incentives[41,42] and, in many cases where the counselor has a personal history with abortion, a desire to see the counselor's own prior moral choice affirmed by the decisions of her clients.[24,44]

It is important to remember that the initial effort to legalize abortion in the first 60 years of the 20th century was led and funded by eugenicists and population control advocates, not feminists. For these population control zealots, "the woman's rights issue was just another smokescreen for eugenicist goals."[45] In fact, abortion was not even mentioned in Betty Friedan's *The Feminine Mystique*, often credited with launching the modern feminist movement in 1963. Friedan's subsequent advocacy for abortion was instead sparked by Lawrence Lader, biographer of Planned Parenthood founder Margaret Sanger, who promised the political and financial support of major foundations dedicated to population control if feminists joined their campaign for more permissive abortion laws.[33–35] Arguably, with Lader's help the nascent women's rights movement was co-opted and bought off by population controllers precisely because the argument that women wanted more access to abortions was more palatable than the argument that abortion was needed to reduce population growth.[7,33–38,46] This alliance was invaluable. According to Lader: "In a larger sense, each woman who decides whether or not a fetus should become a child affects the population charts," and therefore increasing abortion rates, he argued, was essential to reduce the social burden of the "unwanted classes" and the related risk of "the violent rebellion of minority groups."[47]

While the rhetoric has changed, the end game has not. Foundations and activist groups, like Planned Parenthood and the Population Council, which have a long history in advocating for abortion first for eugenic reasons, second for population control, third to safeguard the world's environment, and finally to enhance the autonomy of women, are all operating from a variety of motives. Their focus on abortion is understandable. Every pregnancy represents social change. Every new person born into the world brings both burdens and benefits on society, and will both strengthen and weaken the economic, political, and environmental resources of his or her population, community, or social group. It is precisely this line of thinking by the National Security Council in 1974 that led the U.S. government to prioritize population control as a centerpiece of U.S. foreign policy, including liberalization of abortion laws around the world.[34,37,38]

These institutional biases regarding the quantity and "quality" of human beings born into the world underlie the well-funded research and public health policy statements which presume more abortions benefit women and understate its risks.[48]

Over-the-Counter Mifepristone Will Further Erode Women's Autonomy

Abortion proponents often idealize abortion as a private choice through which women direct their own destinies. But as outlined above, there is ample evidence to show that many, perhaps most abortions are unwanted, the outcome of women being pressured by others, or circumstances, collective opinion, misinformation and institutional pressures designed to make abortion practically the "only sensible choice" when, in fact, women are being denied the support and resources they need to welcome an unplanned pregnancy.

Therefore, there is a very real danger that the push for over-the-counter mifepristone is driven by social engineers' intent on increasing abortion rates not only in the United States, but around the world, especially in developing countries that still ban most abortions. A shift to over-the-counter access to mifepristone in the United States would likely make mifepristone more easily available in developing countries, either as a legal drug or on the black market. As a result, male partners, family members, and social workers would then have readier access to this abortifacient when pressuring women to "do the best thing." And if women suffer complications, or even death, these tragedies would be labeled as "unsafe abortions" by the population control leaders and exploited in their demands to legalize "safe abortions."

In short, there is no evidence that legalization of abortion has produced any health benefits to women.[6,49,50], Conversely, there is overwhelming evidence that it contributes to an increase in health problems.[6,49–52]. Yet, population controllers (driven by ideological commitment to increase abortion rates, especially in "underserved" nations and communities) simply ignore or discount the evidence of risks and maintain the pretense that every legal abortion produces benefits to women and society—without any data to support this view. From within this worldview, the problem of illegal abortions is reimagined as evidence of women's desire for legal abortions. Complications from illegal abortions are treated as an argument for making abortion legal, even absent evidence of medical benefits from legal abortions. This is not an evidence-based medical argument. It is an ideological argument that is unsupported by good quality research.

As a result, the population controller's success at expanding abortion access around the world is a two-edged sword. It makes it easier for women who desire abortion to obtain one. But it also makes it far easier for the social structures designed to pressure women into unwanted abortions to succeed. This is why the noted feminist scholar Germaine Greer has criticized the pro-abortion campaign, writing:

> "What women 'won' was the right to undergo invasive procedures in order to terminate unwanted pregnancies, unwanted not just by them but by their parents, their sexual partners, the governments who would not support mothers, the employers who would not employ mothers, the landlords who

> would not accept tenants with children, the schools who would not accept students with children. . . . If the child is unwanted, whether by her or her
>
> partner or parents, it will be her duty to undergo an invasive procedure and an emotional trauma and so sort the situation out. The crowning insult is that this ordeal is represented to her as some kind of a privilege. Her sad and onerous duty is garbed in the rhetoric of a civil right. Where other people
>
> decide that a woman's baby should not be born she will be pressured to carry out her duty to herself, to the fetus, to other people, to the health establishment, to the state by undergoing abortion. Her autonomy is the least important consideration. In both cases she is confronted by people who know better than she what she ought to do."[53]

It is important here to recognize that most people have multiple reasons and motivations behind their views. That is why the idea of empowering women to make their own free, informed choice to advance their own self-interests can rest easily next to the view that there are too many people in the world, especially among the poor who are badly equipped to feed, educate and raise productive adults. Therefore, from a social engineering mindset, if one can convince poor women that abortion is in their self-interests (and make it easier for them to do so with a dose of mifepristone), one can achieve two good ends with every abortion.

Bottom line: let us drop the pretense that the campaign for "reproductive rights" is simply advocacy for women's autonomy. Once the notion of any social benefits from abortion has entered into one's judgments, we are now talking about social engineering. Moreover, we would argue that all efforts to expand abortion access include elements of social engineering.

The only way to prevent the abuse of abortion for social engineering purposes is to increase, not decrease, the role of physicians in pre-abortion screening and counseling. The highest priority should be screening for any feelings of pressure to abort from other persons or circumstances that could be addressed by other means. Screenings should then continue to examine all evidence-based risk factors that will help a woman to identify when the abortion poses more risks than benefits to her life.[7] The importance of the physician's duty to screen for contraindicated abortions is the subject of a later section.

Finally, in keeping with the theme of these last two subsections, it is worth noting that the petition for the FDA to remove all REMS and allow telemed prescriptions did not originate from women trying to avoid the involvement of physicians in their pursuit of self-induced abortions. Most women considering abortions desire, expect, and rely on medical consultation, especially regarding the risks associated with medical options, including abortion.[23] This push for unregulated access to mifepristone did not arise from the spontaneous desires of women. This push is driven by the manufacturer and other parties that have vested interests in population

control, a form of social engineering that is often at odds with women's own individual best interests.

The Risks of Mifepristone Have Not Been Adequately Studied, Are Frequently Understated, and Are Greater than Frequently Described

Preferential Political Treatment and the Waiver of Randomized Trials

Expanding abortion access has been a government priority since the 1970's, largely driven by concerns regarding population control.[35] In 1996, after repeated entreaties from the Clinton Administration, the French manufacturer of mifepristone, Roussel-Uclaf, handed over technologies and patent rights for U.S. manufacture of the drug to the Population Council.[34,35,37]. This donation simultaneously freed Roussel-Uclaf from liabilities they feared would arise from widespread use of this abortifacient and placed it under the control of a fiercely dedicated abortion and population control advocacy group that was fully committed to its manufacture and distribution. The plan for this donation was first recommended to president-elect Clinton by Ron Weddington, co-counsel with his wife Sara in *Roe v Wade*, in a 1992 letter where he proposed expanding access to cheap, chemical abortions "to eliminate the barely educated, unhealthy and poor segment of our country" since "26 million food stamp recipients is more than the economy can stand."[54]

To advance their objectives, the Population Council created a private company, Danco, to manufacture and distribute mifepristone while shielding its investors and shareholders from public scrutiny. This secrecy also serves to hide any conflicts of interests related to the foundations, institutions, and researchers engaged in the research and promotion of mifepristone. With political pressure behind rapid expansion of abortion access, the FDA subsequently agreed to Danco's request to fast-track approval of the mifepristone and misoprostol abortion regimen. It was approved under Subpart H Accelerated Approval Regulations which are designed to be used for drugs that treat serious or life-threatening illnesses and provides meaningful therapeutic benefit over existing therapies—conditions that do not apply to chemical abortion, especially in comparison to the alternative of vacuum aspiration abortions. In addition, the requirement that a drug to be used on a pediatric population be tested in that population was waived without explanation, although many mifepristone prescriptions are for minors.[55] This preferential treatment resulted in the FDA's waiver of the normal requirement of two randomized, blinded, placebo-controlled trials demonstrating significant efficacy and minimal risks. Instead, the FDA's approval in 2000 of Danco's application was based on a single published trial that was non-blinded, non-randomized, and utilized only a historical, non-concurrent control.[56] For the sake of appearances, the FDA's expedited approval also stated that Danco would be required to conduct two post-marketing studies, but neither was ever completed.[57]

Due to the absence of more meaningful data, the FDA's approval required the manufacturer of mifepristone to report all "serious" Adverse Events (AEs) to the FDA. This condition provided at least the appearance of ongoing concern and scrutiny given the lack of higher quality data. But like the original approval process, the FDA's AE reporting requirement

was more for show than serious medical research. This is evident from the fact that the FDA's AE rules required the manufacturer to implement a process for prescribing physicians to report any observed complications but does not require the prescribing physician to engage in any systematic process for follow-up of all patients. Instead, by instructing patients to go to an emergency room in the event of any complications the prescriber remains ignorant of any complications. Moreover, since the emergency room staff is not required to report the complications any other reporting of adverse events is entirely voluntary.

In addition to evading the FDA's requirement for reporting complications to the manufacturer, abortion providers also chose to ignore the FDA's approved regimen, which only allowed oral use of mifepristone and oral use of misoprostol. Within two weeks of the FDA's initial approval, abortion providers were already experimenting with vaginal administration of misoprostol. It was later discovered that this experiment contributed to a tenfold increased risk of death from *Clostridium sordellii* infections alone following mifepristone abortions as compared to all reported death due to surgical abortions.[58,59] Further research implicated both mifepristone immune suppression[60,61] as well as misoprostol immune suppression when administered vaginally.[62] These finding eventually led Planned Parenthood, in 2007, to switch from its off label vaginal regimen to a new off label buccal administration of mifepristone supplemented with antibiotics. [63] But sepsis deaths, from both vaginal and buccal administration of misoprostol, continued.[64] Still, even though both vaginal and buccal regimens violated the FDA's post-marketing restrictions, the FDA was carefully silent about these violations--most likely due to the U.S. government's preferential tolerance of abortion methods that advance its population control policies.

Even after widespread use for over 20 years, there have still been no randomized trials investigating the mid- to longer-term complications associated with mifepristone-induced abortions. The FDA's politically motivated waiver of the normal safety research protocols has simply been extended without ever looking back.

In the meantime, the FDA has shown its lack of interest in any complications associated with mifepristone. Under its revised regulations, the manufacturer only needs to report any deaths brought to their attention that are due to mifepristone. Curiously, this dismissal of concern about tracking of non-fatal complications occurred at the same time as the FDA extended its permission to use mifepristone from 49 days of gestation up to 70 days of gestation. Predictably, these later abortions would involve higher complication rates,[65] but the FDA decided it no longer had any interest in tracking these complications. In addition, the FDA also accepted buccal administration of mifepristone as an approved regimen and has further accommodated the requests of abortion providers by also allowing patients to self-administer misoprostol in their own homes. Notably, this latter accommodation required the FDA to blatantly dismiss concerns about the risks associated with decreased efficacy with errors in timing related to self-administration of misoprostol, acting without comment, much less any demand for the experimental data normally required for a drug's approval.[66,67]

In summary, even though mifepristone-induced abortions have been used in the United States for over 20 years, there have still been no randomized trials to systematically investigate the immediate, short-, mid-, and long-term risks. Indeed, what literature has been published has nearly always been funded and conducted by groups and organizations committed to expanding abortion access, often with a history of advocacy for population control.[68] The absence of randomized and double-blind studies underscores the concern that the studies of efficacy and risks that have been published reflect selective investigation goals and selective reporting of results which will best advance political and social engineering objectives. Yet, despite the dearth of higher quality studies and a clear overreliance on marketing studies done by pro-mifepristone advocates, the FDA is seriously considering a reduction in, or the complete elimination of, physician involvement in the prescription and administration of chemical abortions. This is at the request of the Population Council and other population controllers who have invested in Danco. It is the dream scenario for population control zealots, pimps, and sexual predators. But it is a nightmare for the women placed at increased risk of unwanted, unnecessary and unsafe legal abortions.

Physical Risks Are Greater for Medical than Surgical Abortion and Occur Often More than Mifepristone Advocates Readily Admit

The stark inadequacy of the FDA's AE system is demonstrated by the fact that from 2000 through 2017, only 4,179 adverse events were reported in association with 3.2 million mifepristone-induced abortions.[57] This AE reported complication rate (0.13%) is a fraction of the complications reported in the initial clinical trial which reported that 1.3% of women required hospitalization and 2.9% required surgical intervention.[56]. But population scale medical studies demonstrate that the above reports upon which the FDA has relied are not reliable.

For example, a record linkage study of all abortions in Finland (surgical n=20,251, medical n=22,368) found that 20.0% of women undergoing mifepristone-induced abortions experienced adverse events, including 15.6% suffering hemorrhage, 5.9% requiring surgical intervention, and nine deaths per 100,000 abortions.[69] Similarly, another records-based study examining all Medicaid-funded abortions from 1999-2015 (surgical n= 361,924; mifepristone n=67,706) revealed that 35.5% of women undergoing a mifepristone- induced abortion required emergency room treatment within 30 days of their abortions.[70] This complication rate was approximately 100 times higher than reported in data volunteered by Planned Parenthood clinics [71] and 273 times the AE complication rate reported to the FDA.[57] This stark contrast between record-based analyses of mifepristone complications and less objective studies prepared by mifepristone advocates underscores the skepticism that should be reserved for data and analyses drawn exclusively from these sources.

In studies comparing medical to surgical abortion, it is consistently found that the immediate and short-term complications associate with chemical abortions are four times to six

times greater than those associated with surgical abortion.[69,70,72] In part, the higher risks associated with mifepristone/misoprostol abortions may result from potent suppression of the immune system by both medications, thereby increasing the risk of infection and possible sepsis.[58,60] Mifepristone also inhibits contraction of uterine blood vessels, predisposing to hemorrhage with possible transfusion.[73] If the pregnancy tissue is not completely expelled, there is an increased risk of both hemorrhage and infection, and this often requires surgical completion. Moreover, as noted in the warnings and precautions insert for mifepristone: "Patients with serious bacterial infections and sepsis can present without fever, bacteremia or significant findings on pelvic examination. A high index of suspicion is needed to rule out serious infection and sepsis."

A surgical abortion is less likely to result in complications and is completed in a much shorter period of time.[74,75] The average woman undergoing chemical abortion bleeds for nine to 16 days, and eight percent will bleed for longer than a month. The side effects of cramping, vaginal bleeding, nausea, weakness, fever, chills, vomiting, headache, diarrhea, and dizziness occur in 99% of patients[56,57], which likely contribute to the higher rates of psychological distress associated with chemical abortions, as does the possibility of being exposed to a view of the aborted fetus.[76]

The higher rate of incomplete abortions following chemical abortions is also problematic. One literature review of 45,000 chemical abortions found that almost 5% failed, requiring surgery and 1% failed to even kill the fetus.[77] A second review of 18,000 cases found nearly 8% failed in the first trimester, and almost 40% failed in the 2nd trimester.[78] When the FDA loosened its restrictions in 2016, allowing the gestational age limit to be extended from 7 weeks to 10 weeks gestation, the predictable increase in failure rates followed, with a rise from a 2% failure rate prior to 7 weeks to 7% by 10 weeks.[67] These failure rates are not negligible. Many of the nearly one in 20 women with failed abortions will present to an emergency room bleeding heavily, where they will often require immediate surgery and sometimes hospitalization for blood transfusion or intravenous antibiotics.

Clearly, chemical abortion is more hazardous to women's health than surgical abortion. It is also a more prolonged ordeal, which, as discussed in the next section, can involve a higher psychological cost. From the perspective purely of minimizing the risks to women's health, there is no medical justification for chemical abortions. They are more dangerous, period. The only rationales for promoting chemical abortions are (a) reducing the involvement of medical personnel to increase the profits per day that can be collected by abortion providers, (b) alleviating staffing shortages of abortion clinics due to the few providers willing to perform surgical abortions, and (c) advancing the agenda of institutions and governments committed to expanding the use of abortion as a social engineering tool. In light of the latter motivation, the ongoing efforts to permanently remove the REMS restrictions on chemical abortions[3,79] are properly understood as a campaign to remove all physician oversight of chemical abortions, thereby reducing costs and increasing access to cheaper abortions…at the expense of women's health.

Abortion Has Greater Psychological Risks than Abortion Advocates Readily Admit

Elevated rates of depression and anxiety observed in animal experiments with mifepristone-induced abortions[80] suggest that there may be a biological component of the increased rates of psychological problems observed after abortion in adult women.[6,81] The best data on American women is found in a 2016 study using the National Longitudinal Study of Adolescent to Adult Health (NLSAAH) that provided three models of analyses, including controls for 25 confounding factors.[51] In addition, the author conducted a fixed-effects regression analysis controlling for within-person variations to control "for all unobserved or unmeasured variance that may covary with abortion and/or mental health." These lagged models, employed as additional means of examining effects of prior mental illness, confirmed that the risks associated with abortion cannot be fully explained by prior mental disorders. The study also identified a dose effect, with each exposure to abortion (up to four) associated with a 23 percent (95% CI, 1.16–1.30) increase of relative risk of subsequent mental disorders. In addition, a subsequent 2019 analysis using the same data set revealed that approximately 20% of the women having abortions reported wanting the child.[81] Unsurprisingly, the women who aborted wanted children experienced higher rates of depression (RR 2.22, 95% CI 1.3–3.8) and suicidality (RR 3.44 95% CI 1.5–7.7). Notably, no refutation of these findings has been published. They are undisputed.

A comprehensive review of the literature also reveals that there is no dispute that negative emotions are common after abortion and that abortion contributes to mental illness.[6] The only dispute is over when, if ever, abortion is *the sole cause* of mental illness, since pre-existing mental health issues are common and are significantly associated with higher rates of post-abortion mental health problems.[6,81,82] But pre-existing mental illness is just one of the 15 risk factors explaining the higher rates of mental illness consistently observed after abortion and identified by the American Psychological Association Task Force on Mental Health and Abortion (TFMHA) in 2008.[6,82] Among the other risk factors identified by the APA are "perceived pressure from others to terminate a pregnancy," "ambivalence about the abortion," "a prior history of mental health problems" and "a history of prior abortion." These risk factors alone, much less in combination with the other 12 risk factors not identified here, appear among the majority of women seeking an abortion.[6]

Screening for such risk factors, especially coercion, is the duty of abortion providers.[7]. Eliminating the involvement of licensed healthcare providers in the prescription and administration of chemical abortions would demolish this safeguard and would likely increase the rate of coerced and unwanted abortions.

Reviews of the literature have also shown that there are no studies showing any emotional or mental health benefits from abortion. Instead, a metanalysis of all studies comparing abortion to carrying an unwanted pregnancy to term shows a "small to moderate increased risk of some mental health issues."[50] In short, increased psychological risks are consistently associated with abortion while there has been no finding of psychological benefits.

Regarding the differences in the psychological effects associated with medical versus surgical abortions, the literature is surprisingly limited. One of the few randomized trials found that two weeks after the abortion, chemical abortion was linked to higher scores on emotional distress scales than surgical abortion.[83] The women provided with chemical abortions also reported more pain and bleeding and less willingness to consider a chemical abortion in the future. Another study surveying volunteers a few hours and six weeks after their abortions found that 38% of the women had symptoms of post-traumatic stress disorder (PTSD) and that the risk was significantly greater after a chemical abortion compared to a surgical abortion.[76] These findings are consistent with the theory that chemical abortions are more psychologically stressful because (a) women are more likely to see blood and products of conception, (b) by taking the medication directly, women cannot shift blame for the abortion to the surgeon who "did it" to them, and (c) the abortion process is much more prolonged.

Normally, abortion providers offer post-abortion follow-ups, a time when women can identify and receive referrals for any negative physical or emotional reactions. Removing physician involvement from the prescription and administration of mifepristone has not only increased the risk that women will experience physical and emotional problems compared to surgical abortions, it has also decreased the likelihood of them receiving timely referrals for follow-up care.

Abortion Is Consistently Associated with Elevated Risk of Premature Death

Abortion-related death, as defined by the CDC, includes not only direct deaths, but also "indirect complication caused by a chain of events initiated by an abortion, or an aggravation of a pre- existing condition by the physiologic or psychologic effects of abortion."[84] Therefore, the proper identification of chemical-abortion-related deaths should include follow-up investigations to identify deaths resulting from suicide, risk-taking behavior and substance abuse, all of which are consistently associated with abortion,[6] but this has never been done.

In addition, the relatively few deaths reported to the FDA have been entirely limited to only those deaths attributable to chemical abortions that have come directly to the attention of the manufacturer.

To shine light on this gap in mifepristone research, it is important to consider what record linkage studies can tell us about the true mortality rate associated with abortion. Without record linkage, only 1% of deaths following abortion will be identified through death certificates alone.[85] When record linkage of abortion records and death certificates is employed, however, literally every study linking death certificates to reproductive history has revealed an elevated risk of death following abortion, with approximately 20 maternal deaths per 100,000 within 180 days and 34 to 83 deaths within one year, significantly higher than the risk of death associated with childbirth.[49] There is also a dose effect, with each abortion increasing the risk of premature death by about 50%.[86]

To date, there are no studies examining if the elevated risk of death is different for medical versus surgical abortions. There is no reason, then, to believe that chemical abortions are safer. Indeed, given the fact that complication rates after chemical abortions tend to be higher than those following surgical abortions,[69,70,72] it seems most likely that mortality rates are also higher.

Notably, there is not a single records linkage study that has been published which contradicts the finding that abortion is associated with an increased rate of premature death. This fact is especially notable since the pro-abortion research groups and foundations which fund population control activities have access to the same databases. If it were possible for them to publish findings showing reduced risk of premature death following chemical abortion compared to surgical abortions, it is almost certain that they would have done so. The absence of such publications does not prove the absence of research. It is more likely evidence that the association between abortion and premature death in women simply cannot be disproven when record linkage is used to measure mortality risks using a common standard of measure. Therefore, abortion advocates choose to simply ignore the evidence that does not suit their cause and instead rely on inaccurate and improperly compared statistics.[87,88]

The Efficacy of Mifepristone in Achieving Women's Goals Has Not Been Established

For the sake of convenience, all studies of the efficacy of chemical abortion define efficacy simply as the rate of fetal death or completed abortion. But the proper definition of efficacy is not so simple. The proper definition of efficacy should include measures of a treatment's success in helping the patient to achieve the specific results she desires. By way of analogy, is it proper to count the women who regret lopsided breast implants as efficaciously served? Is it proper to count a Lasik surgery as efficacious purely based on measurements of improved light refraction, ignoring complaints of persistent pain or other complications?

As discussed above, physical and psychological complications are common after abortion. Though negative and positive feelings often coexist, negative feelings are more common and varied.[6,21] Structured interviews of women who received abortions at participating clinics reveal that the majority report at least one negative emotion they attribute to their abortions.[16,89,90] Even non-random and partisan surveys that report a high percentage of women believe they made the best decision they could at the time of their abortions also reveal that the majority also reported regret, sorrow, and other negative feelings.[48,89] In addition, the best evidence indicates that positive feelings decrease with time while negative feelings are more likely to increase.[6,91,92] The assertion that "relief" is the most common feeling after abortion is itself disingenuous since "relief" is overly broad. It includes relief that a stressful experience is over, relief the pressure from male partners and parents has ceased, and other forms of relief that have nothing to do with the conclusion that abortion contributed more good than harm to a woman's life.[6]

In short, the efficacy of mifepristone abortions has not actually been tested in relation to helping women achieve the goals that they hope for when consenting to an abortion. For example, many women will abort a wanted pregnancy because it is unwanted by her partner. Her goal in having the abortion is to satisfy her partner's desires and to save the relationship. But in most such cases, the abortion doesn't save the relationship and is more likely to hasten a breakup.[39] Abortions in these cases are not efficacious. Indeed, they contribute to the opposite of the desired result.

Nor is it an efficacious health care policy to facilitate chemical abortions without screening by health providers if, as the best evidence indicates, it will lead to an increase in the number of coerced and unnecessary abortions,[6] risk of premature death,[49] emergency room visits,[70] substance abuse,[93] suicidal behavior,[50,51,87] post-partum psychosis[94] and other negative effects associated with abortion.[6] Inadequate screening will never advance the individual health needs of women.[6,7] The only parties that benefit from inadequate screening are those individuals pressuring women into unwanted abortions, the abortion providers who financially benefit from higher abortion rates, and the population controllers who perceive the pressures on women to abort as something that should be accommodated.[34,35]

In addition, it is notable that throughout history, most pregnancies have been unplanned. In light of this fact, the principles of evolutionary biology would therefore suggest that women are generally resilient and adaptable when it comes to reorganizing their lives to accept and welcome unplanned children. In support of this view, research has shown that on average women who once sought an abortion but carried to term are more likely to be glad that they delivered rather than aborted and suffer no physical or psychological harm following delivery.[48,95]

This fact should also be considered in weighing the value of allowing over-the-counter abortifacients. If (a) most women are able to adjust to delivering unplanned pregnancies; (b) most are likely to be glad that they gave birth to these unplanned children after the fact; (c) the alternative, abortion, is associated with physical risks, negative emotional reactions for the majority of women, and an increased risk of mental illness (even after adjusting for prior mental health); and (d) there is no evidence of physical or mental health benefits, or even evidence that abortion produces the benefits women hope for (saving a relationship, for example). If any or all of the foregoing are true, what is the *medical justification* for removing physician oversight of abortifacients?

The parties who gain the most advantage from removing physician oversight over medically induced abortions are the individuals and institutions most interested in pressuring or seducing women into undergoing unwanted or unnecessary abortions. But even if, from a social engineering point of view, there are social benefits from increasing abortion rates among targeted populations of disadvantaged women, none of these social policy advantages is an appropriate *medical justification* for eliminating the role of physicians in protecting patients from coerced, unsafe, and unnecessary medical procedures. If anything, these social considerations, which are

all too often converted into social pressure to compel women to submit to unwanted abortions, underscore the importance of the physician's role as a third-party mediator who can and should be obligated to protecting the autonomy of patients who are feeling pressured into unwanted, unsafe, or unnecessary abortions. The alert doctor will identify these pressures, any ambivalence, maternal attachment or moral concerns of the patient, and then offer assistance or referrals that can help the woman to achieve her objectives in a manner that is in better accord with her own personal preferences, maternal desires, and moral compass.

Physician Screening, Administration and Follow-Up Is Not Only Necessary, But Should Be Enhanced

The Benefits of the Existing REMS Should Not be Abandoned

It is useful to recognize the many ways in which the FDA's current Risk Evaluation and Mitigation Strategy [REMS] for mifepristone help to reduce the harm to women that would otherwise occur without these regulations.

First, mifepristone must currently be dispensed directly to the woman seeking abortion, though this requirement has not been enforced since April 2021, as decided by the FDA due to the Covid-19 pandemic. This prevents illicit use by others who may benefit from the loss of her baby, such as sex traffickers, incestuous abusers, and coercive male partners or parents. Interaction with the health care system is an opportunity for abused women to be identified and helped. Reducing or removing the limitations on distribution of mifepristone will eliminate an important opportunity for intervention.

Second, under current REMS the prescribing health care provider must be able to assess the duration of pregnancy because underestimation of gestational age will lead to far higher failure rates and greater risk of serious, life-threatening complications.[96] Unfortunately, this provision, too, is often evaded simply by asking women what the date was of their last menstrual period. In other words, the ability to assess the gestational age does not always translate into an actual medical evaluation. Advocates for decreased medical oversight assume that a woman will be able to accurately diagnose her unborn child's gestational age based on a last menstrual period (LMP) calculator, but clinical experience suggests otherwise. Increasing obesity in the American patient population has led to a high incidence of polycystic ovarian syndrome causing irregular menses. Sometimes a woman will have implantation bleeding which she assumes is a normal period even though she is already pregnant. Thus, it is a frequent occurrence for a woman to underestimate gestational age by a month or more. One study found almost 15% of Atlanta women were in error by more than two weeks when calculating gestational age based on LMP.[96]

Third, ruling out an ectopic pregnancy is critically important because mifepristone has no effect on a tubal pregnancy, which can rupture, causing catastrophic bleeding or death. Although ectopic implantation occurs in only 2% of pregnancies, it accounts for 13% of maternal deaths.

A woman is 30% more likely to die from a missed ectopic while undergoing chemical abortion than if she had not chosen an abortion, because she may assume that pain and bleeding are a sign that the abortion pills are working, rather than a sign that her life is in danger.[97] Unfortunately, the current REMS only requires that the healthcare provider have the capability of diagnosing an ectopic pregnancy. It does not require a medical assessment. This should be corrected. An ultrasound should be required, not optional. This is especially necessary since half of women with ectopic pregnancies have no risk factors.

Fourth, evaluation of Rh status and provision of Rhogam if indicated will prevent a mother from mounting an immune response to her future unborn children. In 2017, the American College of Obstetricians and Gynecologists stated that "Rh D immune globulin should be given to Rh D-negative women who have a pregnancy termination, either medical or surgical."[98] They further documented that "Rh testing is standard of care in the U.S. and Rh immunoglobulin should be administered if indicated."[99] If these recommendations are ignored and isoimmunization occurs, 14% of untreated infants will be stillborn and half will suffer neonatal death or brain injury.[98,100] Although ACOG has historically been a strong advocate for prophylactic immunoprophylaxis in any kind of first-trimester pregnancy loss (including abortion), in its most recent practice bulletin it remarked that "shared decision making" could allow omitting this step, once again demonstrating their prioritization of social engineering ideology over the welfare of women (and in this case, their future children).

Fifth, a provider is ethically obligated to provide surgical intervention in the 5-8% of cases where chemical abortion fails. Without a physician-patient relationship or proximity to emergency care, a woman experiencing these common complications finds herself abandoned and at high risk for adverse events.

Sixth, an important task of providers is to verify that an intrauterine device (IUD) is not in place, or alternatively to remove the IUD prior to a chemical abortion. Without medical supervision, it is likely that in many cases this risk factor would be overlooked or ignored. Pregnancy in the presence of an IUD has a high likelihood of implantation in a tube (ectopic) and the foreign body dramatically increases the risk of infection, which as previously reported is already high with chemical abortion.

Women's Health Would Be Better Protected by Expanding REMS

Due to FDA waivers in the approval process, mifepristone-induced abortions have never been thoroughly tested relative to short- and long-term risks, nor has the efficaciousness of abortion in achieving the diverse goals of patients been examined, nor has there been any research identifying the physical, psychological, or social indicators that could be used to identify the women who are most likely to achieve their stated objectives, which are generally much more complicated than simply ending the pregnancy, especially in the majority of cases where there are conflicting maternal desires or moral beliefs. Rather than eliminating the current

REMS, they should be modified to require systematic data gathering in order to properly address the concerns identified in this paper.

As a minimum requirement, revised REMS should require the creation of a centralized and secure abortion drug registry. Each prescription of mifepristone should be entered into the registry with sufficient data regarding each patient to enable record linkage to death certificates and other medical records by public health officials. As previously mentioned, studies in Finland have demonstrated that only 1 percent of abortion-associated deaths can be identified without record linkage between death certificates and an abortion drug registry.[85] This is especially important since there is a large body of evidence demonstrating a link between abortion and elevated rates of suicide and risk-taking behaviors.[6] Since the definition of abortion-related deaths includes deaths from suicide and other psychological sequelae,[84] it is absurd to suggest that mifepristone is not associated with elevated risk of deaths without first completing such record linkage studies. The abortion registry can also be used to link to medical records to identify other complications, both to women and to children born as a result of failed abortion attempts.[64]

In addition, the REMS should require a centralized electronic database for collection of patient intake and follow-up surveys. Prior to each abortion, patients should be required to complete an intake form identifying risk factors, indicators for abortion, expectations, and objectives. A non-personally identifying patient ID code should provide linkage for each patient to the abortion drug registry. The risk factors, at a minimum, should include the 15 risk factors for negative psychological outcomes identified by the APA's 2008 task force.[6] This would include a scale for ranking perception of pressure from other persons, prior mental health, emotional attachment to the pregnancy, moral conflicts with abortion, level of ambivalence, low expectation of coping well with the abortion, difficulty in making the decision to abort, and prior history of abortion or natural losses. Since prior abortions are a risk factor, additional questions should identify any negative reactions to the prior abortion. The section identifying expectations and objectives should include scales for simply not wanting to be pregnant, hoping to please others, hoping to save a relationship, hoping to preserve or advance career or educational opportunities, et cetera. Patients should also be given instructions on accessing and completing a follow-up survey to assess psychological adjustments, physical sequalae, and progress toward each patient's desired results one month, six months, one year after their abortion. Preferably, the FDA would require the design of surveys to include input from both abortion proponents and abortion critics, thereby guaranteeing that all issues of interest are addressed. This data would be incredibly useful in developing evidence-based risks versus benefits assessments. Specifically, the data would identify patterns that best predict when medically induced abortion helps women to achieve their goals with minimal risks and when, and how often, mifepristone abortions may be the result of coercion or other defects in decision making that are likely to produce significantly more negative effects than benefits.

As noted above, the REMS should include collection of data on reproductive history of each patient. This is important because exposure to multiple abortions is associated with higher

rates of both physical and psychological complications compared to exposure to a single abortion.[51,52,86,94,101–103] In addition, the occurrence of a first induced abortion increases the risk of subsequent abortions.[104–106] There is also evidence that some women fall into this pattern because of a desire for replacement pregnancies which are pursued while the pressures to undergo unwanted abortions are still in place.[106] An additional contributing factor in repeat abortions is self-punishing behavior.[39,107] Therefore, the REMS should facilitate further research into the effects of multiple abortions.

Until systematic data on all women undergoing chemical abortion has been collected and analyzed for a period of at least two years, the REMS should be revised to require prescription and administration of all pre-abortion testing by a physician certified to prescribe mifepristone. Moreover, the physician should not only have the ability to test adverse risk factors, but should be required to do so. For example, each woman should receive an ultrasound to confirm intrauterine location of the pregnancy before receiving mifepristone. Each woman should also receive blood typing, and be given the opportunity if she is Rh negative, to receive Rhogam concurrent with mifepristone. In addition, each woman should be screened for anemia, as mifepristone abortions are capable of producing massive hemorrhage which could be life threatening for a woman with pre-existing anemia. The prescriber should observe the woman taking mifepristone, in order to make sure that the mifepristone is not given to another woman.

In regard to follow-up care, each woman who has taken mifepristone should be required to return to the facility to receive the second drug, misoprostol, in order to make sure that she actually needs the misoprostol. Up to 5% of women will completely miscarry with mifepristone alone prior to seven weeks gestation, and thus not need misoprostol administration. Both mifepristone and misoprostol have been associated with clinically significant immune suppression and the avoidance of misoprostol is a health benefit for women.

Women should also be required to return to the abortion provider in two weeks after the ingestion of mifepristone in order to ensure that the abortion has been completed, and that there are no further retained products of conception, as the presence of retained products of conception puts the woman at high risk of infection and hemorrhage.

Finally, to further ensure that women receive the highest quality of care from mifepristone providers, the certification of the prescribing practitioner should require training and implementation of the highest standards of Shared Decision Making (SDM). SDM has been called the pinnacle of patient-centered care.[108] The goal of SDM "is to make the inevitable trade-offs between harms and benefits evident to patients."[109] The failure to carefully screen for risk factors and to invite an examination of the preferences and goals will lead to a silent misdiagnosis[110] that may result in irreparable harm to the patient. In no area of clinical care can this dilemma be more pronounced than in providing abortion to women who may have high levels of ambivalence, may be facing pressure from other people or circumstances that run counter to their own self-interests, and may have other risk factors that place them at high risk of negative psychological outcomes.[6,7] For these reasons, abortion providers can and should be

required to guarantee the implementation of rigorous standards for informed consent, evidence-based assessments of risks versus benefits, and Shared Decision Making. Research suggesting the need for improving physicians' capacity for practicing SDM[111,112], including for physicians with extensive knowledge of SDM[113], highlights the urgency for closing the gap between knowledge and action.[114] Strengthening the requirement for better screening and SDM practices for certification of physicians qualified to prescribe mifepristone would close this gap and better serve patients.

Systematic data collection as outlined above is a necessary precursor before any consideration should be given to the elimination of physician involvement in mifepristone prescriptions, pre-abortion risk assessment, alternative counseling, decision-making counseling and routine follow-up evaluations. If the goal is evidence-based medicine, the FDA should, and can, require the systematic collection of evidence required to demonstrate that self-managed abortions will not endanger women's lives and will produce more benefits than harm to their health and well-being. This will thereby decrease the risk that women will undergo unwanted, unnecessary, and unsafe abortions.

Conclusions

Easy access to abortion has made it easier for women to be pressured into unwanted abortions. In many cases, women are extremely ambivalent about their pregnancies and abortion decisions and desire more, not less, information and involvement from medical experts. Given the stress surrounding an abortion decision, especially when women feel lack of support from others and pressure to abort, some women will be more vulnerable to the inordinate influence of others and defective decision making. It is therefore especially important in these cases for women to receive high quality pre-abortion screening, risk-benefits assessments, full disclosure of risks, and decision-making assistance.

In addition, there is strong evidence that mifepristone abortions are associated with more physical risks than ideological proponents generally admit. Also, there is incontrovertible evidence that the majority of women exposed to abortion have negative feelings, including regret, that abortions at least contribute to (if not solely cause) clinically significant mental health problems. Moreover, the best evidence shows that these negative effects cannot be fully explained by prior mental health issues.

Meanwhile, there are no studies establishing any physical or mental health benefits from medically induced abortion. The benefits are simply presumed. And this belief is itself based on the presumption that all abortions are wanted as a free, well-informed, self-actuating choice that advances women's self-interests in accord with their own personal values. How often that actually happens is unknown. What is known is that more often than not, women feel pressured by others and/or circumstances, feel rushed to abort with less than full disclosure of risks and alternatives, and more often than not feel that they are violating their own maternal and/or moral

compass. In other words, there is no evidence of how often abortion (surgical or medical) is efficacious in helping women achieve their own goals and desires. But it is indisputable that women want more than simply "a completed abortion," and therefore that measure of efficacy is inappropriate and even insulting.

Finally, there is no evidence of benefit to women from eliminating pre-abortion screening and counseling, much less scheduling of follow-up appointments to evaluate the woman's physical and emotional adjustments. The elimination of physician prescriptions, in-person administration, and follow-up care is certain to harm, rather than improve, women's health.

Rather than eliminating the REMS on mifepristone, the REMS should be expanded to create an abortion drug registry enabling record linkage to death certificates and to require better collection of data on pre-existing risk factors and follow-up data on both physical and psychological complications associated with first-time and subsequent abortions.

In summary, even though mifepristone-induced abortions have been used in the United States for over 20 years, there have been no randomized trials to systematically investigate its immediate, short, mid-, and long-term risks. Indeed, even though Surgeon General C. Everett Koop recommended a five-year longitudinal study to investigate abortion's risks and benefits as far back as 1989, that research was opposed by abortion advocates and has still not been undertaken. The failure of abortion providers to support and undertake prospective longitudinal studies of a nationally representative sample of women contributes to our belief that the ideological biases of abortion providers have led to a combination of disinterest, willful ignorance, or even a conspiracy to hide the widespread dangers of unwanted and contraindicated abortions. This ignorance advances the interests of population control zealots, sex traffickers, and sexual predators. But it is a nightmare for the women placed at increased risk of unwanted, unnecessary, and unsafe legal abortions. If the FDA's goal is to protect women's health, the REMS for mifepristone should be expanded to ensure better data collection, not further weakened or eliminated.

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