



RU-486: Dangerous for Women: Deadly for the Unborn

- *A massive spike in RU-486 complications in Ohio followed USDA label change*
- *Abortion pill study appears to be rebutted by Ohio data, flawed in science*
- *FDA should reconsider abortion pill label, and lawmakers should close loopholes in Ohio law for consistent reporting and oversight*

Background

On March 29, 2016, the FDA announced sweeping changes to the label of the abortion-inducing drug, RU-486 (Mifeprax). A label contains information on a prescription drug and includes the approved dosage, side effects, dosing schedule, and other information on the drug that a physician or a patient needs to know or follow. Changes to the label expanded from seven to ten weeks the point in pregnancy when the pill could be used, altered (reduced) the approved dosing rate, eliminated the requirement that only a physician administer the pill, and allowed the second dose of the pill regimen to be taken outside of a physician's office. The FDA did not remove the requirement that the label include a Risk Evaluation and Mitigation Strategy, also called a REMS or black-box warning and used for drugs with known potentially dangerous and serious side effects. In laymen's terms – the FDA label change approved changes to the instructions that come with the abortion pill's prescription and use but did not withdraw the warning of its potential danger to women.

The move especially impacted states like Ohio, where state law (O.R.C. 2919.123) requires that RU-486 be administered in person by a physician and exactly according to the label. Ohio's law was passed in 2004, but was not fully in effect until October of 2012 after the US 6th Circuit Court of Appeals ruled it was constitutional.

The label change was cheered by abortion advocates¹ who expressed “delight” in the change to the label, noting that the new label mirrors the protocols used by abortion providers in states where off-label prescribing is permitted, but many pro-life and faith organizations expressed concern that the Obama Administration's move placed the lobbying efforts of abortion advocates before the interests of women's health and safety and the lives of unborn children.

Methods

Greater Columbus Right to Life has undertaken an exhaustive review of the data² available on RU-486's use in Ohio between January 2012 and July 2017. Our findings indicate that the number and type of serious complications from RU-486 (also known as Mifeprax, mifepristone, or the abortion pill) have skyrocketed since the date the label changes took effect (April 29,

¹ <https://prochoice.org/new-fda-label-for-medical-abortion-pill-mifeprax/>

² The raw data can be reviewed on the Greater Columbus Right to Life website at <http://www.gctrl.org/abortion-pill-resources.html>.

2016). Our data was compiled from public records on abortion and abortion pill complications. Ohio law requires specific information to be reported to the Ohio Department of Health for every abortion that is performed. That information is confidential, but the Ohio Department of Health is required to publish certain statistics each year (abortion statistics report). Ohio law also requires that certain serious complications from RU-486 be reported to the Ohio Medical Board on a form called the “Report of RU-486 Event” (RU-486 report). Thus, it should be noted that while we made a good-faith effort to review and compile information accurately, the basis of our findings relies on second-hand sources that could be flawed by inaccuracies in the reporting or unintentional errors by those who maintain the records and responded to our requests. Should any new information come to light or corrected data be provided, we will provide the necessary corrections.

Findings Summary

In reviewing the RU-486 report data from January of 2012 until July of 2017, there was a significant decrease in the number of abortion pill complications that correlated with full enforcement of Ohio’s abortion pill label law, and Ohio saw a massive increase in the reported number of abortion pill complications following the FDA’s change to the label.

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Not only did the RU-486 report data show an increase in the total number of abortion pill complications after the FDA label change, but the data also indicates a shift in the types of complications reported. It is also important to note that while the RU-486 event reports are available from the Ohio Medical Board, there is a lag in the abortion statistics report which by law has to be published prior to October 1st of the year following the reporting year. Consequently, the statewide abortion statistics report is not yet available for 2016 or 2017. This means that while we can see the changes in the total number of abortion pill complications, we cannot compare those to the total number of medical abortions for 2016 and 2017.

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We do know that between 2013 and 2015, there were an average of 812 medical pill abortions performed each year (855 in 2013, and 791 in each of 2014 and 2015) according to Ohio’s abortion statistics reports³. Comparing the fifteen months following the FDA label change to the fifteen months just prior to the FDA label change, there was a five-fold increase in the total number of reported complications. In order for the rate of complications to remain the same before and after the label change, abortions using RU-486 would need to increase to more than 4,000 doses a year under the label change.

Beyond the rate of complication per dose, the data also suggests that the types of abortion complications have shifted since the FDA changed the label. While the most common RU-486 complication reported continues to be failed or incomplete abortion, since the label change there has been a significant increase in reports of hematometra (a condition where the uterus fills with blood). In addition, a first-time reported complication was indicated for a patient who had such severe complications that she was hospitalized and needed a blood transfusion.

³ There were 806 Ru-486 abortions in 2012. Previous reports did not differentiate medical abortion methods.

We compiled the available data on RU-486 event reports to show the distribution of patients, reported complications, and types of complications reported between January and September of 2012 when Ohio's label law was not fully in effect, from October of 2012 until March of 2016 when Ohio's label law was fully in effect and prohibited providing RU-486 to a patient after seven weeks (49 days) gestation, and between April of 2016 and July 7, 2017 when Ohio's label law was fully in effect but the FDA label changes permitted reduced dosing and use up to ten weeks (70 days) gestation. The cutoff of July 7th simply responds to the date of the last report filed with the state board. Reports may have been filed after that date for procedures prior to that date, as state law does not establish a firm reporting timeline.

Date	2012 Jan-Sep	2012 Oct-Dec	2013	2014	2015	2016 Jan-Mar	2016 Apr- Dec	2017 Jan-7/7	
Patients	23	6	21	12	15	6	49	51	
Reported Events	23	6	21	12	15	6	50	54	
Failed or incomplete abortion **	22	3	18	12	15	5	47	44	
Hematometra		1						5	
Bleeding **	1	1				1	2	3	
Requiring Transfusion							1		
Hospitalization								1	
Infection		1	1					1	
Other			2						
Note:	<i>Prior to OH label law being upheld</i>	<i>Governing label law required in-person administration by physician before 7 weeks (49 days) of pregnancy.</i>					<i>Label expands to 10 weeks (70 days).</i>		

** Summary data includes inferences drawn or data sections combined. For example, "Failed or incomplete abortion" consolidates data reported as an incomplete abortion and also "Other" statistics noted to be a failed or incomplete abortion. Some procedures reported more than one event.

It might be of joyful interest to some that while most reports indicating an incomplete or failed medical abortion noted that the doctor used another drug or obtained a surgical procedure to complete the abortion, in at least some instances it is unclear how or if the abortion was completed. In 2016, a Columbus abortion provider (Romanos) notes, "failed medication abortion. Continuing pregnancy."

There are other interesting observations from the RU-486 complication reports. One Columbus area abortion provider (Romanos) at Planned Parenthood has reported 31 complications. Five noted a failed or incomplete abortion between August of 2014 (ostensibly around the time she started working at Planned Parenthood) and March 2016 (when the old FDA label applied). In each instance during that time, her remarks suggest the patient's complication was due to Ohio's law requiring abortion providers to follow the FDA label, blaming the law for the complication. Examples of her comments included, "FDA protocol resulted in incomplete procedure," "failed

MAB (nonviable IUP⁴) due to FDA regimen,” “failed medical ab likely result of FDA protocol,” and similar statements – each one, tying the FDA label requirements to the complication. However, from April of 2016 until July of 2017, under the new FDA label, that same provider documented 24 failed or incomplete abortions. In only one instance did her remarks mention the FDA regimen, noting: “FDA medication abortion @ 9w3d failed. D&C for ongoing IUP on 12.31.16.” This relatively neutral statement was noted alongside statements like, “Failed medication abortion with D&C procedure,” or “D&C completed” or “Surgical ab after medical ab on (date).”

The shift in these comments is interesting to observe. The doctor’s initial comments reflect a derision for Ohio’s label law and an unwillingness to admit that the abortion pill poses specific dangers to women and unborn children beyond the regulation of the pill’s use. The subsequent comments reflect no attribution whatsoever of the reasons for the medical abortion failure, despite their increasing frequency. One might presume the statement, “Failed medical abortion due to Planned Parenthood’s preferred Mifeprex prescribing protocol” not to be in the best interest of the abortion lobby, regardless of its impact on Ohio women.

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Abortion advocates have worked very hard to promote a narrative that abortion is safe and moral and that laws restricting abortion interfere with medicine to the detriment of women’s rights and women’s health. Ohio’s label law has been under particular attack. For example, [ThinkProgress](#)⁵, [The Daily Beast](#)⁶, and [Time Magazine](#)⁷ reported in the Fall of 2016 that Ohio’s FDA label regimen law had made the abortion pill more dangerous and more expensive for women. The articles, which were widely shared on social media, based their claims on a study published in August of 2016 by PLOS Medicine⁸. The study was co-authored by another Columbus abortion provider (Keder), also at Planned Parenthood.

This study, conducted by the University of California San Francisco, concluded that the Ohio law requiring the abortion pill to be administered according to the FDA label made intervention after medical abortions more necessary for Ohio women. One of the most frequently quoted summary points includes, “The data showed that women who had medication abortions in the postlaw period (after Ohio’s FDA label law became effective) were three times as likely to need additional interventions to complete their abortion compared to women in the prelaw period.” The study was based on medical records from abortion pill patients at four Ohio clinics between 2010 and 2014. It was published in August of 2016, about five months after the FDA label law change. In those five months, Planned Parenthood of Columbus reported seven patients with failed or incomplete abortions and one patient with severe bleeding. Included among those

⁴ IUP – refers to “intrauterine pregnancy.” This simply means a continuing pregnancy that is present in the uterus (as opposed to an ectopic pregnancy – located outside of the uterus).

⁵ <https://thinkprogress.org/data-shows-ohio-abortion-law-knowingly-hurt-women-af4e5d9948c6/>

⁶ <http://www.thedailybeast.com/no-ohio-abortion-restrictions-didnt-help-womenand-may-have-hurt-some>

⁷ <http://time.com/4472497/abortion-restrictions-in-ohio-hurt-womens-health-study-finds/>

⁸ <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002110> (clarification added)

reported complications were patients of the study's co-author (Keder) who apparently did not find it noteworthy that the study's conclusions were complicated by the fact that in five months after the label change there was one more failed/incomplete abortion than there had been reported in the **prior four years** or that the clinic experienced its first reported severe bleed after the label change. Moreover, it is somewhat incomprehensible that the study survived peer-review given that it fundamentally misrepresented the pool of women studied. Let us explain.

The study indicates that of the 5095 patient charts reviewed, 930 were excluded because it was a second or subsequent abortion for that patient; 352 were excluded because the chart was lost and could not be found; and seventeen were excluded because of missing data. This left 3,796 available charts, of which about 1013 were excluded because they represented patients who had an abortion after seven weeks gestation before Ohio's FDA law took effect. The study declaring that a comparison of Ohio's patient outcomes before and after the FDA label showed the law increased serious complications for Ohio's women excluded almost half of the abortions restricted by the law - those taking a low dose of the pill further in pregnancy. This is absurd.

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While the headlines read 'round the world declared Ohio's pro-life policies were endangering women's lives by restricting off-label prescriptions of abortifacient drugs, we are reminded exactly why Ohio lawmakers adopted the FDA label provisions in 2004 and exactly why the FDA did not remove the black-box warning: RU-486 is dangerous for women and deadly to unborn children.

It is becoming more evident that the FDA label changes have increased the rate of serious complications from the abortion pill and that claims to the contrary rely on bad data and questionable mathematical manipulation from researchers representing the abortion industry – where there is economic and political incentive to underreport abortion pill complication data, whether it is from what appears to be systematic failure to report from entire networks of abortion providers or whether it is from the UCSF study which notes two complications requiring blood transfusions in the post-law period, a time when no transfusions are noted in reports to the Ohio Medical Board.

This is not an academic study, and it relies on the veracity of reported data from second and third parties. We observed inconsistencies that are beyond the scope of our resources to study. The raw data reveals lapses that we cannot explain - times where there are no reports for a particular clinic that are inconsistent with its history, entire networks of abortion providers failing to report a single complication, and there are also some apparent conflicts between the abortion pill complications reported to the Ohio Medical Board and all-method abortion complications reported by the Ohio Department of Health. Abortion complications reported to the Ohio Department of Health, unlike those to the Ohio Medical Board, are confidential beyond the aggregate statistics provided in the Department's annual report.

For example, in 2015, there were fifteen RU-486 Events reported to the Ohio Medical Board. All fifteen were failed or incomplete abortions. However, according to the 2015 Ohio Abortion Statistics Report from the Ohio Department of Health, there were only (at most) thirteen failed or incomplete abortions reported that could be attributed to medical abortions.⁹

Regardless of how passionately abortion advocates seek to reframe the debate... the end of medicine is to protect, preserve, and save life, and the rights of women will never be secured by pitting their interests against those of their youngest and most vulnerable children.

It is worth noting that we do not oppose the abortion pill because its use presents potentially dangerous side effects to women or because it so often fails to fully abort an unborn child; we oppose medical abortion for the same reason that we oppose all abortion: it is always wrong to intentionally kill an innocent human, and unborn children are fully human. Regardless of how passionately abortion advocates seek to reframe the debate as one of either a sanitized medical procedure or a matter of protecting the rights of women, it is incontrovertible that the end of medicine is to protect, preserve, and save life, and that the rights of women will never be secured by pitting their interests against those of their youngest and most vulnerable children. Indeed, we will never achieve the protection of human rights as long as we turn a blind eye to the dehumanization of another – regardless of whether we rest the foundation of those rights on the basis of science or faith or both.

That medical abortion pill complication rates have increased so dramatically is a serious claim that deserves further review, especially if they suggest that the concerns raised by pro-life and faith-based organizations that the FDA decision prioritized the powerful abortion lobby to the detriment of women’s health and safety and the lives of unborn children.

Action Items:

In light of this information, we support the following action items.

1. Pro-life groups and individuals should petition the FDA to reconsider the March 2016 label changes in light of the available data.
2. State laws and regulations regarding abortion, specifically medical abortions, should be updated to ensure that data is consistently and accurately reported, and this information should be available to women who are contemplating abortion.
3. Referrals should be made to the appropriate state and federal agencies to determine if the medical records provided to the UCSF research team were done with the appropriate patient consent.

⁹ There are two reporting forms compiled by the Ohio Department of Health. The first is the “Confidential Reporting Form” required under O.R.C.3701.79. The second is the Post Abortion Care Report, required by Ohio Administrative code, section 3701-47-03. The Post-Abortion Care Report lists 8 patients with a gestation of less than 9 weeks with complications of failed or incomplete abortion and another five with pregnancies beyond 9 weeks gestation. This report does not specify method of abortion. The Confidential Reporting Form reports five patients with failed or incomplete abortions, but does not specify gestational range or type of abortion. However, since in 2015, the medical abortion pill could only be legally prescribed up to seven weeks, there were no more than 13 reported medication abortion complications reported to the Ohio Department of Health.

4. The laws that require abortion reporting and complications should be reviewed and updated to ensure that reporting is consistent, timely, and available for public inspection, and hospitals should be required to report induced abortion complication data.

If you support these action items, you can [sign our petition](#) online today.

The mission of Greater Columbus Right to Life is to build a culture that protects innocent human life from the moment of conception until natural death.

This report and others like it are a just a small part of the groundbreaking work being done by Greater Columbus Right to Life, but it represents hundreds of hours of research, analysis and writing. If you found this to be of value, please consider making a donation so that we can continue to focus on restoring the dignity of all human life. Donations to Greater Columbus Right to Life are generally considered tax-deductible.

If you would like to support our work, you can give securely online via our website or by mailing a donation to our office. You can also learn more about the Dangerous for Women: Deadly for Unborn Children project at gctrl.org/abortion-pill.