Greater Columbus Right to Life
Growing a Community of Life

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 (Mifeprex). 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 advocates[1] 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 data[2] 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 Mifeprex, mifepristone, or the abortion pill) have skyrocketed since the date the label changes took effect (April 29,

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[1] https://prochoice.org/new-fda-label-for-medical-abortion-pill-mifeprex/

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

ATTACHMENT 1

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.

In the fifteen months following the FDA label change...there was a five-fold increase in the total number of reported complications.

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 reports[3]. 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:	*Prior to OH label law being upheld*	*Governing label law required in-person administration by physician before 7 weeks (49 days) of pregnancy.*					*Label expands to 10 weeks (70 days).*	

*** 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 IUP[4]) 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 Medicine[8]. 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

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[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 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.

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.***

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 are serious claims that deserve further review, especially if when 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.

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[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.

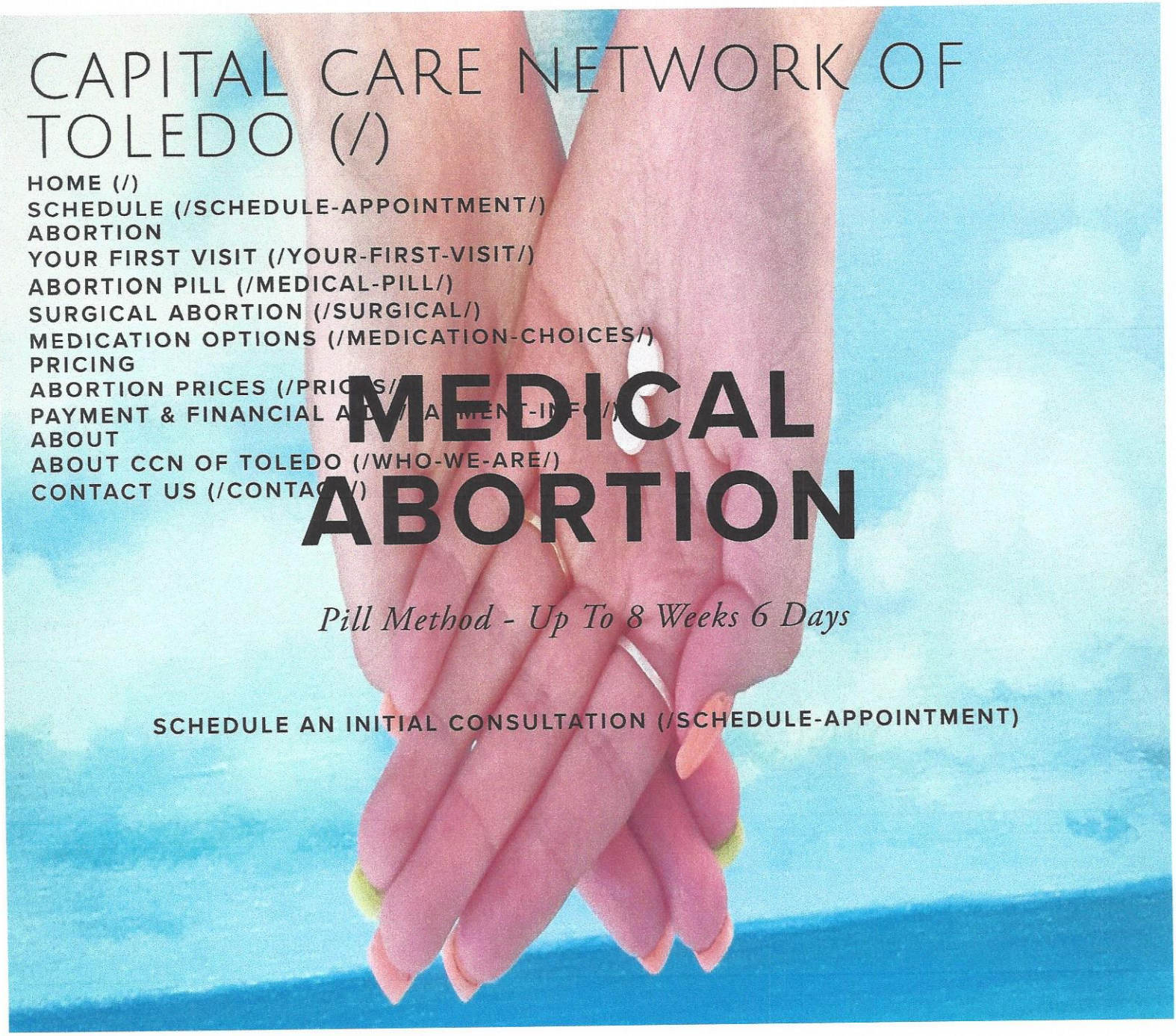
4. The laws that require abortion reporting and complications should be reviewed and updated to ensure that reporting is consistent, timely, and available for public inspection, and hospitals should be required to report induced abortion complication data.

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 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 on line 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 gcrtl.org/abortion-pill.



CAPITAL CARE NETWORK OF TOLEDO (/)

MEDICAL ABORTION

Pill Method - Up To 8 Weeks 6 Days

SCHEDULE AN INITIAL CONSULTATION (/SCHEDULE-APPOINTMENT)

Abortion

YOUR FIRST VISIT (/YOUR-FIRST-VISIT/)

ABORTION PILL (/MEDICAL-PILL/)

SURGICAL ABORTION (/SURGICAL/)

MEDICATION OPTIONS (/MEDICATION-

OHIO LAW REQUIRES ALL PATIENTS TO UNDERGO AN INITIAL CONSULTATION (/YOUR-FIRST-VISIT) AT LEAST 24 HOURS PRIOR TO HAVING AN ABORTION.

During your first appointment, you will receive an ultrasound to determine whether or not your pregnancy is less than ***8 weeks 6 days.***

If you meet this requirement, a patient advocat ill help you schedule your medical abortion at our

ATTACHMENT 2

WHAT IS A MEDICAL ABORTION ?

This method uses oral medications to terminate an early pregnancy, instead of surgery. It consists of two different types of pills: **Mifeprex™** (http://www.fda.gov/downloads/Drugs/DrugSafety/ucm088643.pdf) and **Misoprostol** (http://www.webmd.com/women/mifepristone-and-misoprostol-for-abortion).

When paired together, these two medications are a safe and effective way to end an early pregnancy (less than 8 weeks 6 days as determined by ultrasound).

WHAT IS MIFEPREX ?

Mifeprex™ (http://earlyoptionpill.com/) (also known as RU-486 or mifepristone) is a progesterone-receptor antagonist. That's just a fancy way of saying it blocks the hormone that's necessary for a pregnancy to grow. This medication is given to the patient by a doctor on Day 1 (Appointment #2).

WHAT IS MISOPROSTOL?

Misoprostol (also called Cytotec™) causes the uterus to contract and expel the pregnancy (similar to a miscarriage), usually within 48 hours of taking medication. During this time, you will have bleeding, cramping, and flu-like symptoms.

CAN I GET THESE PILLS FROM MY FAMILY DOCTOR?

Unfortunately, these medications are **not** available through pharmacies or at most regular doctor's offices. **Mifeprex** and **Misoprostol** are different from birth control pills or emergency contraception pills (Plan B). Ohio has strict regulations when it comes to dispensing medical abortion medications. Our staff has received specific training to guide you through this 2-visit process and phone follow-ups.

HOW MUCH DOES IT COST?

- **$425** (POSITIVE BLOOD TYPES)
- **$485** (NEGATIVE BLOOD TYPES)

Cost includes:

- STEP 1: IN-OFFICE INITIAL CONSULTATION
- STEP 2: IN-OFFICE VISIT TO

RECEIVE MIFEPREX DOSE & MISOPROSTOL DOSE

- STEP 3: 1-WEEK POST-ABORTION FOLLOW-UP BY PHONE
- STEP 4: 3-WEEK POST-ABORTION FOLLOW-UP BY PHONE
- PRESCRIPTION FOR ANTIBIOTICS & PAIN RELIEVERS
- RHOGAM INJECTION (ONLY FOR NEGATIVE BLOOD TYPES)

MEDICAL ABORTION PROS:

- AVOIDS SURGERY + ANESTHESIA
- GREATER SENSE OF CONTROL + PRIVACY
- FEELS MORE NATURAL, "LIKE A MISCARRIAGE"

MEDICAL ABORTION CONS:

- REQUIRES 2 IN-OFFICE VISITS + PHONE FOLLOW-UPS
- 92-95% EFFECTIVE, NOT AS PREDICTABLE AS SURGICAL ABORTION

WHAT ARE THE POSSIBLE RISKS?

Although cramping and bleeding are an expected part of ending a pregnancy, in rare instances, serious and potentially life-threatening bleeding, infections, or other problems can occur

following a miscarriage, medical abortion, or childbirth. Prompt medical attention is needed in these circumstances.

Serious infection has resulted in death in a very small number of cases; in most of these cases misoprostol was used in the vagina. **There is no information that use of Mifeprex and misoprostol caused these deaths.**

At Capital Care Network, we **do not** administer misoprostol vaginally. **Our patients are instructed to take misoprostol orally. We also provide all patients with antibiotics to reduce the risk of infection.** These infections are almost always caused by an organism that is already present in your body, and are not due to an organism introduced at the time of your abortion.

If you have any questions, concerns, or problems, please call our office: 419-478-6801. If you are a current patient at our clinic and you are worried about any side effects or symptoms you are experiencing, please call the **24-hour emergency number** that was provided to you during your first appointment.

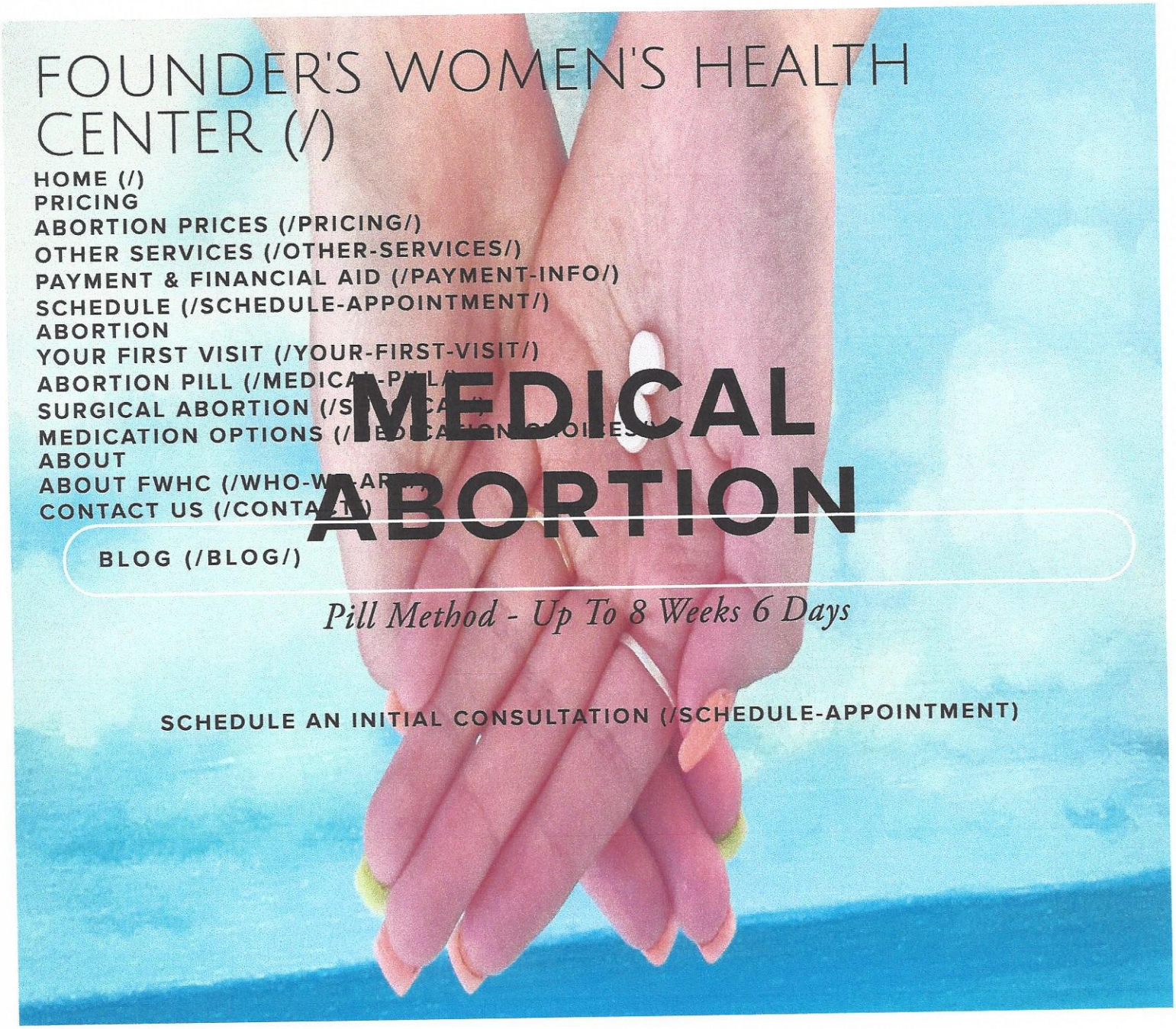
WHEN CAN I RESUME MY BIRTH CONTROL REGIMEN?

You can resume birth control the Sunday after your procedure. If you are interested in birth control, a nurse can go over your options with you in the Recovery Room after your abortion procedure.

We can provide you with a prescription for oral contraception or vaginal rings, which you can take to your pharmacy to get it filled.

We also offer the Depo Provera shot (for an additional fee).

CAPITAL CARE NETWORK, 1160 W SYLVANIA AVE, TOLEDO, OH, 43612, UNITED STATES



FOUNDER'S WOMEN'S HEALTH CENTER (/)

HOME (/)
PRICING
ABORTION PRICES (/PRICING/)
OTHER SERVICES (/OTHER-SERVICES/)
PAYMENT & FINANCIAL AID (/PAYMENT-INFO/)
SCHEDULE (/SCHEDULE-APPOINTMENT/)
ABORTION
YOUR FIRST VISIT (/YOUR-FIRST-VISIT/)
ABORTION PILL (/MEDICAL-PILL/)
SURGICAL ABORTION (/SURGICAL/)
MEDICATION OPTIONS (/MEDICATION-OPTIONS/)
ABOUT
ABOUT FWHC (/WHO-WE-ARE/)
CONTACT US (/CONTACT/)
BLOG (/BLOG/)

MEDICAL ABORTION

Pill Method - Up To 8 Weeks 6 Days

SCHEDULE AN INITIAL CONSULTATION (/SCHEDULE-APPOINTMENT)

Abortion

YOUR FIRST VISIT (/YOUR-FIRST-VISIT/)

ABORTION PILL (/MEDICAL-PILL/)

SURGICAL ABORTION (/SURGICAL/)

MEDICATION OPTIONS (/MEDICATION-

OHIO LAW REQUIRES ALL PATIENTS TO UNDERGO AN INITIAL CONSULTATION (HTTPS://AMANDA-PATTON.SQUARESPACE.COM/YOUR-FIRST-VISIT) AT LEAST 24 HOURS PRIOR TO HAVING AN ABORTION.

*During your first appointment, you will receive an ultrasound to determine whether or not your pregnancy is less than **8 weeks 6 days**.*

If you meet this requirement, a patient advocat

ATTACHMENT 3

WHAT IS A MEDICAL ABORTION ?

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CAN I GET THESE PILLS FROM MY FAMILY DOCTOR?

Unfortunately, these medications are **not** available through pharmacies or at most regular doctor's offices. **Mifeprex** and **Misoprostol** are different from birth control pills or emergency contraception pills (Plan B).

Ohio has strict regulations when it comes to dispensing medical abortion medications. Our staff has received specific training to guide you through this 3-visit process.

FWHC's medical abortion protocol is dictated by Ohio state law.

HOW MUCH DOES IT COST?

- **$550 (POSITIVE BLOOD TYPES)**
- **$610 (NEGATIVE BLOOD TYPES)**

Cost includes:

- VISIT 1: INITIAL CONSULTATION
- VISIT 2: MIFEPREX DOSE & MISOPROSTOL DOSE
- VISIT 3: 2-WEEK FOLLOW-UP
- PRESCRIPTION FOR ANTIBIOTICS & PAIN RELIEVERS
- RHOGAM INJECTION (ONLY FOR NEGATIVE BLOOD TYPES)

MEDICAL ABORTION PROS:

- AVOIDS SURGERY & ANESTHESIA
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- FEELS MORE NATURAL, "LIKE A MISCARRIAGE"

MEDICAL ABORTION CONS:

- REQUIRES 3 IN-OFFICE APPOINTMENTS
- HIGHER FINANCIAL COST
- 92-95% EFFECTIVE, NOT AS PREDICTABLE AS SURGICAL ABORTION

WHAT ARE THE POSSIBLE RISKS?

Although cramping and bleeding are an expected part of ending a pregnancy, in rare instances, serious and potentially life-

threatening bleeding, infections, or other problems can occur following a miscarriage, medical abortion, or childbirth. Prompt medical attention is needed in these circumstances.

Serious infection has resulted in death in a very small number of cases; in most of these cases misoprostol was used in the vagina. **There is no information that use of Mifeprex and misoprostol caused these deaths.**

At Founder's Women's Health Center, we **do not** administer misoprostol vaginally. **Our patients are instructed to take misoprostol orally. We also provide all patients with antibiotics to reduce the risk of infection.** These infections are almost always caused by an organism that is already present in your body, and are not due to an organism introduced at the time of your abortion.

If you have any questions, concerns, or problems, call our main office: 614-251-1800. If you are a current patient at our clinic and you are worried about any side effects or symptoms, please call our **24-hour emergency number: 1-800-548-6781**.

WHEN CAN I RESUME MY BIRTH CONTROL REGIMEN?

You can resume birth control on the Sunday after your procedure. If you are interested in birth control, a nurse can go over your options with you in the Recovery Room after your abortion procedure.

We can provide you with a prescription for oral contraception or vaginal rings, which you can take to your pharmacy to get it filled.

We also offer the Depo Provera shot and IUD insertion (for an additional fee).

FOUNDER'S WOMEN'S HEALTH CENTER, 1243 E BROAD ST, COLUMBUS, OH, 43205 614-251-1800

that you're well informed about what to expect before, during, and after you receive any of the services we provide. Whether you're just curious or gathering facts while making a decision, we hope this breakdown of what we do is helpful. As always, we are available to answer any questions you still have at our toll-free number (1-800-466-2205).

What We Do:

- Medical or Non-Surgical Abortion up to 9½ weeks
- First Trimester Surgical Abortion up to 11 weeks and 6 days - Available at our Columbus & Toledo offices
- Second Trimester Abortion up to 19 weeks and 6 days - Available at our Columbus & Toledo offices
- Emergency Contraception
- Free Urine Pregnancy Testing
- Information on abortion procedures, options and support

Abortion Services

Your visit to our center will include a consultation and an ultrasound by our professional staff.

During your visit we assess your medical and contraceptive history and perform ultrasound and blood work. Every appointment for an abortion includes a private discussion with a patient advocate. Here you'll have the chance to ask questions and explore your decision in a confidential, non-judgmental atmosphere. We'll also discuss alternatives to abortion, the procedure, including its risks and possible complications, and birth control methods.

Medical or Non-Surgical Abortion:
(Up to 9½ weeks)

Non-surgical abortion (also called Medical Abortion) is a safe and effective way to end an early pregnancy using a combination of drugs. We use the drug Mifeprex® (also known as RU-486 or mifepristone) in combination with misoprostol (also called Cytotec). Mifeprex® causes changes in the uterine lining. Misoprostol causes the uterus to contract and expel the pregnancy. This method of abortion is safe and effective in terminating pregnancies up to 63 days (9 weeks) from the last normal menstrual period.

How it Works

After your first visit (the consultation) we will schedule your appointment to receive an oral dose of Mifeprex® from the physician. You'll take the second drug (misoprostol) home with you to insert vaginally between 6 and 72 hours later. About one to four hours after taking misoprostol, your uterus will begin to contract. You'll have cramping and bleeding, and the pregnancy will be expelled. The process is usually completed within 24 hours.

Three weeks after taking Mifeprex®, you will take a pregnancy test to determine whether the abortion has been completed. If the results are positive or faint positive you will need to come in for a follow up. During this visit we will perform an ultrasound to determine whether or not you are still pregnant. An advocate will go over your options which include a surgical abortion to end the pregnancy.

The Effectiveness of Abortion Using Mifeprex®

Studies have shown that non-surgical abortion using Mifeprex® is highly effective. Worldwide, millions of women have successfully used mifepristone for many years. There is a 5-7% chance that this abortion method will fail, making it necessary for the woman to return for a surgical abortion (at no additional charge). We have had 95% effectiveness with Mifeprex® and misoprostol.

Symptoms and Side Effects

Most women will experience cramping and bleeding, which usually means that the method is working. Bleeding may be similar to, or greater than, a normal heavy period. You may see blood clots and tissue that come from the uterus. This is an expected part of ending the pregnancy. Bleeding or spotting will usually last an average of 9 to 16 days and may last for up to 30 days. In rare cases (1 woman in 100), bleeding can be very heavy and may need to be stopped by a surgical procedure. Common side effects include nausea, vomiting, abdominal pain, fatigue, fever, headache, dizziness, and diarrhea.

After the abortion, we'll give you written and verbal instructions for after-care. We'll also give you birth control if requested. No follow-up appointment is necessary although we will require the results of a pregnancy test to ensure the abortion is complete. Our staff is available twenty-four hours a day to answer any of your post-abortion questions or concerns.

Advantages and Disadvantages of Non-surgical Abortion

Women in the clinical trials cited several reasons for choosing non-surgical over surgical abortion, including avoiding surgery or anesthesia, greater privacy, a greater sense of control, and wanting a method that is "more natural, like a miscarriage." However, non-surgical abortion may require more visits to the clinic and may take several weeks to complete. If the method is unsuccessful, the woman will need to undergo a surgical abortion. Also, there are the side effects mentioned previously.

Our Locations
Akron, Ohio
Columbus, Ohio
Lima, Ohio
Toledo, Ohio
Fort Wayne, Indiana

Non Affiliated Sites
Dayton, Ohio
Columbus, Ohio

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Testimonials

"You made me feel comfortable. I was very scared but I trusted you. Thank you." See what else women are saying about Capital Care Network.

More Testimonials

twitter Join the conversation

ATTACHMENT 4

Call to schedule an appointment

614.430.3711
1.800.466.2205

Services

We offer a wide range of services to women. We want to give you honest, straight-forward information so that you're well informed about what to expect before, during, and after you receive any of the services we provide. Whether you're just curious or gathering facts while making a decision, we hope this breakdown of what we do is helpful. As always, we are available to answer any questions you still have at our toll-free number (1-800-466-2205).

What We Do:

- Medical or Non-Surgical Abortion up to 6 weeks 6 days
- First Trimester Surgical Abortion up to 11 weeks and 6 days - Available at our Columbus & Toledo offices
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Your visit to our center will include a consultation and an ultrasound by our professional staff.

During your visit we assess your medical and contraceptive history and perform ultrasound and blood work. Every appointment for an abortion includes a private discussion with a patient advocate. Here you'll have the chance to ask questions and explore your decision in a confidential, non-judgmental atmosphere. We'll also discuss alternatives to abortion, the procedure, including its risks and possible complications, and birth control methods.

Medical or Non-Surgical Abortion:
(Up to 6 weeks 6 days)

Non-surgical abortion (also called Medical Abortion) is a safe and effective way to end an early pregnancy using a combination of drugs. We use the drug Mifeprex® (also known as RU-486 or mifepristone) in combination with misoprostol (also called Cytotec). Mifeprex® causes changes in the uterine lining. Misoprostol causes the uterus to contract and expel the pregnancy. This method of abortion is safe and effective in terminating pregnancies up to 48 days (6 weeks 6 days) from the last normal menstrual period.

How it Works

After your first visit (the consultation) we will schedule your appointment to receive an oral dose of Mifeprex® from the physician. You will receive an oral dose of the second drug (misoprostol) in our office two days after receiving the Mifeprex®. About one to four hours after taking misoprostol, your uterus will begin to contract. You'll have cramping and bleeding, and the pregnancy will be expelled. The process is usually completed within 24 hours.

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Akron, Ohio

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614.251.1800
1.800.282.9490

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Toledo, Ohio
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Akron, Ohio

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Follow us online

Testimonials

"You made me feel comfortable. I was very scared but I trusted you. Thank you." See what else women are saying about Capital Care Network.

More Testimonials

Call to schedule an appointment

614.251.1800
1.800.282.9490

Capital Care now manages Founder's Women's Health Center. We refer all patients to Founder's -- Click here to learn more.

Capital Care Network provides comprehensive women´s health care

Schedule an Appointment

Call to speak with our friendly and caring staff to schedule an appointment.

Local - 614.251.1800
Toll Free - 1.800.282.9490

Community Involvement

Capital Care Network is committed to public partnership and education. Our community advocacy group includes staff, community members, and volunteers. We partner with other local organizations and aid in coordination of events that help increase knowledge and awareness.

Our Locations

Columbus, Ohio

Lima, Ohio
(We refer Lima patients to Columbus or Toledo)

Toledo, Ohio

Fort Wayne, Indiana
(We refer Fort Wayne patients to Columbus or Toledo)

Non Affiliated Sites

Akron, Ohio

Contact us online

Follow our Blog

Women's Health First

Testimonials

"You made me feel comfortable. I was very scared but I trusted you. Thank you."

See what else women are saying about Capital Care Network.

More Testimonials

Who We Are.

In 1975 the Capital Care Women's Center group was founded in Columbus, Ohio to provide safe medical procedures for women seeking abortions. Since then we have grown to include emergency contraceptives, birth control, pregnancy testing, and reproductive health information to women across five cities and two

Who We Serve.

We see thousands of women every year but each one is unique. Our patients range in age from teenagers to women in their late forties, coming from all types of cultural, racial, religious, and education backgrounds. Some women travel down the street, some travel down the highway, and some come from cities in

Why Choose Us?

Our female owned and operated offices provide a non-judgmental, private, and respectful environment. Our caring and professional staff includes physicians, registered and licensed practical nurses, trained medical assistants, and patient advocates. We strive to personalize our care, create an environment that is

Please see REMS updated 3/29/2016

MEDICATION GUIDE

Mifeprex® (MIF-eh-prex)
(mifepristone)

Read this information carefully before taking Mifeprex* and misoprostol. It will help you understand how the treatment works. This MEDICATION GUIDE does not take the place of talking with your health care provider (provider).

What is Mifeprex?

Mifeprex is used to end an early pregnancy. It blocks a hormone needed for your pregnancy to continue. It is not approved for ending later pregnancies. Early pregnancy means it is 49 days (7 weeks) or less since your last menstrual period began. When you use Mifeprex (Day 1), you also need to take another medicine misoprostol, 2 days after you take Mifeprex (Day 3), to end your pregnancy. But, about 5-8 out of 100 women taking Mifeprex will need a surgical procedure to end the pregnancy or to stop too much bleeding.

What is the most important information I should know about Mifeprex?

What symptoms should I be concerned with? Although cramping and bleeding are an expected part of ending a pregnancy, rarely, serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion, or childbirth. Prompt medical attention is needed in these circumstances. Serious infection has resulted in death in a very small number of cases; in most of these cases misoprostol was used in the vagina. There is no information that use of Mifeprex and misoprostol caused these deaths. If you have any questions, concerns, or problems, or if you are worried about any side effects or symptoms, you should contact your provider. Your provider's telephone number is _____.

Be sure to contact your provider promptly if you have any of the following:

Heavy Bleeding. Contact your provider right away if you bleed enough to soak through two thick full-size sanitary pads per hour for two consecutive hours or if you are concerned about heavy bleeding. In about 1 out of 100 women, bleeding can be so heavy that it requires a surgical procedure (surgical abortion/D&C) to stop it.

Abdominal Pain or "Feeling Sick". If you have abdominal pain or discomfort, or you are "feeling sick", including weakness, nausea, vomiting or diarrhea, with or without fever, more than 24 hours after taking misoprostol, you should contact your provider without delay. These symptoms may be a sign of a serious infection or another problem (including an ectopic pregnancy, a pregnancy outside the womb).

Fever. In the days after treatment, if you have a fever of 100.4°F or higher that lasts for more than 4 hours, you should contact your provider right away. Fever may be a symptom of a serious infection or another problem (including an ectopic pregnancy).

Take this MEDICATION GUIDE with you. When you visit an emergency room or a provider who did not give you your Mifeprex, you should give them your MEDICATION GUIDE so that

ATTACHMENT 5

OHIO DEPARTMENT OF HEALTH

246 North High Street
Columbus, Ohio 43215

614/466-3543
www.odh.ohio.gov

John R. Kasich / Governor

Theodore E. Wymyslo, M.D. / Director of Health

MAR 0 5 2013

T & S Management of Columbus, LLC
Capital Care Network
c/o Terrie Hubbard, R.N.
1243 East Broad Street
Columbus, Ohio 43205

Re: **Notice of Proposal to Revoke License; and**
Notice of Prohibition of Facility from Performing Services
Facility Name: **Capital Care Network**
License Number: **1008AS**

Dear Ms. Hubbard and T & S Management:

You hereby are notified that I propose to issue an order revoking the Health Care Facility license of Capital Care Network located at 2127 State Road, Cuyahoga Falls, Ohio, 44223 (Capital Care), to operate as an ambulatory surgical facility, for violations of section 3702.30 of the Revised Code (R.C.) and Chapter 3701-83 of the Ohio Administrative Code (O.A.C.). This action is taken under authority of section 3702.32 of the R.C., paragraph (C)(2) of O.A.C. rule 3701-83-05.1 and in accordance with Chapter 119. of the R.C.

Additionally, you are hereby notified that I am issuing an order that prohibits Capital Care from performing medical services including surgical procedures, pharmaceutical services, and anesthesia services. This action is taken under authority of section 3702.32 of the R.C., paragraph (C)(3) of O.A.C. rule 3701-83-05.1 and in accordance with Chapter 119. of the R.C. This order is effective at 12:01 a.m. on the first day following the day of receipt of this order.

Representatives of the Ohio Department of Health conducted a licensure compliance inspection at Capital Care, on February 14, 2013. A copy of the report is enclosed and incorporated into this notice by reference. The above listed actions are based on the violations found on the February 14, 2013, inspection.

You are hereby notified that you may request a hearing before me or my duly authorized representative regarding my order to prohibit Capital Care from performing medical, pharmaceutical, and anesthesia services and my proposal to revoke Capital Care's license to operate. Such request must be made in writing and received within thirty days of receipt of this letter and should be directed to the Office of General Counsel, Ohio Department of Health, 246 North High Street, Seventh Floor, Columbus, Ohio, 43215. A request is considered timely if it is received by the Ohio Department of Health via facsimile, hand delivery, or ordinary United States mail within thirty days of the date of receipt of this letter.

At a hearing you may appear in person or be represented by an attorney. You may present evidence and you may examine witnesses appearing for and against you. You also may present your position, contentions or arguments in writing rather than appear in person for a hearing. If you are a corporation, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.

Please be advised that if you do not request a hearing within the thirty (30) days allowed, I will issue an adjudication order revoking Capital Care's license to operate. Please call Kathryn Kimmet at (614) 644-6220 if you have any questions about this matter.

Sincerely,

Theodore E. Wymyslo, M.D.
Director of Health

Certified Mail Return Receipt Requested:

7012 3050 0002 1677 2760:	**Capital Care Network**
7012 3050 0002 1677 2753:	**T & S Management of Columbus, LLC**

c: Kathryn Kimmet, Chief, Bureau of Regulatory Compliance
Rachel Belenker, Office of the General Counsel
Tamara Malkoff, Assistant Bureau Chief, Bureau of Information and Operational Support
Capital Care Network

State Medical Board of Ohio

30 E. Broad St., 3rd Floor
Columbus, Ohio 43215
(614) 466-3934
www.med.ohio.gov

July 12, 2017

David M. Burkons, M.D.
1611 South Green Road, Suite 004
South Euclid, OH 44121

RE: Case No. 15-CRF-117

Dear Doctor Burkons:

Please find enclosed certified copies of the Entry of Order; the Report and Recommendation of R. Gregory Porter, Esq., Hearing Examiner, State Medical Board of Ohio; and an excerpt of draft Minutes of the State Medical Board, meeting in regular session on July 12, 2017, including motions modifying the Conclusions of the Hearing Examiner, approving and confirming the Findings of Fact and Order of the State Medical Board of Ohio.

Section 119.12, Ohio Revised Code, may authorize an appeal from this Order. Any such appeal must be filed in accordance with all requirements specified in Section 119.12, Ohio Revised Code, and must be filed with the State Medical Board of Ohio and the Franklin County Court of Common Pleas within (15) days after the date of mailing of this notice.

THE STATE MEDICAL BOARD OF OHIO

Kim G. Rothermel, M.D.
Secretary

KGR:jam
Enclosures

CERTIFIED MAIL NO. 91 7199 9991 7036 7571 2536
RETURN RECEIPT REQUESTED

cc: Douglas E. Graff, Esq.
CERTIFIED MAIL NO. 91 7199 9991 7036 7571 2543
RETURN RECEIPT REQUESTED

Mailed 8-8-17

ATTACHMENT 7

CERTIFICATION

I hereby certify that the attached copy of the Entry of Order of the State Medical Board of Ohio; Report and Recommendation of R. Gregory Porter, Esq., State Medical Board Hearing Examiner; and excerpt of draft Minutes of the State Medical Board, meeting in regular session on July 12, 2017, including motions modifying the Conclusions of the Hearing Examiner; approving and confirming the Findings of Fact and Order of the State Medical Board of Ohio; constitute a true and complete copy of the Findings and Order of the State Medical Board in the matter of David M. Burkons, M.D., Case No. 15-CRF-117, as it appears in the Journal of the State Medical Board of Ohio.

This certification is made by authority of the State Medical Board of Ohio and in its behalf.

Kim G. Rothermel, M.D.
Secretary

(SEAL)

July 12, 2017
Date

BEFORE THE STATE MEDICAL BOARD OF OHIO

IN THE MATTER OF *

* CASE NO. 15-CRF-117

DAVID M. BURKONS, M.D. *

ENTRY OF ORDER

This matter came on for consideration before the State Medical Board of Ohio on July 12, 2017.

Upon the Report and Recommendation of R. Gregory Porter, Esq., State Medical Board Hearing Examiner, designated in this Matter pursuant to R.C. 4731.23, a true copy of which Report and Recommendation is attached hereto and incorporated within, and upon the modification, approval and confirmation by vote of the Board on the above date, the following Order is hereby entered on the Journal of the State Medical Board of Ohio for the above date.

Amended Conclusion of Law No. 4: The acts, conduct, and/or omissions of Dr. Burkons as described in Finding of Fact 4, independent of any rule violation, constitute a "departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in R.C. 4731.22(B)(6).

It is hereby ORDERED that:

A. **SUSPENSION OF CERTIFICATE**: The certificate of David M. Burkons, M.D., to practice medicine and surgery in the State of Ohio shall be SUSPENDED for a period of 180 days.

B. **PROBATION**: Upon reinstatement, Dr. Burkons' certificate shall be subject to the following PROBATIONARY terms, conditions, and limitations for a period of at least three years:

1. **Obey the Law**: Dr. Burkons shall obey all federal, state, and local laws, and all rules governing the practice of medicine and surgery in Ohio.

2. **Declarations of Compliance**: Dr. Burkons shall submit quarterly declarations under penalty of Board disciplinary action and/or criminal

prosecution, stating whether there has been compliance with all the conditions of this Order. The first quarterly declaration must be received in the Board's offices on or before the first day of the third month following the month in which Dr. Burkons' certificate is restored or reinstated. Subsequent quarterly declarations must be received in the Board's offices on or before the first day of every third month.

3. **Personal Appearances**: Dr. Burkons shall appear in person for an interview before the full Board or its designated representative during the third month following the month in which Dr. Burkons' certificate is restored or reinstated, or as otherwise directed by the Board. Subsequent personal appearances shall occur every **six** months thereafter, and/or as otherwise directed by the Board. If an appearance is missed or is rescheduled for any reason, ensuing appearances shall be scheduled based on the appearance date as originally scheduled.

4. **Monitoring Physician**: Within 30 days of the date of Dr. Burkons' reinstatement or restoration, or as otherwise determined by the Board, Dr. Burkons shall submit the name and curriculum vitae of a monitoring physician for prior written approval by the Secretary and Supervising Member of the Board. In approving an individual to serve in this capacity, the Secretary and Supervising Member will give preference to a physician who practices in the same locale as Dr. Burkons and who is engaged in the same or similar practice specialty.

   The monitoring physician shall monitor Dr. Burkons and his medical practice, and shall review Dr. Burkons' patient charts. The chart review may be done on a random basis, with the frequency and number of charts reviewed to be determined by the Board.

   Further, the monitoring physician shall provide the Board with reports on the monitoring of Dr. Burkons and his medical practice, and on the review of Dr. Burkons' patient charts. Dr. Burkons shall ensure that the reports are forwarded to the Board on a quarterly basis and are received in the Board's offices no later than the due date for Dr. Burkons' declarations of compliance.

   In the event that the designated monitoring physician becomes unable or unwilling to serve in this capacity, Dr. Burkons shall immediately so notify the Board in writing. In addition, Dr. Burkons shall make arrangements acceptable to the Board for another monitoring physician within 30 days after the previously designated monitoring physician becomes unable or unwilling to serve, unless otherwise determined by the Board. Dr. Burkons shall further ensure that the previously designated monitoring physician also notifies the Board directly of his or her inability to continue to serve and the reasons therefor.

The Board, in its sole discretion, may disapprove any physician proposed to serve as Dr. Burkons' monitoring physician, or may withdraw its approval of any physician previously approved to serve as Dr. Burkons' monitoring physician, in the event that the Secretary and Supervising Member of the Board determine that any such monitoring physician has demonstrated a lack of cooperation in providing information to the Board or for any other reason.

5. **Tolling of Probationary Period While Out of Compliance**: In the event Dr. Burkons is found by the Secretary of the Board to have failed to comply with any provision of this Order, and is so notified of that deficiency in writing, such period(s) of noncompliance will not apply to the reduction of the probationary period under this Order.

6. **Required Reporting of Change of Address**: Dr. Burkons shall notify the Board in writing of any change of residence address and/or principal practice address within 30 days of the change.

C. **TERMINATION OF PROBATION**: Upon successful completion of probation, as evidenced by a written release from the Board, Dr. Burkons' certificate will be fully restored.

D. **REQUIRED REPORTING WITHIN 30 DAYS OF THE EFFECTIVE DATE OF THIS ORDER**:

1. **Required Reporting to Employers and Others**: Within 30 days of the effective date of this Order, Dr. Burkons shall provide a copy of this Order to all employers or entities with which he is under contract to provide healthcare services (including but not limited to third-party payors), or is receiving training, and the Chief of Staff at each hospital or healthcare center where he has privileges or appointments. Further, Dr. Burkons shall promptly provide a copy of this Order to all employers or entities with which he contracts in the future to provide healthcare services (including but not limited to third-party payors), or applies for or receives training, and the Chief of Staff at each hospital or healthcare center where he applies for or obtains privileges or appointments.

   In the event that Dr. Burkons provides any healthcare services or healthcare direction or medical oversight to any emergency medical services organization or emergency medical services provider in Ohio, within 30 days of the effective date of this Order, he shall provide a copy of this Order to the Ohio Department of Public Safety, Division of Emergency Medical Services.

   These requirements shall continue until Dr. Burkons receives from the Board written notification of the successful completion of his probation.

PLOS | MEDICINE

Comparison of Outcomes before and after Ohio's Law Mandating Use of the FDA-Approved Protocol for Medication Abortion: A Retrospective Cohort Study

Ushma D. Upadhyay , Nicole E. Johns, Sarah L. Combellick, Julia E. Kohn, Lisa M. Keder, Sarah C. M. Roberts

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Abstract

Background

In February 2011, an Ohio law took effect mandating use of the United States Food and Drug Administration (FDA)-approved protocol for mifepristone, which is used with misoprostol for medication abortion. Other state legislatures have passed or enacted similar laws requiring use of the FDA-approved protocol for medication abortion. The objective of this study is to examine the association of this legal change with medication abortion outcomes and utilization.

Methods and Findings

We used a retrospective cohort design, comparing outcomes of medication abortion patients in the prelaw period to those in the postlaw period. Sociodemographic and clinical chart data were abstracted from all medication abortion patients from 1 y prior to the law's implementation (January 2010–January 2011) to 3 y post implementation (February 2011–October 2014) at four abortion-providing health care facilities in Ohio. Outcome data were analyzed for all women undergoing abortion at ≤49 d gestation during the study period. The main outcomes were as follows: need for additional intervention following medication abortion (such as aspiration, repeat misoprostol, and blood transfusion), frequency of continuing pregnancy, reports of side effects, and the proportion of abortions that were medication abortions (versus other abortion procedures). Among the 2,783 medication abortions ≤49 d gestation, 4.9% (95% CI: 3.7%–6.2%) in the prelaw and 14.3% (95% CI: 12.6%–16.0%) in the postlaw period required one or more additional interventions. Women obtaining a medication abortion in the postlaw period had three times the odds of requiring an additional intervention as women in the prelaw period (adjusted odds ratio [AOR] = 3.11, 95% CI: 2.27–4.27). In a mixed effects multivariable model that uses facility-months as the unit of analysis to account for lack of independence by site, we found that the law change was associated with a 9.4% (95% CI: 4.0%–18.4%) absolute increase in the rate of requiring an additional intervention. The most common subsequent intervention in both periods was an additional misoprostol dose and was most commonly administered to treat incomplete abortion. The percentage of women requiring two or more follow-up visits increased from 4.2% (95% CI: 3.0%–5.3%) in the prelaw period to 6.2% (95% CI: 5.5%–8.0%) in the postlaw period ($p = 0.003$). Continuing pregnancy was rare (0.3%). Overall, 12.6% of women reported at least one side effect during their medication abortion: 8.4% (95% CI: 6.8%–10.0%) in the prelaw period and 15.6% (95% CI: 13.8%–17.3%) in the postlaw period ($p < 0.001$). Medication abortions fell from 22% (95% CI: 20.8%–22.3%) of all abortions the year before the law went into effect (2010) to 5% (95% CI: 4.8%–5.6%) 3 y after (2014) ($p < 0.001$). The average patient charge increased from US$426 in 2010 to US$551 in 2014, representing a 16% increase after adjusting for inflation in medical prices. The primary limitation to the study is that it was a pre/post-observational study with no control group that was not exposed to the law.

Conclusions

Ohio law required use of a medication abortion protocol that is associated with a greater need for additional intervention, more visits, more side effects, and higher costs for women relative to the evidence-based protocol. There is no evidence that the change in law led to improved abortion outcomes. Indeed, our findings suggest the opposite. In March 2016, the FDA-protocol was updated, so Ohio providers may now legally provide current evidence-based protocols. However, this law is still in place and bans physicians from using mifepristone based on any new developments in clinical research as best practices continue to be updated.

Author Summary

Why Was This Study Done?

- An Ohio law went into effect in 2011 that required abortion providers to use a protocol for medication abortion that had been approved by the US Food and Drug Administration (FDA) in 2000.
- This protocol conflicted with the protocol supported by several international guidelines and used by most abortion providers throughout the US.
- The protocol approved by the FDA in 2000 required a higher, more expensive dose of oral mifepristone, a lower dose of oral misoprostol administered only at a provider's office 48 h later, and limited use up to 49 d after a woman's last menstrual period.
- This research was conducted to explore the abortion outcomes for women who received medication abortion before the 2011 law went into effect compared with outcomes after the law was in place.

What Did the Researchers Do and Find?

ATTACHMENT 8

- Using chart data from 2,783 women who obtained a medication abortion between 2010 and 2014 collected retrospectively from four clinics in Ohio, we examined the proportion of women who received an additional medical intervention to complete the abortion, the experience of side effects, and the rate of medication abortion versus aspiration abortion in Ohio.
- The data showed that women who had medication abortions in the postlaw period were three times as likely to need additional interventions to complete their abortion compared to women in the prelaw period.
- In addition, side effects such as nausea and vomiting were significantly more likely among women after the law change, and there was an 80% decline in medication abortion in Ohio between 2010 and 2014.

What Do These Findings Mean?

- These results suggest that after the 2011 law was enacted, there was a greater need for additional intervention, as well as more visits, more side effects, and higher costs for women compared to before the law.
- Although the FDA updated the medication abortion protocol in March 2016 to match the evidence, this protocol may also become outdated in the future, and health providers in Ohio will be required to provide care based on legislation, rather than the most up-to-date research and evidence-based practice.

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Data Availability: All relevant data are available from UCSF Library Datashare: https://datashare.ucsf.edu/xtf/view?docId=ucsf/ark%2B%3Db7272%3Dq67h1ggv/mrt-datacite.xml. Data have been deidentified and all protected health information removed.

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Abbreviations: ACA, Affordable Care Act; aIRR, adjusted incidence rate ratio; AOR, adjusted odds ratio; API, application programming interface; BMI, body mass index; c-section, cesarean section; ED, emergency department; FDA, United States Food and Drug Administration; GED, general educational development test; IRR, incidence rate ratio; LMP, last menstrual period; UCSF, University of California, San Francisco

Introduction

Medication abortion is a nonsurgical abortion in which two medications are taken to induce an abortion. Mifeprex is the brand name for the drug mifepristone (previously called RU-486). Mifepristone is used in combination with misoprostol for a medication abortion. While it is sometimes called a medical abortion, we use the term medication abortion because it most accurately represents the use of drug-based methods that can terminate pregnancy [1].

The US Food and Drug Administration (FDA) first approved the sale of Mifeprex for medication abortion in September 2000 after a lengthy and charged political process, 54 mo after the application was first submitted [2,3]. The regimen that was approved specified 600 mg of oral mifepristone followed 2 d later by 400 mcg of misoprostol taken orally in a provider's office within the first 49 d after a woman's last menstrual period (Table 1). Research showed this regimen to be very safe [4,5], and at the time the application was first submitted, it had the most published clinical evidence to support it. However, as early as the mid-1980s, investigators were examining modifications to this initially approved regimen [6–9]. A large body of research has developed on alternative dosages of the drugs and timing and route of administration to improve success rates for medication abortion.

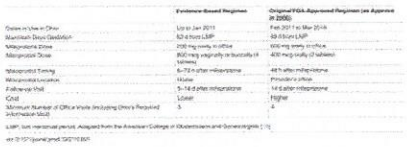

Table 1. Protocol comparison.
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Thus, since 2000 (and even before [2]), abortion providers have been employing alternative regimens for medication abortions, based on the published literature [10–12]. These evidence-based regimens include a lower, less expensive 200 mg dose of oral mifepristone and a higher 800 mcg dose of misoprostol administered buccally or vaginally at home (Table 1). These regimens also allow extending use up to 63 d after a woman's last menstrual period [13,14] and, more recently, up to 70 d, although effectiveness rates decline with increasing gestation [15–17]. At equivalent gestations, these evidence-based regimens have higher effectiveness rates (95%–99%) [18,19] than the regimen approved by the FDA in 2000 (88%–92%) [4,5]. Today, evidence-based regimens are routinely administered throughout the US and the world and are recommended by guidelines of the American College of Obstetricians and Gynecologists, [18] the National Abortion Federation, [20] and the World Health Organization [21].

It is legal and common practice in the US for physicians to prescribe pharmaceuticals off-label; one study estimated that 21% of all US prescriptions are for off-label use [22]. Health care providers prescribing medications off-label have the responsibility to be well informed about the product and to base its use on firm scientific rationale and sound medical evidence [23]. Indeed, it is precisely because of off-label use that abortion providers and researchers have been able to refine the medication abortion regimen to maximize effectiveness and minimize side effects.

Abortion providers in Ohio also used off-label evidence-based regimens for medication abortion. However, in February 2011, an Ohio law took effect mandating that abortion providers use the FDA-approved protocol for medication abortion. The law prohibits off-label use of mifepristone, and thus, at the time it was enacted, it prohibited use of the evidence-based regimens for medication abortion.

In response to the growing body of clinical evidence, the FDA approved a revised label in March 2016 [3,24] to bring the medication abortion protocol in line with the off-label prescribing of mifepristone and misoprostol that had become the standard of care [13,25]. Thus, between February 2011 and March 2016, all abortion providers in the state of Ohio were legally required to use the FDA protocol as approved in 2000.

Other state legislatures passed or enacted similar laws requiring use of the FDA-approved protocol. North Dakota [26] and Texas [27] had such laws in effect. Arizona, Arkansas, and Oklahoma passed similar laws, but they were enjoined by court order. As a result of the FDA decision in March 2016, Ohio's abortion providers immediately reverted back to the protocol that they were using before 2011 [28]. In the three states where the law is in effect, including Ohio, abortion providers can now legally offer patients medication abortion based on the currently available evidence as long as new research does not further improve clinical best practices.

The primary objective of this study was to examine whether the 2011 Ohio law change from an evidence-based regimen (first column in Table 1) to the FDA regimen (as approved in 2000) was associated with the need for additional intervention following medication abortion. Medication abortions are typically considered effective if no additional interventions, such as subsequent aspiration or repeat dose(s) of misoprostol are required to complete the abortion. Additionally, we sought to examine the number of follow-up visits, continuing pregnancy rate, experience of side effects, proportion of medication abortions (versus other abortion procedures), and average patient charges for medication abortion.

Materials and Methods

Data

The University of California, San Francisco (UCSF) Committee on Human Research granted ethical approval for this study (original approval date: 30 June 2014; study number: 14–13766). We compared several medication abortion outcomes and utilization before the law to after the law. Data came from two sources: (1) abstracted patient chart data from four abortion-providing facilities in Ohio and (2) administrative data from the same four facilities.

The UCSF research team provided a full day of on-site training to each of the six data abstractors in the standardized data abstraction protocol, which covered data abstraction methods, basic research principles, ethical conduct of research, and detailed instructions for all data abstraction fields. Each abstractor was given a training manual that they kept on hand as they abstracted data into a standardized electronic form (See S2 Text, "Data Abstraction Protocol"). They abstracted sociodemographic and clinical chart data for all medication abortion patients from 1 y prior to the law's implementation (January 2010–January 2011) to 3 y post implementation (February 2011–October 2014). Each abstractor received an approximate equal balance of pre- and postlaw charts and was instructed and reminded to enter all data and clinical notes as they appeared in the chart and to use notes fields to explain any errors or discrepancies noticed. Outside of the notes fields, abstractors were instructed not to interpret the data, even if they thought there was an error. Abstractors checked for data entry errors by performing regular checks on charts chosen by the UCSF research team at random. Errors were corrected and addressed by more frequent checks and additional training and clarification. All data were abstracted from paper charts and were entered into and immediately saved on an encrypted and HIPAA-compliant electronic platform that was only accessible to the UCSF research team. For each medication abortion, women typically had the following visits: an information/ultrasound visit, a mifepristone visit, a misoprostol visit (in the postlaw period only), and a follow-up visit. Some patients had additional follow-up visits if needed. To ensure independence among observations, if a patient had more than one medication abortion during the study period, only the first was abstracted. Abstraction occurred between September 2014 and April 2015.

Facility-level administrative data were also collected to assess trends in medication abortions over time. We obtained the total number of abortions and total number of medication abortions from all four sites for each year between 2010 and 2014. We also obtained average patient pricing for medication abortion in 2010 and 2014.

Measures

Sociodemographic measures abstracted from the patient charts included age, highest level of education, race/ethnicity, insurance status, zip code, height, weight, and previous births. (Insurance status did not necessarily reflect how the patient paid for the abortion.) Clinical information included dates of care, weeks/days gestation, medications administered, patient-reported side effects, diagnoses in the case of adverse events, and additional care following initiation of the medication abortion provided within the facility, or at an outside facility if reported to the abortion facility. We defined the need for additional intervention as needing repeat misoprostol, repeat mifepristone and misoprostol, aspiration, blood transfusion, surgery, or hospital admission following a medication abortion. Adverse event diagnoses included continuing pregnancy, incomplete or possible incomplete abortion, acute hemorrhage, or infection. Distance travelled to abortion care was calculated based on home zip code (the most detailed location information available) to facility using the "traveltime3" STATA module, which utilizes a Google Maps application programming interface (API) to calculate driving distance. Because gestation is not always recorded at the mifepristone visit if it was recorded at the information visit, we imputed gestation at the mifepristone visit based on the number of days since the information visit for 11% of abortions. Body mass index (BMI) was calculated based on height and weight. Days to first follow-up was calculated based on the mifepristone administration date and the first follow-up visit date. When missing, the number of previous births was computed based on number of previous vaginal births, number of previous cesarean sections (c-sections), number of previous pregnancies, number of previous abortions, and number of previous miscarriages. All other data were analyzed as they appeared in the chart.

Data Analysis

We performed the analysis in four steps. First, we described the characteristics of the study population in the pre- and postlaw periods and compared distributions using chi-squared tests.

Second, we estimated the rate of additional intervention in the pre- and postlaw periods for women who had a medication abortion ≤49 d since their last menstrual period (LMP). To check whether the increases in additional intervention were due to pre-existing time trends, we conducted an interrupted time series analysis. We produced monthly averages of additional intervention rates and constructed a segmented linear regression model including only month, pre/postlaw time period, and a month by pre/postlaw time period interaction to examine trends in rates pre- versus postlaw.

Multivariable logistic regression was used to model the adjusted odds of requiring an additional intervention, controlling for potential confounders and utilizing robust standard error estimation. Because only one abortion per woman was included, there was no need to account for within-woman clustering for multiple abortions. We adjusted for factors that were both available in the charts and that have been suggested or demonstrated in the literature as potentially affecting risk of an unsuccessful medication abortion [17,29,30]. The multivariable models included the following covariates: age, highest level of education, race/ethnicity, insurance status, distance travelled, BMI, gestation at mifepristone administration visit, number of previous births, and site. An abortion was the unit of analysis. All variables in the models were categorical, and many included a "not in chart" category that was retained in the models.

To account for within-clinic similarities and trends, as well as to take into account existing time trends at the site level, we constructed univariate and multivariable mixed-effects autoregressive models with the clinic-month as the unit of analysis, as recommended by a peer reviewer. The rate of additional intervention was calculated for each clinic in each month, and all covariates in the models above were aggregated to the clinic-month level (e.g., % of abortions at clinic 1 in month 1 with private insurance). An autoregressive residual structure was included to account for correlation within sites over time; a range of plausible autoregressive orders were tested. Because of a relatively small number of clusters, we used restricted maximum likelihood and Kenward-Roger denominator degrees-of-freedom adjustment [31].

We conducted the following set of post hoc sensitivity analyses to test the robustness of the finding of increased need for additional intervention in the postlaw period, all of which were recommended by peer reviewers.

1. We replicated the adjusted model for additional intervention with only those cases for which we had complete data for all factors in the model and excluded the "not in chart" category to assess any potential changes in statistical significance.
2. We replicated the adjusted model excluding those women who did not return for a follow-up visit to determine whether the outcomes were influenced by follow-up rates.
3. We conducted a post hoc analysis to test the hypothesis that the lengthened recommended time to follow-up (5–14 d following misoprostol administration prelaw, lengthened to 14 d following the misoprostol visit postlaw) may have increased the additional time "at risk," thereby driving up intervention rates. For these analyses, we excluded the 28% of the sample who did not return for a follow-up visit. We first conducted a t-test to compare average days to first follow-up visit between pre- and postlaw charts, to assess whether days to follow-up actually increased. We then conducted univariate and multivariable Poisson regression analysis for ungrouped data [32] using person-date level data with a log-time offset to determine whether the association between pre/post-law and additional intervention was sensitive to days to follow-up.
4. We explored how the exclusion of second and higher order abortions may have impacted our results by examining data from one clinic site where higher order abortions were inadvertently abstracted but subsequently excluded from the analytic sample. We compared intervention rates among those with only one abortion to those with second and higher order abortions.
5. Finally, to understand the extent of the impact of missing charts on the results, we developed counterfactuals using extreme assumptions about the intervention rate among those missing charts and whether they were from the pre- or postlaw periods and then calculated pre- and postintervention rates based on the two scenarios. We started with an assumption that all missing charts were from the prelaw period and that, in this group, the intervention rate was the upper confidence limit from the postlaw period. Then, we assumed all missing charts were in the post-law period and that, in this group, the intervention rate was the lower confidence limit from the prelaw period. We then calculated overall intervention rates.

Third, we calculated frequencies of adverse events diagnosed, number of follow-up visits, and patient-reported side effects among the total sample. We tabulated adverse events for all women who had an intervention, reported at any follow-up visit, by time period. We also constructed two multivariable models examining the factors associated with no follow-up visits and 2+ follow-up visits. Because the postlaw protocol requires an additional visit for misoprostol administration, it is possible that this provides more opportunity for women to report side effects in the postlaw period. To assess this bias, we calculated side effects in two ways: we estimated the percent of women reporting at least one side effect at any visit and the percent of women reporting at least one side effect at any visit excluding the misoprostol administration visit. As with intervention rates, we conducted a sensitivity analysis as

recommended by a peer reviewer, using univariate and multivariable Poisson regression analysis for ungrouped data with a log-time offset to determine whether the association between pre/post-law and reported side effects was impacted by the number of days to follow-up. Multivariable models for both number of follow-up visits and side effects controlled for age, highest level of education, race/ethnicity, insurance status, distance travelled, BMI, gestation at mifepristone administration visit, previous births, and site. All analyses described above were limited to ≤49 d from LMP because medication abortions were not performed after 49 d in the postlaw period and because of the known association between weeks gestation and need for additional intervention [17,19].

Fourth, we used facility-level administrative data to calculate the proportion of abortions that were medication abortions versus other abortion procedures at all facilities as well as the mean charge for patients in US dollars for medication abortion in 2010 and 2014. The mean charge was weighted by the total number of medication abortion patients at each facility in each year. Statistical significance was set at $p < 0.05$. All statistical analyses were conducted using Stata version 13.1.

Our original primary hypothesis was that among women at ≤49 d gestation, the odds of additional intervention would increase after the implementation of the FDA regimen, adjusting for potential confounders (See S1 Text, "Preliminary Analysis Plan"). We planned to use multivariable logistic regression to assess this question and, after examining the data, added the interrupted time series analysis. We also planned to look for change in the sociodemographic characteristics of patients and in the overall use of medication abortion. We also conducted several analyses that we had planned to explore but did not have a priori stated hypotheses. These included pre- versus postlaw comparisons of the prevalence of adverse events diagnosed, side effects, and facility-level mean charges for medication abortion. We did not plan to conduct all of the post hoc sensitivity analyses, but many were suggested by our peer reviewers, and we believed they were important to test the robustness of our results.

Results

We requested data on all medication abortions in the study period for a total of 5,095 charts: 2,783 prelaw and 2,312 postlaw. Of these, 930 abstracted charts (18%) were excluded because they did not meet inclusion criteria: they were second or higher order abortions for the same patient during the study period, misidentified patients (aspiration rather than medication abortions), treatment for early pregnancy loss/miscarriage, and cases in which the woman did not have an abortion at that facility.

Additionally, 352 charts were missing (6.9%), most often because the chart was transferred to an off-site warehouse or another health center when a patient received care for a separate reason and the chart subsequently could not be located. We could not determine whether missing charts were from pre- or postlaw periods. An additional 17 charts were dropped from the analysis because they had either entire pages or key dates missing. Among the 3,796 available charts, we included 73% (n = 2,783, 1,156 prelaw and 1,627 postlaw) in this analysis because they were ≤49 d from LMP. Most abortions excluded from the prelaw period were excluded because they were >49 d from LMP (medication abortion could not be performed at these gestations in the postlaw period), resulting in a higher number of excluded abortions in the prelaw period than in the postlaw period. We restricted our analyses to ≤49 d from LMP to make the pre- and postlaw samples as comparable as possible given the known association between gestational age and medication abortion effectiveness and outcomes. This sample size afforded us statistical power of 87% to detect a difference of three percentage points or greater in abortion intervention rates between the pre- and postlaw periods, based on an expected rate of 5.2% in the prelaw period [29].

The characteristics of the sample population are listed in Table 2. Over one-third (34%) of the sample were ages 20–24, one-fourth (25%) were ages 25–29, and another one-fourth (25%) were ages 30–39. Most women had a high school diploma or equivalent (37%) or some college (29%). The majority of the women were white (70%). Almost one-third (31%) of the women had private health insurance, and 17% had Medicaid/Medicare. Another 27% did not have health insurance. Most women (86%) travelled <50 mi for abortion care, although 13% travelled 50 mi or more. Half of the women (50%) were healthy weight, and the majority (59%) were at gestations of 42–49 d (6–7 wk). The largest proportion of the women (52%) had not previously given birth. There were significant differences between the prelaw and postlaw populations in this sample by education, race, insurance status, gestation, and number of previous births. The pre- and postlaw populations did not differ significantly by age, distance travelled, BMI, or site visited.

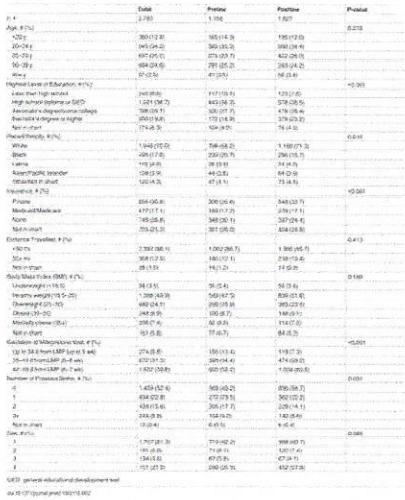

Table 2. Characteristics of the pre- and postlaw populations ≤49 d from LMP at four Ohio abortion-providing facilities, 2010–2014.