IN THE COURT OF COMMON PLEAS
FOR HAMILTON COUNTY, OHIO

PLANNED PARENTHOOD SOUTHWEST OHIO REGION, *et al.*,	:	Case No. A 2101148
Plaintiffs,	:	Judge Alison Hatheway
v.	:	
OHIO DEPARTMENT OF HEALTH, *et al.*,	:	
Defendants.	:	

STATE DEFENDANTS' MOTION FOR A STAY OF PROCEEDINGS

Defendants The Ohio Department of Health ("ODH"), Director Bruce Vanderhoff, Kim Rothermel, Harish Kakarala, Erin Keels, and Candy Sue Rinehart (collectively, "the State"), respectively move this Court to stay proceedings in the above captioned case pending the outcome of *FDA v. Alliance for Hippocratic Medicine*, ___U.S.___, 144 S.Ct. 537, 217 L.Ed.2d 285 (2023). As explained in the attached memorandum in support, the outcome of that case will directly impact several of the claims made by Plaintiffs in this litigation, so a stay will promote efficiency and judicial economy. The State submits the following memorandum in support of this motion. The State sought Plaintiffs' position on this motion, and Plaintiffs oppose a stay in this case. In the interests of judicial economy and to conserve the resources of all parties to this action, the State respectfully requests this Court grant its motion.

Respectfully submitted,

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MEMORANDUM IN SUPPORT

The State respectfully requests that the Court stay this case pending a decision on the merits in *Food and Drug Administration v. Alliance for Hippocratic Medicine*, No. 23-235 (Dec. 13, 2023). A stay would promote efficiency and conserve the resources of the parties and the Court, as there are substantially overlapping legal issues between the instant case and the pending action before the U.S. Supreme Court regarding the rules and regulations for the prescription and administration of Mifepristone.

BACKGROUND

Mifepristone, a drug used in medication abortions, was approved by the FDA in 2000 under an accelerated approval process within a category of drugs used to treat serious or life-threatening illnesses. *Alliance for Hippocratic Med. v. FDA,* 5th Cir. No. 23-10362, 2023 U.S. App. LEXIS 8898, at *8 (Apr. 12, 2023). The drug was sold under the brand name Mifeprex. *Id.* The FDA concluded that post-approval restrictions were required to ensure the safe prescription and use of the drug, which included: "(1) limiting the drug to pregnant women and girls for use through 49 days gestation; (2) requiring three in-person office visits, the first to administer mifepristone, the second to administer misoprostol, and the third to assess any complications and ensure there were no fetal remains in the womb; (3) requiring the supervision of a qualified physician; and (4) requiring the reporting of all adverse events from the drugs." *Id.*, citing FDA Add. 181-91. Through a change in the federal law, the FDA approved a REMS (Risk Evaluation and Mitigation Strategy) for Mifepristone in 2011 that contained the same requirements.

Then in March of 2016, the FDA weakened those original safety restrictions by "(1) increasing the maximum gestational age at which a woman can use the drug from 49 to 70 days; (2)

reducing the number of required in-person office visits from three to one; (3) allowing non-doctors to prescribe and administer the chemical abortions drugs; and (4) eliminating the requirement for prescribers to report non-fatal adverse events from chemical abortion." *Id.* at *9, citing FDA Add. 777-802. But it wasn't until April of 2021 that the FDA announced that it would not enforce the in-person dispensing requirement due to the COVID 19 pandemic and made this change permanent in the final REMS for Mifeprex which were issued in January of 2023. *Id.* at *10, citing FDA Add. 842 (concluding that "the in-person dispensing requirement is no longer necessary."); *see also* REMS Single Shared System for Mifepristone 200 mg (Jan. 2023), https://perma.cc/MJT5-35LF (the "2023 Mail-Order Decision").

A doctor's group filed suit challenging both the original approval of the drug in 2000 and the changes made to the REMS starting in 2016 and the non-enforcement decision of 2021. *See Alliance for Hippocratic Medicine v. United States FDA,* 668 F. Supp. 3d 507 (N.D.Tex.2023). The district court entered an order "staying the effective date of the 2000 Approval" and each of the subsequent changes to the REMS, but "stayed its own order for seven days to allow the defendants time to appeal." *Alliance for Hippocratic Med. v. FDA,* 5th Cir. No. 23-10362, 2023 U.S. App. LEXIS 8898, at *12 (Apr. 12, 2023) On appeal, the Fifth Circuit held that the challenge to the original 2000 approval was untimely but affirmed the district court's order as to the REMS, allowing the continued use of the drug but under the safety restrictions in effect prior to 2016. *Id.* The case was granted certiorari by the United States Supreme Court, and oral argument was heard on March 26, 2024. *See FDA v. Alliance for Hippocratic Medicine*, No. 23-235 (Dec. 13, 2023). The Court has yet to announce its decision in the case.

ARGUMENT

Courts retain the power to stay proceedings pending any potentially dispositive developments. *Phillips v. Conrad*, 1st Dist. Hamilton No. C-020302, 2002-Ohio-7080, ¶ 22, citing *State v. Hochhausler*, 76 Ohio St.3d 455, 466, 1996 Ohio 374, 668 N.E.2d 457 (1996). Factors to consider when granting a stay include "the efficiency and judicial economy that results from staying matters pending resolution of potentially dispositive developments." *Id.* "The determination of whether to issue a stay of proceedings generally rests within the court's discretion and will not be disturbed absent a showing of an abuse of discretion." *State ex rel. Charvat v. Frye*, 114 Ohio St.3d 76, 2007-Ohio-2882, 868 N.E.2d 270, ¶ 16 (internal quotation omitted).

Plaintiffs' Amended Complaint challenges three categories of law that they say place restrictions on medication abortion: the "Telemedicine Ban" found in R.C. 2919.124; the "APCs Ban" which are a combination of several laws—R.C. 2317.56(B), 2919.11, 2919.123, 4723.44(B)(6), 4723.50(B)(1), 4723.151(C), 4730.02(E), 4730.03(F), 4730.39(B)(2), 4730.42(A)(1); Ohio Adm.Code 4723-9-10(K), 4730-2-07(E)—that they say "together restrict qualified and skilled advanced practice clinicians ("APCs") from providing medication abortion;" and the "Evidence-Based Use Ban" found in R.C. 2919.123 which requires abortion providers to prescribe mifepristone in accordance with the FDA's label for the drug. Each of these claims will be impacted, if not controlled by, the Supreme Court's decision in *Food and Drug Administration v. Alliance for Hippocratic Medicine*, No. 23-235 (Dec. 13, 2023).

The Supreme Court will consider the following questions in that case:

1. Whether respondents have Article III standing to challenge FDA's 2016 and 2021 actions.
2. Whether FDA's 2016 and 2021 actions were arbitrary and capricious.

3. Whether the district court properly granted preliminary relief.

The Supreme Court's decision on the propriety of the changes to the REMS for Mifespristone—REMS that were in place to ensure the safety of women taking the drug at almost all times since Mifepristone was first approved for use in the United States—would have a significant impact on the outcome of this case. For one thing, if the Court holds that the changes to the REMS in 2016 and 2021 were arbitrary and capricious, as the Fifth Circuit did, Plaintiffs will have a difficult time proving that they have a likelihood of success on the merits to obtain a preliminary injunction or to succeed on the merits of their claims.

That is because that Court has long required that final rules "articulate a satisfactory explanation for [the] action including a rational connection between the facts found and the choice made." *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, ___U.S.___, 140 S.Ct. 2367, 2383, 207 L.Ed.2d 819 (2020). "This requirement allows courts to assess whether the agency has promulgated an arbitrary and capricious rule by 'entirely fail[ing] to consider an important aspect of the problem [or] offer[ing] an explanation for its decision that runs counter to the evidence before [it].'" *Id.,* quoting *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U. S. 29, 43, 103 S. Ct. 2856, 77 L. Ed. 2d 443 (1983). If the Court invalidates the 2016 and 2021 REMS changes as arbitrary and capricious, it would be because it determined that the FDA made those changes by ignoring a clear problem when rendering its decision or over evidence that counseled against it. In short, it would support the General Assembly's belief that requirements for a dangerous drug are necessary to protect the health and safety of women receiving abortion and cast doubt on Plaintiffs' arguments that these requirements are unnecessary.

Indeed, such a determination would significantly undermine Plaintiffs' assertion that Ohio's requirement that mifepristone be prescribed "in accordance with the FDA drug approval letter" is not supported by sufficient evidence to warrant its continued legality. S*ee Cordray v. Planned Parenthood Cincinnati Region*, 122 Ohio St.3d 361, 2009-Ohio-2972, 911 N.E.2d 871, ¶ 32. Under the drug approval letter and 2011 REMS, Mifespristone can only be dispensed in the presence of the prescribing physician and only for the purpose of ending an early pregnancy up until 49 days gestation. *See* Exhibit A, Mifeprex Risk Evaluation and Mitigation Strategy (2011). The drug approval letter's requirements were codified into the 2011 REMS without substantive change even after the drug had been on the market and in use in the United States for 11 years. Those same requirements remained in force until 2016, and even then, the in-person requirements and 70-day gestational limit remained.

Even under the current REMS, the FDA has not approved Mifepristone for use to terminate an early pregnancy beyond 70 days of gestation. *See* Exhibit B, Mifepristone Risk Evaluation and Mitigation Strategy (2021). Ohio Supreme Court underscored the fact that "the FDA labeling text referred to in the drug approval letter states, "Mifepristone is indicated for use in the termination of pregnancy (through 49 days' pregnancy) and has *no other approved indication for use during pregnancy*." *Cordray v. Planned Parenthood Cincinnati Region*, 122 Ohio St.3d 361, 2009-Ohio-2972, 911 N.E.2d 871, ¶ 15 (emphasis in original.). Despite Mifepristone's more than 20 years on the market, and after having significantly relaxed many of the program's long-existing requirements, the FDA is nonetheless unwilling to approve the drug for abortions beyond 70 days gestation.

Moreover, under the 2011 REMS "[t]o become specially certified, each prescriber must complete and fax to the MIFEPREX distributor the one-time Prescriber's Agreement, agreeing that they meet the qualifications and *will follow the guidelines outlined in the Prescriber's Agreement*." Ex. A at 1., The Prescriber agreement both indicates that the drug is indicated for abortion up to 49 days gestation and that federal law requires the "Mifeprex must be provided by or under the supervision of a physician." *Id.* at 7. And the patient is required to sign an attestation that she is not more the 49 days pregnant, and that she "understand[s] that I will take Mifeprex in my provider's office (Day 1)." *Id.* at 9. Her physician must also sign the form to attest that "[t]he patient signed the PATIENT AGREEMENT in my presence after I counseled her and answered all her questions. I have given her the MEDICATION GUIDE for mifepristone." *Id.*

Critically, the REMS program exists because, despite Plaintiffs assertions of unquestioned safety, Mifepristone is of a class of drugs that pose serious risks to those who take it. The 2021 REMS make this plain: "The goal of the REMS for mifepristone is to mitigate the risk of serious complications associated with mifepristone." Exhibit B at 1. The Supreme Court's decision will directly impact the outcome of both the preliminary and permanent relief at issue in this case. Of course, if this Court does not stay these proceedings, and renders a decision on the preliminary injunction motion, a decision in the federal case may force the parties and this Court to relitigate that motion, at the very least. Therefore, it is in the interest of judicial economy and efficiency of all involved that the Court stay this case pending the Supreme Court's decision.

CONCLUSION

For all these reasons, the State respectfully request that the Court grant the State's Motion for a Stay of Proceedings.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that the foregoing was filed electronically and served upon the following via electronic mail this 5th day of June, 2024:

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**Motion for pro hac vice forthcoming*

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Exhibit A: Mifeprex Risk Evaluation and Mitigation Strategy (2011)

NDA 20-687 MIFEPREX (mifepristone) Tablets, 200 mg

Danco Laboratories, LLC PO Box 4816
New York, NY 10185

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOALS

A. To provide information to patients about the benefits and risks of MIFEPREX before they make a decision whether to take the drug.

B. To minimize the risk of serious complications by requiring prescribers to certify that they are qualified to prescribe MIFEPREX and are able to assure patient access to appropriate medical facilities to manage any complications.

II. REMS ELEMENTS

A. Medication Guide

1. A Medication Guide will be dispensed with each MIFEPREX prescription in accordance with 21 CFR 208.24.

2. Please see the appended Medication Guide.

B. Elements to Assure Safe Use

1. Healthcare providers who prescribe MIFEPREX will be specially certified.

   Danco will ensure that healthcare providers who prescribe MIFEPREX are specially certified.

   a. To become specially certified, each prescriber must complete and fax to the MIFEPREX distributor the one-time Prescriber's Agreement, agreeing that they meet the qualifications and will follow the guidelines outlined in the Prescriber's Agreement.

   b. The following materials are part of the REMS and are appended:

      i. Prescriber's Agreement.

      ii. Patient Agreement.

2. MIFEPREX will be dispensed only in certain health care settings, specifically clinics, medical offices, and hospitals.

   Danco will ensure that MIFEPREX will only be available to be dispensed in a clinic, medical office, or hospital, by or under the supervision of a specially certified prescriber. MIFEPREX will not be distributed to or dispensed through retail pharmacies.

3. MIFEPREX will only be dispensed to patients with documentation of safe use conditions.

   Danco will ensure that MIFEPREX will only be dispensed to patients with documentation of the following safe use conditions:

   a. The patient has completed and signed the Patient Agreement, and the Patient Agreement has been placed in the patient's medical record.

   b. The patient has been provided copies of the signed Patient Agreement and the Medication Guide.

C. Implementation System

The Implementation System will include the following:

1. Distributors who distribute MIFEPREX will be certified. To become certified, distributors must agree to:

   a. Ship drug only to site locations identified by specially certified prescribers in signed Prescriber's Agreements, and maintain secure and confidential records of shipments.

   b. Follow all distribution guidelines, including those for storage, tracking package serial numbers, proof of delivery, and controlled returns.

2. Danco will assess the performance of the certified distributors with regard to the following:

   a. Whether a secure, confidential and controlled distribution system is being maintained with regard to storage, handling, shipping, and return of MIFEPREX.

   b. Whether MIFEPREX is being shipped only to site locations identified by specially certified prescribers in the signed Prescriber's Agreement and only available to be dispensed to patients in a clinic, medical office, or hospital by or under the supervision of a specially certified prescriber.

3. If Danco determines the distributors are not complying with these requirements, Danco will take steps to improve their compliance.

D. Timetable for Submission of Assessments

Danco will submit REMS assessments to the FDA one year from the date of the approval of the REMS and every three years thereafter. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the assessment reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Danco will submit each assessment so that it will be received by the FDA on or before the due date.

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

they understand that you are having a medical abortion with Mifeprex.

What to do if you are still pregnant after Mifeprex with misoprostol treatment. If you are still pregnant, your provider will talk with you about the other choices you have, including a surgical procedure to end your pregnancy. There is a chance that there may be birth defects if the pregnancy is not ended.

Talk with your provider. Before you take Mifeprex, you should read this MEDICATION GUIDE and sign a statement (PATIENT AGREEMENT). You and your provider should discuss the benefits and risks of your using Mifeprex.

Who should not take Mifeprex?

Some women should not take Mifeprex. Do not take it if:

- It has been more than 49 days (7 weeks) since your last menstrual period began.
- You have an IUD. It must be taken out before you take Mifeprex.
- Your provider has told you that you have a pregnancy outside the uterus (ectopic pregnancy).
- You have problems with your adrenal glands (chronic adrenal failure).
- You take a medicine to thin your blood.
- You have a bleeding problem.
- You take certain steroid medicines.
- You cannot return for the next 2 visits.
- You cannot easily get emergency medical help in the 2 weeks after you take Mifeprex.
- You are allergic to mifepristone, misoprostol, or medicines that contain misoprostol, such as Cytotec or Arthrotec.

Tell your provider about all your medical conditions to find out if you can take Mifeprex. Also, tell your provider if you smoke at least 10 cigarettes a day.

How should I take Mifeprex?

- **Day 1 at your provider's office:**
  - Read this MEDICATION GUIDE.
  - Discuss the benefits and risks of using Mifeprex to end your pregnancy.
  - If you decide Mifeprex is right for you, sign the PATIENT AGREEMENT.
  - After getting a physical exam, swallow 3 tablets of Mifeprex.
- **Day 3 at your provider's office:**
  - If you are still pregnant, take 2 misoprostol tablets.
  - Misoprostol may cause cramps, nausea, diarrhea, and other symptoms. Your provider may send you home with medicines for these symptoms.
- **About Day 14 at your provider's office:**
  - This follow-up visit is very important. You must return to the provider about 14 days after you have taken Mifeprex to be sure you are well and that you are not pregnant.
  - Your provider will check whether your pregnancy has completely ended. If it has not ended, there is a chance that there may be birth defects. If you are still pregnant, your provider will talk with you about the other choices you have, including a surgical procedure to end your pregnancy.

What should I avoid while taking Mifeprex and misoprostol?

Do not take any other prescription or non-prescription medicines (including herbal medicines or supplements) at any time during the treatment period without first asking your provider about them because they may interfere with the treatment. Ask your provider about what medicines you can take for pain.

If you are breastfeeding at the time you take Mifeprex and misoprostol, discuss with your provider if you should stop breastfeeding for a few days.

What are the possible and reasonably likely side effects of Mifeprex?

Cramping and bleeding are expected with this treatment. Usually, these symptoms mean that the treatment is working. But sometimes you can get cramping and bleeding and still be pregnant. This is why you must return to your provider on Day 3 and about Day 14. See "How should I take Mifeprex?" for more information on when to return to your provider. If you are not already bleeding after taking Mifeprex, you probably will begin to bleed once you take misoprostol, the medicine you take on Day 3. Bleeding or spotting can be expected for an average of 9–16 days and may last for up to 30 days. Your bleeding may be similar to, or greater than, a normal heavy period. You may see blood clots and tissue. This is an expected part of ending the pregnancy.

Other common symptoms of treatment include diarrhea, nausea, vomiting, headache, dizziness, back pain, and tiredness. These side effects lessen after Day 3 and are usually gone by Day 14. Your provider will tell you how to manage any pain or other side effects.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

When should I begin birth control?

You can become pregnant again right after your pregnancy ends. If you do not want to become pregnant again, start using birth control as soon as your pregnancy ends or before you start having sexual intercourse again.

* * *

Medicines are sometimes prescribed for purposes other than those listed in a MEDICATION GUIDE. For more information, ask your provider for the information about Mifeprex that is written for health care professionals. Ask your provider if you have any questions.

This MEDICATION GUIDE has been approved by the U.S. Food and Drug Administration.

Rev 3: 4/22/09
*Mifeprex is a registered trademark of Danco Laboratories, LLC.

M I F E P R E X®
(Mifepristone) Tablets, 200 mg

PRESCRIBER'S AGREEMENT

We are pleased that you wish to become a provider of Mifeprex* (Mifepristone) Tablets, 200 mg, which is indicated for the medical termination of intrauterine pregnancy through 49 days from the first day of the patient's last menstrual period (see full prescribing information). Prescribing Information, Mifeprex Medication Guides and PATIENT AGREEMENT forms will be provided together with your order of Mifeprex.

Prior to establishing your account and receiving your first order, you must sign and return this letter to the distributor, indicating that you have met the qualifications outlined below and will observe the guidelines outlined below. If you oversee more than one office facility, you will need to list each facility on your order form prior to shipping the first order.

By signing the reverse side, you acknowledge receipt of the PRESCRIBER'S AGREEMENT and agree that you meet these qualifications and that you will follow these guidelines for use. You also understand that if you do not follow these guidelines, the distributor may discontinue distribution of the drug to you.

Under Federal law, Mifeprex must be provided by or under the supervision of a physician who meets the following qualifications:

- Ability to assess the duration of pregnancy accurately.

- Ability to diagnose ectopic pregnancies.

- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.

- Has read and understood the prescribing information of Mifeprex. The prescribing information is attached to this letter, and is also available by calling our toll free number, 1-877-4 Early Option (1-877-432-7596), or logging on to our website, www.earlyoptionpill.com.

In addition to these qualifications, you must provide Mifeprex in a manner consistent with the following guidelines.

- Under Federal law, each patient must be provided with a Medication Guide. You must fully explain the procedure to each patient, provide her with a copy of the Medication Guide and PATIENT AGREEMENT, give her an opportunity to read and discuss them, obtain her signature on the PATIENT AGREEMENT, and sign it yourself.

- The patient's follow-up visit at approximately 14 days is very important to confirm that a complete termination of pregnancy has occurred and that there have been no complications. You must notify Danco Laboratories in writing as discussed in the Package Insert under the heading DOSAGE AND ADMINISTRATION in the event of an on-going pregnancy which is not terminated subsequent to the conclusion of the treatment procedure.

- While serious adverse events associated with the use of Mifeprex are rare, you must report any hospitalization, transfusion or other serious event to Danco Laboratories, identifying the patient solely by package serial number to ensure patient confidentiality.

- Each package of Mifeprex has a serial number. As part of maintaining complete records for each patient, you must record this identification number in each patient's record.

Danco Laboratories, LLC
P.O. Box 4816
New York, NY 10185
1-877-4 Early Option (1-877-432-7596)
www.earlyoptionpill.com

ACCOUNT SETUP FORM

MIFEPREX™ (Mifepristone) Tablets, 200 mg; NDC 64875-001-03

To set up your account:

1

Read the Prescriber's Agreement on the back of this Account Setup Form.

2

Complete and sign this form.

3

Fax the completed Account Setup Form to the Danco distributor at 1-866-227-3343. Your account information will be kept strictly confidential.

4

The distributor will call to finalize your account setup and take your initial order.

5

Subsequent orders may be phoned in and are usually shipped within 24 hours.

6

Unopened, unused product may be returned for a refund or exchange up to a year after the expiration date.

Billing information

Bill to Name _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Attention _____

Shipping information (❑ Check if same as above)

Ship to Name _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Attention _____

Additional site locations

I will also be prescribing Mifeprex* at these additional locations:

Name _____ Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Name _____ Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

(Any additional sites may be listed on an attached sheet of paper.)

Request additional materials

❑ Medication Guides ❑ Patient Agreements

❑ State Abortion Guidelines ❑ Patient Brochures

Establishing your account (required only with first order)

Each facility purchasing Mifeprex must be included on this form (see additional site locations box above) before the distributor can ship the product. Please read the Prescriber's Agreement on the reverse of this form and sign below.

By signing below, you acknowledge receipt of the Prescriber's Agreement and agree that you meet these qualifications and that you will follow these guidelines for use.

Print Name _____ Signature _____

Medical License # _____ Date _____

Fax this completed Account Setup Form to the authorized distributor. Fax: 1-866-227-3343

Please fax any questions to the above number or call 1-800-848-6142.

*Mifeprex is a trademark of Danco Laboratories, LLC.

MIFEPREX™
(Mifepristone) Tablets, 200 mg

Mifeprex® (Mifepristone) Tablets, 200 mg

PATIENT AGREEMENT

Mifeprex* (mifepristone) Tablets

1. I have read the attached MEDICATION GUIDE for using Mifeprex and misoprostol to end my pregnancy.
2. I discussed the information with my health care provider (provider).
3. My provider answered all my questions and told me about the risks and benefits of using Mifeprex and misoprostol to end my pregnancy.
4. I believe I am no more than 49 days (7 weeks) pregnant.
5. I understand that I will take Mifeprex in my provider's office (Day 1).
6. I understand that I will take misoprostol in my provider's office two days after I take Mifeprex (Day 3).
7. My provider gave me advice on what to do if I develop heavy bleeding or need emergency care due to the treatment.
8. Bleeding and cramping do not mean that my pregnancy has ended. Therefore, I must return to my provider's office in about 2 weeks (about Day 14) after I take Mifeprex to be sure that my pregnancy has ended and that I am well.
9. I know that, in some cases, the treatment will not work. This happens in about 5 to 8 women out of 100 who use this treatment.
10. I understand that if my pregnancy continues after any part of the treatment, there is a chance that there may be birth defects. If my pregnancy continues after treatment with Mifeprex and misoprostol, I will talk with my provider about my choices, which may include a surgical procedure to end my pregnancy.
11. I understand that if the medicines I take do not end my pregnancy and I decide to have a surgical procedure to end my pregnancy, or if I need a surgical procedure to stop bleeding, my provider will do the procedure or refer me to another provider who will. I have that provider's name, address and phone number.
12. I have my provider's name, address and phone number and know that I can call if I have any questions or concerns.
13. I have decided to take Mifeprex and misoprostol to end my pregnancy and will follow my provider's advice about when to take each drug and what to do in an emergency.
14. I will do the following:
    - contact my provider right away if in the days after treatment I have a fever of 100.4°F or higher that lasts for more than 4 hours or severe abdominal pain.
    - contact my provider right away if I have heavy bleeding (soaking through two thick full-size sanitary pads per hour for two consecutive hours).
    - contact my provider right away if I have abdominal pain or discomfort, or I am "feeling sick", including weakness, nausea, vomiting or diarrhea, more than 24 hours after taking misoprostol.
    - take the MEDICATION GUIDE with me when I visit an emergency room or a provider who did not give me Mifeprex, so that they will understand that I am having a medical abortion with Mifeprex.
    - return to my provider's office in 2 days (Day 3) to check if my pregnancy has ended. My provider will give me misoprostol if I am still pregnant.
    - return to my provider's office about 14 days after beginning treatment to be sure that my pregnancy has ended and that I am well.

Patient Signature: _____

Patient Name (print): _____

Date: _____

The patient signed the PATIENT AGREEMENT in my presence after I counseled her and answered all her questions. I have given her the MEDICATION GUIDE for mifepristone.

Provider's Signature: _____

Name of Provider (print): _____

Date: _____

After the patient and the provider sign this PATIENT AGREEMENT, give 1 copy to the patient before she leaves the office and put 1 copy in her medical record. Give a copy of the MEDICATION GUIDE to the patient.

Rev 2: 7/19/05
*Mifeprex is a registered trademark of Danco Laboratories, LLC.

Exhibit B: Mifepristone Risk Evaluation and Mitigation Strategy (2021)

Initial Shared System REMS approval: 04/2019
Most Recent Modification: 05/2021

Mifepristone Tablets, 200 mg

Progestin Antagonist

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

SINGLE SHARED SYSTEM FOR MIFEPRISTONE 200MG

I. GOAL

The goal of the REMS for mifepristone is to mitigate the risk of serious complications associated with mifepristone by:

a) Requiring healthcare providers who prescribe mifepristone to be certified in the Mifepristone REMS Program.

b) Ensuring that mifepristone is only dispensed in certain healthcare settings by or under the supervision of a certified prescriber.

c) Informing patients about the risk of serious complications associated with mifepristone.

II. REMS ELEMENTS

A. Elements to Assure Safe Use

1. Healthcare providers who prescribe mifepristone must be specially certified.
   a. To become specially certified to prescribe mifepristone, healthcare providers must:
      i. Review the Prescribing Information for mifepristone.
      ii. Complete a *Prescriber Agreement Form*. By signing a *Prescriber Agreement Form*, prescribers agree that:
         1) They have the following qualifications:
            a) Ability to assess the duration of pregnancy accurately
            b) Ability to diagnose ectopic pregnancies
            c) Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
         2) They will follow the guidelines for use of mifepristone (see b.i-v below).
   b. As a condition of certification, healthcare providers must follow the guidelines for use of mifepristone described below:
      i. Review the *Patient Agreement Form* with the patient and fully explain the risks of the mifepristone treatment regimen. Answer any questions the patient may have prior to receiving mifepristone.

ii. Sign the *Patient Agreement Form* and obtain the Patient's signature on the *Form*

iii. Provide the patient with a copy of the *Patient Agreement Form* and Medication Guide.

iv. Place the signed *Patient Agreement Form* in the patient's medical record.

v. Record the serial number from each package of mifepristone in each patient's record.

vi. Report any deaths to the Mifepristone Sponsor that provided the mifepristone, identifying the patient by a non- identifiable reference and the serial number from each package of mifepristone.

c. Mifepristone Sponsors must:

i. Ensure that healthcare providers who prescribe their mifepristone are specially certified in accordance with the requirements described above and de-certify healthcare providers who do not maintain compliance with certification requirements

ii. Provide the Prescribing Information and their *Prescriber Agreement Form* to healthcare providers who inquire about how to become certified.

The following materials are part of the REMS and are appended:

- *Prescriber Agreement Form for Danco Laboratories, LLC*
- *Prescriber Agreement Form for GenBioPro, Inc.*
- *Patient Agreement Form*

2. Mifepristone must be dispensed to patients only in certain healthcare settings, specifically clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber.

a. Mifepristone Sponsors must:

i. Ensure that their mifepristone is available to be dispensed to patients only in clinics, medical offices and hospitals by or under the supervision of a certified prescriber.

ii. Ensure that their mifepristone is not distributed to or dispensed through retail pharmacies or other settings not described above.

3. Mifepristone must be dispensed to patients with evidence or other documentation of safe use conditions.

a. The patient must sign a *Patient Agreement Form* indicating that the patient has:

i. Received, read and been provided a copy of the *Patient Agreement Form*.

ii. Received counseling from the prescriber regarding the risk of serious complications associated with mifepristone.

B. Implementation System

1. Mifepristone Sponsors must ensure that their mifepristone is only distributed to clinics, medical offices and hospitals by or under the supervision of a certified prescriber by:

a. Ensuring that distributors who distribute their mifepristone comply with the program requirements for distributors. The distributors must:

i. Put processes and procedures in place to:

   a. Complete the healthcare provider certification process upon receipt of a Prescriber Agreement Form.

   b. Notify healthcare providers when they have been certified by the Mifepristone REMS Program.

   c. Ship mifepristone only to clinics, medical offices, and hospitals identified by certified prescribers in their signed *Prescriber Agreement Form*.

   d. Not ship mifepristone to prescribers who become de-certified from the Mifepristone REMS Program.

   e. Provide the Prescribing Information and their Prescriber Agreement Form to healthcare providers who (1) attempt to order mifepristone and are not yet certified, or (2) inquire about how to become certified.

ii. Put processes and procedures in place to maintain a distribution system that is secure, confidential and follows all processes and procedures, including those for storage, handling, shipping, tracking package serial numbers, proof of delivery and controlled returns of mifepristone.

iii. Train all relevant staff on the Mifepristone REMS Program requirements.

iv. Comply with audits by Mifepristone Sponsors, FDA or a third party acting on behalf of Mifepristone Sponsors or FDA to ensure that all processes and procedures are in place and are being followed for the Mifepristone REMS Program. In addition, distributors must maintain appropriate documentation and make it available for audits.

b. Ensuring that distributors maintain secure and confidential distribution records of all shipments of mifepristone.

2. Mifepristone Sponsors must monitor their distribution data to ensure compliance with the REMS Program.

3. Mifepristone Sponsors must audit their new distributors within 90 calendar days after the distributor is authorized to ensure that all processes and procedures are in place and functioning to support the requirements of the Mifepristone REMS Program. Mifepristone Sponsors will take steps to address their distributor compliance if noncompliance is identified.

4. Mifepristone Sponsors must take reasonable steps to improve implementation of and compliance with the requirements of the Mifepristone REMS Program based on monitoring and assessment of the Mifepristone REMS Program.

5. Mifepristone Sponsors must report to FDA any death associated with mifepristone whether or not considered drug-related, as soon as possible but no later than 15 calendar days from the initial receipt of the information by the applicant. This requirement does not affect the applicants other reporting and follow-up requirements under FDA regulations.

C. Timetable for Submission of Assessments

The NDA Sponsor must submit REMS assessments to FDA one year from the date of the initial approval of the REMS (04/11/2019) and every three years thereafter. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. The NDA Sponsor must submit each assessment so that it will be received by the FDA on or before the due date.

Mifeprex* (Mifepristone) Tablets, 200 mg, is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. Please see Prescribing Information and Medication Guide for complete safety information.

To set up your account to receive Mifeprex, you must:
1. complete, 2. sign, and 3. fax page 2 of this form to the distributor.

If you will be ordering for more than one facility, you will need to list each facility on your order form before the first order will be shipped to the facility.

Prescriber Agreement: By signing page 2 of this form, you agree that you meet the qualifications below and will follow the guidelines for use. You also understand that if you do not follow the guidelines, the distributor may stop shipping Mifeprex to you.

Mifeprex must be provided by or under the supervision of a healthcare provider who prescribes and meets the following qualifications:

- Ability to assess the duration of pregnancy accurately.
- Ability to diagnose ectopic pregnancies.
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Has read and understood the Prescribing Information of Mifeprex. The Prescribing Information is available by calling our toll free number, 1-877-4 Early Option (1-877-432-7596), or logging on to our website, www.earlyoptionpill.com.

In addition to meeting these qualifications, you also agree to follow these guidelines for use:

- Review the Patient Agreement Form with the patient and fully explain the risks of the Mifeprex treatment regimen. Answer any questions the patient may have prior to receiving Mifeprex.
- Sign and obtain the patient's signature on the Patient Agreement Form.
- Provide the patient with a copy of the Patient Agreement Form and the Medication Guide.
- Place the signed Patient Agreement Form in the patient's medical record.
- Record the serial number from each package of Mifeprex in each patient's record.
- Report deaths to Danco Laboratories, identifying the patient by a non-identifiable patient reference and the serial number from each package of Mifeprex.

ACCOUNT SETUP MIFEPREX® (Mifepristone) Tablets, 200 mg; NDC 64875-001-01

TO SET UP YOUR ACCOUNT:

1. Read the Prescriber Agreement on page 1 of this form.
2. Complete and sign this form.
3. Fax this page to the Danco distributor at 1-866-227-3343. Your account information will be kept strictly confidential.
4. The distributor will call to finalize your account setup and take your initial order.
5. Subsequent orders may be phoned or faxed and are usually shipped within 24 hours.

Mifeprex® (Mifepristone) Tablets, 200 mg
THE ORIGINAL EARLY OPTION PILL

BILLING INFORMATION

Bill to Name _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Attention _____

SHIPPING INFORMATION ☐ *Check if same as above*

Ship to Name _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Attention _____

ADDITIONAL SITE LOCATIONS *I will also be prescribing Mifeprex* at these additional locations:*

Name _____ Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Name _____ Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

(Any additional sites may be listed on an attached sheet of paper.)

REQUEST ADDITIONAL MATERIALS

☐ **Medication Guides** ☐ **State Abortion Guides** ☐ **Patient Brochures** ☐ **Patient Agreement Form**

ESTABLISHING YOUR ACCOUNT *(required only with first order)*

Each facility purchasing Mifeprex must be included on this form (*see additional site locations box above*) before the distributor can ship the product to the facility.

By signing below, you agree that you meet the qualifications and that you will follow the guidelines for use on page 1 of the Prescriber Agreement.

Print Name _____ Signature _____

Medical License # _____ Date _____

FAX THIS COMPLETED FORM TO THE AUTHORIZED DISTRIBUTOR. FAX: 1-866-227-3343

Please fax any questions to the above number or call 1-800-848-6142.

*MIFEPREX is a registered trademark of Danco Laboratories, LLC.

Mifepristone Tablets, 200 mg, is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. Please see Prescribing Information and Medication Guide for complete safety information.

To set up your account to receive mifepristone, you must:
1. complete, 2. sign and 3. fax page 2 of this form to the distributor.

If you will be ordering for more than one facility, you will need to list each facility on your order form before the first order will be shipped to the facility.

Prescriber Agreement: By signing page 2 of this form, you agree that you meet the qualifications below and will follow the guidelines for use. You also understand that if you do not follow the guidelines, the distributor may stop shipping mifepristone to you.

Mifepristone must be provided by or under the supervision of a healthcare provider who prescribes and meets the following qualifications:

- Ability to assess the duration of pregnancy accurately.
- Ability to diagnose ectopic pregnancies.
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Has read and understood the Prescribing Information for mifepristone. The Prescribing Information is available by calling our toll free number, 1-855-MIFE-INFO (1-855-643-3463), or logging on to our website, www.MifeInfo.com.

In addition to having these qualifications, you also agree to follow these guidelines for use:

- Review the Patient Agreement Form with the patient and fully explain the risks of the mifepristone treatment regimen. Answer any questions the patient may have prior to receiving mifepristone.
- Sign and obtain the patient’s signature on the Patient Agreement Form.
- Provide the patient with a copy of the Patient Agreement Form and the Medication Guide.
- Place the signed Patient Agreement Form in the patient's medical record.
- Record the serial number from each package of mifepristone in each patient’s record.
- Report deaths to GenBioPro, identifying the patient by a non-identifiable patient reference and the serial number from each package of mifepristone.

ACCOUNT SETUP

Mifepristone Tablets, 200 mg; NDC 43393-001-01

TO SET UP YOUR ACCOUNT:

1. **Read the Prescriber Agreement on Page 1 of this form.**
2. **Complete and sign this form.**
3. **Fax this page to the GenBioPro distributor at 1-877-239-8036.**
   Your account information will be kept strictly confidential.
4. **The distributor will call to finalize your account setup and take your initial order.**
5. **Subsequent orders may be phoned or faxed and are usually shipped within 24 hours**

BILLING INFORMATION

Bill to Name _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Attention _____

SHIPPING INFORMATION ☐ *Check if same as above*

Ship to Name _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Attention _____

ADDITIONAL SITE LOCATIONS *I will also be prescribing mifepristone at these additional locations:*

Name _____ Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Name _____ Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

(Any additional sites may be listed on an attached sheet of paper)

REQUEST ADDITIONAL MATERIALS

☐ **Medication Guides** ☐ **State Abortion Guides** ☐ **Patient Brochures** ☐ **Patient Agreement Form**

ESTABLISHING YOUR ACCOUNT *(required only with first order)*

Each facility purchasing mifepristone tablets must be included on this form (*see additional site locations box above*) before the distributor can ship the product to the facility.
By signing below, you agree that you meet the qualifications and that you will follow the guidelines for use on page 1 of the Prescriber Agreement.

Print Name _____ Signature _____

Medical License # _____ Date _____

FAX THIS COMPLETED FORM TO THE AUTHORIZED DISTRIBUTOR. FAX: 1-877-239-8036

Please fax any questions to the above number or call 1-877-239-8036

Healthcare Providers: *Counsel the patient on the risks of mifepristone. Both you and the patient must sign this form.*

Patient Agreement:

1. I have decided to take mifepristone and misoprostol to end my pregnancy and will follow my provider's advice about when to take each drug and what to do in an emergency.
2. I understand:
   a. I will take mifepristone on Day 1.
   b. My provider will either give me or prescribe for me the misoprostol tablets, which I will take 24 to 48 hours after I take mifepristone.
3. My healthcare provider has talked with me about the risks, including:
   - heavy bleeding
   - infection
   - ectopic pregnancy (a pregnancy outside the womb)
4. I will contact the clinic/office right away if in the days after treatment I have:
   - a fever of 100.4°F or higher that lasts for more than four hours
   - severe stomach area (abdominal) pain
   - heavy bleeding (soaking through two thick full-size sanitary pads per hour for two hours in a row)
   - stomach pain or discomfort, or I am "feeling sick," including weakness, nausea, vomiting, or diarrhea, more than 24 hours after taking misoprostol
5. My healthcare provider has told me that these symptoms could require emergency care. If I cannot reach the clinic or office right away, my healthcare provider has told me who to call and what to do.
6. I should follow up with my healthcare provider about 7 to 14 days after I take mifepristone to be sure that my pregnancy has ended and that I am well.
7. I know that, in some cases, the treatment will not work. This happens in about 2 to 7 out of 100 women who use this treatment. If my pregnancy continues after treatment with mifepristone and misoprostol, I will talk with my provider about a surgical procedure to end my pregnancy.
8. If I need a surgical procedure because the medicines did not end my pregnancy or to stop heavy bleeding, my healthcare provider has told me whether they will do the procedure or refer me to another healthcare provider who will.
9. I have the MEDICATION GUIDE for mifepristone. I will take it with me if I visit an emergency room or a healthcare provider who did not give me mifepristone so that they will understand that I am having a medical abortion with mifepristone.
10. My healthcare provider has answered all my questions.

Patient Signature: _____ **Patient Name** (print): _____ **Date**: _____

The patient signed the PATIENT AGREEMENT in my presence after I counseled the patient and answered all questions. I have given the patient the MEDICATION GUIDE for mifepristone.

Provider's Signature: _____ **Name of Provider** (print): _____ **Date**: _____

After the patient and the provider sign this PATIENT AGREEMENT, give 1 copy to the patient before the patient leaves the office and put 1 copy in the medical record.