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SCOTUS Agrees to Hear Case
Will Review Fifth Circuit's Decisions on Mifepristone

We at Danco are gratified that the Supreme Court has granted Danco's and the United States' requests to review the Fifth Circuit's August decision invalidating changes that FDA approved to the conditions of use for Mifeprex® in 2016 and in 2021. That decision is inconsistent with established Supreme Court principles governing standing and administrative law challenges. Danco continues to be at the forefront of this fight and is working closely with the reproductive rights community and pharmaceutical industry to support the changes made by FDA.

Danco remains confident in the safety and effectiveness of Mifeprex® under the 2023 REMS that currently governs its use. Because the Supreme Court's stay will remain in place until that Court issues a decision, Mifeprex® will continue to be available under the current FDA-approved conditions, which include use in pregnancy up to 10 weeks gestation, with prescribing after in-person or telehealth examination and dispensing by certified healthcare professionals, brick-and-mortar pharmacies, or mail-order pharmacies.

The FDA actions at issue were well supported by extensive safety and effectiveness data from clinical trials and decades worth of real-world experience in millions of patients. The changes in 2016 and 2021—approved by FDA after careful analysis—have expanded the availability and use of Mifeprex®, providing crucial individual and public health benefits.

Mifeprex® is the most commonly used medication for termination of early pregnancy. Over 5 million women have used Mifeprex® in the United States since its approval in 2000. Mifeprex® is ~97% effective in terminating early pregnancy; approximately 3% of women will require surgical intervention for ongoing pregnancy, heavy bleeding, incomplete expulsion, or other reasons such as patient request.

MIFEPREX: Important Safety Information

WARNING: SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING

Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following MIFEPREX use. No causal relationship between the use of MIFEPREX and misoprostol and these events has been established.

- **Atypical Presentation of Infection. Patients with serious bacterial infections and sepsis can present without fever, bacteremia or significant findings on pelvic examination. A high index of suspicion is needed to rule out serious infection and sepsis.**
- **Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed.**

MIFEPREX is only available through a restricted program called the Mifepristone REMS Program.

Before prescribing MIFEPREX, inform the patient about these risks. Ensure the patient knows whom to call and what to do if she experiences sustained fever, severe abdominal pain, prolonged heavy bleeding, or syncope, or if she experiences abdominal pain or discomfort or general malaise for more than 24 hours after taking misoprostol.

Contraindications

- Administration of MIFEPREX and misoprostol for the termination of pregnancy is contraindicated in patients with any of the following conditions:
- Confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass (the treatment procedure will not be effective to terminate an ectopic pregnancy)
- Chronic adrenal failure (risk of acute renal insufficiency)
- Concurrent long-term corticosteroid therapy (risk of acute renal insufficiency)
- History of allergy to mifepristone, misoprostol, or other prostaglandins (allergic reactions including anaphylaxis, angioedema, rash, hives, and itching have been reported)
- Hemorrhagic disorders or concurrent anticoagulant therapy (risk of heavy bleeding)
- Inherited porphyrias (risk of worsening or of precipitation of attacks)
- Use of MIFEPREX and misoprostol for termination of intrauterine pregnancy is contraindicated in patients with an intrauterine device (“IUD”) in place (the IUD might interfere with pregnancy termination). If the IUD is removed, MIFEPREX may be used.

Warnings and Precautions

Infection and Sepsis

As with other types of abortion, cases of serious bacterial infection, including very rare cases of fatal septic shock, have been reported following the use of MIFEPREX. Healthcare providers evaluating a patient who is undergoing a medical abortion should be alert to the possibility of this rare event. A sustained (> 4 hours) fever of 100.4°F or higher, severe abdominal pain, or pelvic tenderness in the days after a medical abortion may be an indication of infection.

A high index of suspicion is needed to rule out sepsis if a patient reports abdominal pain, discomfort, or general malaise (including weakness, nausea, vomiting or diarrhea) more than 24 hours after taking misoprostol. Very rarely, deaths have been reported in patients who presented without fever, with or without abdominal pain, but with leukocytosis with a marked left shift, tachycardia, hemoconcentration, and general malaise.

Uterine Bleeding

Uterine bleeding occurs in almost all patients during a medical abortion. Prolonged heavy bleeding (soaking through two thick full-size sanitary pads per hour for two consecutive hours) may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed to prevent the development of hypovolemic shock. Counsel patients to seek immediate medical attention if they experience prolonged heavy vaginal bleeding following a medical abortion.

Excessive uterine bleeding usually requires treatment by uterotonics, vasoconstrictor drugs, surgical uterine evacuation, administration of saline infusions, and/or blood transfusions. Because heavy

bleeding requiring surgical uterine evacuation occurs in about 1% of patients, special care should be given to patients with hemostatic disorders, hypocoagulability, or severe anemia.

Mifepristone REMS Program

MIFEPREX is available only through a restricted program under a REMS called the Mifepristone REMS Program, because of the risks of serious complications. Notable requirements of the Mifepristone REMS Program include the following:

- Prescribers must be certified with the program by completing the Prescriber Agreement Form.
- Patients must sign a Patient Agreement Form.
- MIFEPREX must only be dispensed to patients by or under the supervision of a certified prescriber, or by certified pharmacies on prescriptions issued by certified prescribers.

Ectopic Pregnancy

MIFEPREX is contraindicated in patients with a confirmed or suspected ectopic pregnancy because MIFEPREX is not effective for terminating ectopic pregnancies. Healthcare providers should remain alert to the possibility that a patient who is undergoing a medical abortion could have an undiagnosed ectopic pregnancy because some of the expected symptoms experienced with a medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured ectopic pregnancy.

Women who became pregnant with an IUD in place should be assessed for ectopic pregnancy.

Rhesus Immunization

The use of MIFEPREX is assumed to require the same preventive measures as those taken prior to and during surgical abortion to prevent rhesus immunization.

Adverse Reactions

Most common adverse reactions (>15%) are nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness. The frequency of adverse reactions varies between studies and may be dependent on many factors including the patient population and gestational age.

This is the Important Safety Information. For more information, please see the Full Prescribing Information, including **BOXED WARNING and Medication Guide**, available at **www.earlyoptionpill.com**.