

C A M P A I G N F O R

ACCOUNTABILITY

May 20, 2020

BY Email: janet.woodcock@fda.hhs.gov

Dr. Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

BY Email: donald.ashley@fda.hhs.gov

Mr. Donald D. Ashley, J.D.
Director, Office of Compliance
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Referral of Unlawful Prescription of Dangerous Abortion Pill Reversal

Dear Director Woodcock and Director Ashley,

Campaign for Accountability (“CfA”) respectfully requests that the United States Food and Drug Administration (“FDA”) seize the website domains for, or in the alternative issue warning letters to, Abortion Pill Rescue,¹ American Pregnancy Association,² Obria Medical Clinics,³ and any other entities improperly marketing progesterone treatments to women who have taken mifepristone, the first of the two drugs used for medication abortion. Scientific study of this so-called abortion pill reversal treatment was prematurely terminated because of serious health and safety concerns and these websites should be prevented from endangering other potential patients.

Background

Medication abortion using a combination of mifepristone and misoprostol was first approved by the FDA in 2000, and its approval was updated in 2016 for use through the first ten

¹ Abortion Pill Reversal, ABORTION PILL RESCUE (last accessed May 7, 2020), available at <https://www.abortionpillreversal.com/>.

² Is Progesterone Safe? *Abortion Pill Reversal*, AMERICAN PREGNANCY ASSOCIATION (last accessed May 7, 2020) available at <https://americanpregnancy.org/abortion-pill/abortion-pill-reversal/>.

³ Regret Taking the Abortion Pill?, OBRIA MEDICAL CLINICS (last accessed May 7, 2020), available at <https://www.obria.org/services/abortion-pill-reversal/>.

weeks of pregnancy.⁴ The approved treatment includes two drugs taken orally, first mifepristone followed by misoprostol taken 24 to 48 hours later.⁵ When these two drugs are taken together, a medication abortion terminates the pregnancy in 96% of cases.⁶ Medication abortion has been found to be “safe and effective when used to terminate a pregnancy with the revised labeling.”⁷

In 2012, Dr. George Delgado advanced an experimental treatment purporting to “reverse” abortion by foregoing the second medication abortion drug, misoprostol, and instead administering a regimen of progesterone.⁸ There is no specific protocol for the progesterone regimen, beyond a large amount of progesterone administered by injection or orally or vaginally, for an unspecified length of time.⁹ Mifepristone causes the pregnancy to detach from the uterine lining, and Dr. Delgado’s unproven hypothesis is that administering large doses of progesterone can counteract the effects of a previously administered dose of mifepristone.¹⁰

The FDA has not approved this untested and unproven so-called abortion pill reversal treatment.¹¹ Further, the FDA label for mifepristone neither provides for mifepristone to be given as a stand-alone drug—it requires that it be administered in concert with a dosage of misoprostol—nor provides for a dosage of progesterone with the administration of mifepristone.¹²

The studies upon which Dr. Delgado’s hypothesis is based, including his 2012 and 2018 case studies, are deeply flawed.¹³ Additionally, in 2019, researchers from the University of California, Davis had to halt a study into the efficacy of progesterone in preventing an abortion once mifepristone has been taken due to safety concerns. After three of twelve women enrolled in the study were hospitalized for severe vaginal bleeding, the researchers concluded:

We could not estimate the efficacy of progesterone for mifepristone antagonization due to safety concerns when mifepristone is administered without subsequent

⁴ See *Mifeprex (mifepristone) Information*, U.S. FOOD AND DRUG ADMINISTRATION (Feb. 5, 2018), available at <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information>; Guttmacher Institute, *Evidence You Can Use: Medication Abortion*, GUTTMACHER.ORG (Nov. 2019), available at <https://www.guttmacher.org/evidence-you-can-use/medication-abortion>.

⁵ See *Mifeprex Medication Guide*, U.S. FOOD AND DRUG ADMINISTRATION (Mar. 2016) available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s0201bl.pdf.

⁶ See *Id.* at 13 (Table 3: Outcome Following Treatment with Mifepristone (oral) and Misoprostol (buccal) Through 70 Days Gestation).

⁷ See *Mifeprex (mifepristone) Information*, U.S. FOOD AND DRUG ADMINISTRATION (Feb. 5, 2018), available at <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information>.

⁸ See George Delgado & Mary L. Davenport, *Progesterone Use to Reverse the Effects of Mifepristone*, 46 *Annals of Pharmacotherapy* e36 (Dec. 2012).

⁹ See George Delgado et al., *A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone*, 33 *Issues in Law & Medicine* (2018).

¹⁰ *Id.*

¹¹ See Guttmacher Institute, *Evidence You Can Use: Medication Abortion*, GUTTMACHER.ORG (Nov. 2019), available at <https://www.guttmacher.org/evidence-you-can-use/medication-abortion>.

¹² See *Mifeprex Medication Guide*, U.S. FOOD AND DRUG ADMINISTRATION (Mar. 2016) available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s0201bl.pdf.

¹³ See Daniel Grossman & Kari White, *Abortion “Reversal” – Legislating Without Evidence*, 379(16) *New England Journal of Medicine* 1401-03 (2018).

prostaglandin analogue treatment. Patients in early pregnancy who use only mifepristone may be at high risk of significant hemorrhage.¹⁴

As ethical and rigorous scientific testing has yet to be successfully completed on Dr. Delgado's proposed abortion pill reversal, any patients receiving the treatment are unknowingly serving as test cases.

Abortion Pill Rescue, American Pregnancy Association, and crisis pregnancy centers like Obria Medical Clinics all market Dr. Delgado's abortion pill reversal. Abortion Pill Rescue calls abortion pill reversal an "effective process"¹⁵ while Obria Medical Clinics describe it as a "medical procedure available to reverse the effects of the abortion pill."¹⁶ The American Pregnancy Association states that the method is "not necessarily FDA approved"¹⁷ while the other websites do not reference the lack of FDA approval at all. None of the websites disclose that related studies have been incomplete or terminated due to significant safety concerns. All of these websites include live webchats and hotlines for individuals to be connected with a "medical professional" for administration of the abortion pill reversal treatment.

Legal Violation

The abortion pill reversal treatment offered on these websites is intended to mitigate, prevent, treat, diagnose, or cure a medication abortion in people and appears to involve unapproved new drugs sold in violation of the Federal Food, Drug, and Cosmetic Act ("FD&C Act").

Mifepristone and progesterone are drugs within the meaning of the FD&C Act because they are intended "for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and/or are "intended to affect the structure or any function of the body."¹⁸ Abortion pill reversal promotes the administration of mifepristone without misoprostol and with large amounts of progesterone. However, mifepristone and progesterone are not generally recognized as safe and effective when misused in this way to attempt abortion pill reversal and therefore are new drugs under the FD&C Act.¹⁹

New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior FDA approval.²⁰ The FDA approves new drugs on the basis of scientific

¹⁴ Mitchell D. Creinin et al., *Mifepristone Antagonization With Progesterone to Prevent Medical Abortion*, 135 *Obstetrics & Gynecology* 158-165 (2020), available at https://journals.lww.com/greenjournal/Citation/2020/01000/Mifepristone_Antagonization_With_Progesterone_to.21.aspx.

¹⁵ Abortion Pill Reversal, ABORTION PILL RESCUE (last accessed May 7, 2020), available at <https://www.abortionpillreversal.com/>.

¹⁶ Regret Taking the Abortion Pill?, OBRIA MEDICAL CLINICS (last accessed May 7, 2020), available at <https://www.obria.org/services/abortion-pill-reversal/>.

¹⁷ Is Progesterone Safe? *Abortion Pill Reversal*, AMERICAN PREGNANCY ASSOCIATION (last accessed May 7, 2020) available at <https://americanpregnancy.org/abortion-pill/abortion-pill-reversal/>.

¹⁸ 21 U.S.C. § 321(g)(1)(B)-(C).

¹⁹ 21 U.S.C. § 321(p).

²⁰ 21 U.S.C. § 355(a).

Director Woodcock
Director Ashley
May 20, 2020
Page 4

data and information that the drug is safe and effective and there is no FDA-approved application in effect for the abortion pill reversal products. It appears that Abortion Pill Rescue, American Pregnancy Association, and crisis pregnancy centers like Obria Medical Clinics all facilitate the sale to U.S. consumers of these new drugs, in violation of the FD&C Act. CfA urges the FDA to examine the ethical and legal implications of the abortion pill reversal treatments facilitated by these websites.

Conclusion

Women should not be used as guinea pigs unknowingly, and Americans have the right to expect that the FDA will take action when false, unlawful, and potentially dangerous health treatments are being peddled. Therefore, the FDA should seize the website domains for, or in the alternative issue warning letters to, Abortion Pill Rescue, American Pregnancy Association, Obria Medical Clinics, and any other entities improperly marketing abortion pill reversal treatments to women who have taken mifepristone and investigate the treatments these groups have facilitated.

Sincerely,

A handwritten signature in blue ink, appearing to read "Alice C.C. Huling".

Alice C.C. Huling
Counsel