Exhibit B

CONFIDENTIAL

February 4, 2016

Stephen Ostroff, M.D., Acting Commissioner of Food and Drugs
Robert M. Califf, M.D., Deputy Commissioner for Medical Products and Tobacco
Janet Woodcock, M.D., Director of the Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Drs. Ostroff, Califf, and Woodcock,

The following 30 organizations write to ask the U.S. Food and Drug Administration (FDA) to lift the Risk Evaluation and Mitigation Strategy (REMS) imposed in 2000 when it approved the use of Mifeprex© (mifepristone) for pregnancy termination, and to extend the indicated use through a gestational age of 70 days. In the 15 years since mifepristone's approval, multiple clinical trials, dozens of studies, and extensive experience across the globe have confirmed the FDA's finding that mifepristone is a safe and reliable method of abortion. Studies have shown that mifepristone in combination with misoprostol is up to 99% effective for first trimester abortion[1,2] and that serious complications are rare.[3] The steady increase in use of medication abortion – now 23% of U.S. abortions – shows that many women prefer this option, and that it has the ability to improve access to abortion, even in states with restrictive laws. Provider interest in offering mifepristone has also increased substantially: in 2011, 59% of abortion providers offered early medication abortions, up from 33% in 2008.[4] This growing use of medication abortion has made a major difference in people's lives. We thank the FDA for ensuring mifepristone is available on the market for patients' reproductive health care needs.

However, many who could benefit from mifepristone still do not have access to it due to multiple types of restrictions, including those required by the FDA. In November 2015, a group of organizational and individual researchers submitted a letter to the FDA (hereinafter "Technical Letter") asking the agency to lift the REMS on mifepristone and extend the indicated use to 70 days gestational age, presenting data showing that the current restrictions and limited gestational age indication are unnecessary for the safe and effective use of the drug for pregnancy termination.

As policy, advocacy, social science, research, and academic organizations, we ask the FDA to consider the substantial evidence presented in the Technical Letter, alongside the burdens that the REMS and the label's 49-day gestational age indication place on patient access, which we describe here. The FDA held a public meeting in October 2015 to discuss improving patient access to drugs under REMS,[5] evidencing the agency's own awareness of patient burden caused specifically by restrictions imposed under REMS. We applaud these efforts and urge the FDA to use its regulatory authority to remove the medically unnecessary barriers to mifepristone.

Mifepristone underwent a lengthy approval process in the late 1990s, during which it became subject to a rarely-used approval mechanism: Subpart H of the FDA's Title 21, Chapter 314 regulations. Subpart H is used primarily for drugs with very serious and well-documented safety concerns.[6] In 2007, Subpart H restrictions on all drugs were converted automatically into a Risk Evaluation and Management Strategy (REMS),[7] a mechanism created by Congress whereby FDA can impose Elements to Assure Safe Use (ETASU). Under this law, as the Agency stated in preparation for its October 2015 meeting on REMS,[8] Congress mandated that the FDA engage in a balancing analysis to ensure that the risks mitigated by a REMS program do not unduly burden patients' access to health care:

> [E]lements to assure safe use [ETASU] ... shall–
>
> (A) be commensurate with the specific serious risk listed in the labeling of the drug;
>
> ...
>
> (C) considering such risk, not be unduly burdensome on patient access to the drug, considering in particular–
>
> (i) patients with serious or life-threatening diseases or conditions; and
>
> (ii) patients who have difficulty accessing health care (such as patients in rural or medically underserved areas)….[9]

Although the FDA may have decided 15 years ago that the balance of risk and burden came out in favor of restricting mifepristone's indicated use and distribution, today both science and the current conditions surrounding patient access to abortion care call strongly for a reevaluation of the mifepristone label and REMS restrictions, especially its Elements to Assure Safe Use (ETASU).

We support the following changes to the mifepristone label:

- The drug should be indicated for use in medication abortions beyond 49 days gestation.
- The recommended dose regimen should be mifepristone 200 mg followed 24-48 hours later by misoprostol 800 mcg.
- The location where the patient should take these drugs should not be restricted.
- An in-person visit should be indicated as not always necessary for follow-up assessment.
- Any licensed health care provider should be able to prescribe the drug.

We expand below upon further specific changes that should be made based on scientific evidence of mifepristone's safety and efficacy, as well as the numerous burdens on patients' access to abortion care that would be greatly alleviated if the REMS were eliminated and the gestational age indication in the label were increased to 70 days.

1. **Eliminate the REMS and ETASU for mifepristone.**
   a. **Expand dispensing venues.** The ETASU state that mifepristone may only be dispensed to patients in a clinic, medical office, or hospital, and not through pharmacies.[10] The Technical Letter discusses why this requirement is not medically warranted. The requirement should be removed entirely, so that mifepristone can also be distributed via retail pharmacies like other prescription medications, in addition to being directly distributed to providers.

      This requirement significantly curtails mifepristone's potential to expand patient access to abortion care. The up-front costs (including substantial costs for pre-ordering the drug) and logistical requirements (e.g., increased staffing at provider offices) are a burden to providers and, therefore, deter some health care providers from offering medication abortion. When fewer providers are willing to stock mifepristone in their offices because of the REMS and ETASU, fewer patients can access medication abortion. In some cases this requirement may also force the patient to make an unnecessary visit to a clinic, medical office, or hospital to pick up the medication, rather than being able to pick up an order called into a pharmacy. This requirement is especially significant in underserved and rural areas where access to a health care provider is already difficult, and for those with low incomes for whom taking off work or getting to a provider multiple times in short order is impossible due to cost or family needs.[11] The Turnaway Study, a prospective longitudinal study conducted by Advancing New Standards in Reproductive Health (ANSIRH) at the University of California-San Francisco examining the effects of unintended pregnancy on individuals' lives, demonstrates that the majority of people who seek abortion care are already in difficult financial situations, and are

disproportionately people of color.[12] Costly and unnecessary visits to the doctor significantly increase financial and logistical burdens for these individuals and communities.

Any venue expansion, however, should not preclude the direct distribution of mifepristone to providers who want to dispense from their clinical settings. In many places, pharmacy refusal laws allow pharmacists to decline to fill prescriptions for reproductive health drugs such as emergency contraception and birth control, and federal policy allows providers to refuse to provide abortions.[13] So, although pharmacists' ability to dispense mifepristone would expand patient access to medication abortion in places where providers cannot easily store mifepristone in their offices, providers should retain the option to have mifepristone directly distributed to their offices to ensure continued access to medication abortion for those living in places where pharmacists can refuse to fill mifepristone prescriptions.

b. **Eliminate the Prescriber Agreement certification requirement.** Under the REMS and ETASU, providers must have a physician supervisor submit a Prescriber Agreement form to the drug's distributor attesting: 1) that mifepristone will only be provided by or under the supervision of a physician; and 2) that the physician can assess pregnancy duration, 3) diagnose ectopic pregnancies, and 4) make a plan for a patient to have surgical intervention if necessary.[10] This requirement should be eliminated for several reasons:

i. *The Prescriber's Agreement is unnecessary for the safe dispensation of mifepristone.* As the Technical Letter explains, health care professionals are already subject to many laws, policies, and ordinary standards of practice that ensure they can accurately and safely understand and prescribe medications. Provider certification is not required for health care professionals to dispense other drugs, including drugs that carry black box, or boxed, warnings about their medical risks. Accutane, for example, has a boxed warning that describes the potential risks of the drug,[14] but Accutane prescribers are not required to submit a certification form in order to prescribe it. Mifeprex also has a boxed warning[15] and there is no medical reason for a Prescriber's Agreement to be required in addition.

ii. *The Prescriber's Agreement forces providers to identify themselves as abortion providers to a centralized entity (Danco Laboratories) inspected and regulated by the FDA, which could discourage some from offering medication abortion care to their patients*. In 2014, more than half of U.S. health care facilities that provide abortions (52%) experienced threats and other types of targeted intimidation, and one in five experienced severe violence, such as blockades, invasions, bombings, arsons, chemical attacks, physical violence, stalking, gunfire, bomb threats, arson threats, or death threats.[16] Robert Dear's November 27, 2015, standoff at a Planned Parenthood health center in Colorado, which resulted in three deaths, provides one recent and chilling example of anti-abortion violence.[17] Given such escalating harassment and violence against known abortion providers,[18] clinicians may be understandably reluctant to add their names to a centralized database of mifepristone providers.

iii. *The Prescriber's Agreement would be incompatible and unnecessary if there were an expanded distribution system.* If dispensing venues are expanded as proposed in section 1a, ordinary standards of practice and state regulations would govern pharmacists' and providers' distribution of mifepristone, and a specific certification process would be unnecessary. Furthermore, a distribution system that incorporates the Prescriber's Agreement would be extremely difficult to maintain as a practical matter. Pharmacists would need to check the certification status of each prescriber before filling a prescription, which they do not normally have to do when filling other prescriptions.

Alternatively, pharmacists would need to become certified providers themselves, thus facing the deterrence problem of adding their names to a centralized database of mifepristone providers.

iv. *The Prescriber's Agreement as currently written prevents independent non-physician prescribers from being able to prescribe mifepristone without supervision by a physician.* The Prescriber's Agreement currently states that mifepristone "must be provided by or under the supervision of a physician."[19] However, nowhere in the outline piece of the REMS document written by the FDA is the word "physician" used. The REMS references only "providers" and "prescribers." [10] The Prescriber's Agreement's narrow interpretation of the REMS is medically unnecessary and severely limits patients' access to medication abortion care, because non-physician providers must work under physician supervision to prescribe mifepristone. All states give certain advanced practice clinicians prescribing authority, including for controlled substances, and 27 states allow them to dispense medications directly.[20] Advanced practice clinicians provide an increasing proportion of basic health care in the U.S., and several states authorize these clinicians to provide abortion care. If the Agreement is not eliminated, then at least enlarging the pool of health care providers that can submit the Prescriber's Agreement would help improve access and be consistent with individual state law regarding scope of practice. If the FDA does not eliminate the Agreement altogether, it should make clear that any licensed health care provider with prescribing authority is also eligible for certification to prescribe mifepristone.

c. **Remove the confusing and unnecessary Patient Agreement.** The REMS requires that each patient sign a Patient Agreement form before receiving mifepristone. This requirement is medically unnecessary and interferes with the clinician-patient relationship. It should be eliminated entirely.

In addition to being outdated and inconsistent with requirements for drugs with similar safety profiles, the Patient Agreement creates confusion for patients. Except in the few states that require that patients follow the regimen that appears on the mifepristone label, the majority of clinicians use an evidence-based regimen that is different from the regimen described in the label. Requiring a patient to sign an agreement to a treatment plan that differs from the one prescribed by her provider is confusing and could undermine trust in the clinician.

Patients have been using mifepristone safely and effectively according to evidence-based regimens recommended by their clinicians for many years, diverging from the regimen described in the Patient Agreement.[3] A wealth of data and experience since mifepristone's approval have demonstrated that this drug is extremely safe, that clinicians with routine professional training can provide it appropriately, and that patients are able to use it as directed by their health care provider.[21,22] Requiring a patient to sign an agreement to a treatment plan that differs from the one prescribed by her provider may create unnecessary confusion.

d. **Allow evidence-based follow-up assessment.** Under the Federal Food, Drug, and Cosmetic Act, the FDA should ensure that a REMS does not unduly burden patients, especially those in rural or medically underserved areas.[9] However, the documents appended to the REMS (the Medication Guide, Prescriber's Agreement, and Patient Agreement) all indicate the patient should to return to the clinic for follow-up 14 days after the patient takes mifepristone.[10] Such an in-person appointment is not always medically necessary and, when required, creates significant additional costs for patients, who must find time for another appointment at the provider's office and potentially incur substantial costs for travel, childcare, and/or lost wages.

These burdens are often increased for patients living in rural and other medically underserved areas. In 2008, 33% of all abortion patients traveled more than 25 miles to obtain care, and 74% of all patients living in rural areas traveled at least 50 miles to obtain the procedure.[23] Medical technology and telemedicine have advanced considerably since 2000,[24] and a growing body of evidence shows that alternatives to in-person follow-up, such as serum chorionic gonadotropin (hCG), multi-level pregnancy tests, and telephone counseling are safe, effective, and improve access and satisfaction for patients.[25,26,27]

2. **Increase the gestational age for indicated use on the label.**
The current label indicates use of mifepristone through 49 days after the start of the patient's last menstrual period (LMP). The Technical Letter discusses the substantial evidence demonstrating that the evidence-based medication abortion regimen is highly effective later than 49 days LMP, through at least the 10th week (64-70 days) of gestation.[28,29,30] The National Abortion Federation's (NAF) annual *Clinical Policy Guidelines*, which NAF develops by consensus based on a rigorous review of current medical literature and known patient outcomes, recommend that an evidence-based medication abortion regimen be used through 70 days LMP.[31] The time between 49 and 70 days LMP is critical for patient access, as approximately 30% of women who seek an abortion present for care during this time, according to the Centers for Disease Control.[32]

Consider the current legal and social climate

The overall legal and social climate around abortion care intensifies all of the burdens that the mifepristone REMS places on patients and makes it even more critical that the FDA lift medically unnecessary restrictions on the drug. Since mifepristone's approval, a multitude of laws and regulations at the federal and state level have dramatically restricted access to abortion care. In the first five years of this decade alone, states enacted 288 abortion restrictions – more than the entire previous decade.[33] These restrictions are typically unsupported by medical evidence and serve only to reduce access to abortion care.[34] In 2000, the Guttmacher Institute, a nonpartisan research and policy organization that seeks to advance sexual and reproductive health and rights and ensure the highest standard of sexual and reproductive health care, considered 13 states to be hostile to abortion, meaning that those states had 4-5 types of restrictions on abortion. In 2014, the number of states considered hostile had more than doubled, now including more than half of all states.[34]

Providers have increasingly been forced to close their doors as a result of mounting restrictions. There were about 1,800 abortion providers in the U.S. in 2000. Stand-alone abortion clinics constituted 447 (25%) of all providers in 2000, and those clinics provided 71% of all abortions.[35] By 2008, only 378 abortion clinics were still providing 70% of abortions.[36] Abortion clinic closures have accelerated since 2008, as lawmakers began passing restrictions at an unprecedented rate.[37] The Associated Press estimated in June 2015 that 70 abortion clinics had closed in a dozen states since 2010.[38] This wave of state restrictions and clinic closures has continued unabated in the last five years.

Some of these measures specifically block access to medication abortion by invoking the FDA-approved label. North Dakota, Ohio, and Texas currently require mifepristone to be administered solely according to the regimen that appears on the FDA label.[39] The Arkansas legislature just passed a similar law in 2015, though a federal judge issued a temporary restraining order blocking enforcement of the law until a hearing on March 14, 2016.[40] In these states, mifepristone cannot be prescribed in accordance with evidence-based practices developed in the last 15 years,* which improve patient access in multiple ways:

- enabling patients to take a lower dose of mifepristone, resulting in fewer side effects and lower cost;

*The one deviation that Texas allows from the label is one other dosage amount of Mifeprex and misoprostol.[39]

- allowing patients to take mifepristone, misoprostol, or both at home, and/or confirm termination of pregnancy at home, resulting in fewer visits to the provider;
- and offering medication abortion to patients later than 49 days LMP. [3]

Studies have also shown that these "label laws" have had a negative impact on patient access to abortion. For example, a recent study showed that after passage of laws that restricted use of mifepristone to the FDA label in Texas and Ohio, medication abortion declined dramatically while it rose in New York and California, states without restrictive laws.[41] Furthermore, these laws run counter to the FDA's own guidance, which states that a "package insert is informational only."[42,43,44] As long as the FDA-approved label diverges from evidence-based regimens, states can hide behind it as they restrict access to abortion. If the FDA does not update mifepristone's label to reflect the most current, evidence-based practice, the number of women adversely affected will only increase as additional states pass laws to exploit this discrepancy.

Other state restrictions are not specific to medication abortion, but affect all kinds of abortion care, including access to mifepristone. These medically unnecessary restrictions include the following: requirements that facilities where abortion is provided meet standards for ambulatory surgical centers; physician admitting privileges at local hospitals; and requirements that the patient and prescribing clinician must be in the same physical location, prohibiting the use of telemedicine technology. On top of these legal restrictions, anti-abortion stigma, harassment, and violence deter many health care professionals from providing abortion care. Authorizing distribution of mifepristone in pharmacies could diminish the impact of these barriers and allow providers to offer abortion care without fear of retaliation.

These restrictions, and the concomitant politicization and stigmatization of abortion care, have also seeped into other aspects of health care and prevented progress on the use of mifepristone for other indications. Removing the REMS program would make mifepristone more readily available for non-abortion therapies as well.[45,46]

In summary, the burdens on patient access to medication abortion, exacerbated by the REMS requirements placed on mifepristone, strongly outweigh any medical risk to the patient associated with the drug. In this climate of legal restrictions, clinic closures, and mounting stigma, it is increasingly important that any regulation of mifepristone be based solely on medical evidence, rather than the discretion of politicians who are determined to restrict access to abortion at any price. We recognize that the FDA is not responsible for most restrictions on abortion access. However, whenever the FDA evaluates indications and restrictions on an approved product, it does so in the context of the real-world circumstances in which the product is sold and the condition is treated. We believe this is vital in the case of mifepristone in particular, where the broad landscape of laws regulating abortion has measurable negative impact on the clinical provision of abortion care.

Mifepristone continues to hold immense promise for patient access to a safe and effective early abortion option, but medically unnecessary regulations are impeding its full potential. Extensive scientific and clinical evidence of mifepristone's safety and efficacy, and the ever-increasing burden on patient access to abortion care, clearly demonstrate that mifepristone's REMS program is not needed to protect patients. In light of the FDA's statutory mandate from Congress to consider the burden caused to patients by REMS, and the agency's own stated commitment to ensuring that drug restrictions do not unduly burden patient access, we ask that the FDA lift mifepristone's REMS and amend the label to extend the indicated use to 70 days.

Sincerely,

Advancing New Standards in Reproductive Health (ANSIRH), Department of Obstetrics, Gynecology & Reproductive Sciences, University of California, San Francisco
American Civil Liberties Union
Association of Reproductive Health Professionals
Bixby Center for Global Reproductive Health, Department of Obstetrics, Gynecology & Reproductive Sciences, University of California, San Francisco
Cambridge Reproductive Health Consultants
Carafem
Center for Reproductive Rights
Center on Reproductive Rights and Justice at the University of California, Berkeley, School of Law
Feminist Majority Foundation
Guttmacher Institute
Gynuity Health Projects
Ibis Reproductive Health
Jacobs Institute of Women's Health
Legal Voice
Medical Students for Choice
NARAL Pro-Choice America
National Abortion Federation
National Advocates for Pregnant Women
National Institute for Reproductive Health
National Latina Institute for Reproductive Health
National Network of Abortion Funds
National Partnership for Women and Families
National Women's Health Network
National Women's Law Center
Planned Parenthood Federation of America
Physicians for Reproductive Health
Provide
Reproaction
Reproductive Health Technologies Project
Society of Family Planning

cc:
Valerie Jarrett, Chair, White House Council on Women and Girls
Tina Tchen, Executive Director, White House Council on Women and Girls
Jordan Brooks, Deputy Executive Director, White House Council on Women and Girls
Nancy C. Lee, M.D., Deputy Assistant Secretary of Health, Women's Health, Director of the Office on Women's Health, Department of Health and Human Services
Bobby Clark, Counselor for Public Health and Science, U.S. Department of Health and Human Services, Office of the Secretary

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[42] U.S. Food and Drug Administration, Drug Bulletin 12:1, 4-5 (1982) ("The FD&C Act does not… limit the manner in which a physician may use an approved drug …. With respect to its role in medical practice, the package insert is informational only").
[43] Agency Request for Comments: Citizen Petition Regarding the Food and Drug Administration's Policy on Promotion of Unapproved Uses of Approved Drugs and Devices, 59 Fed. Reg. 59820-01 (Nov. 18, 1994) ("FDA has long recognized that physicians and other health care professionals may prescribe approved therapies for unapproved uses").
[44] Agency Comments on Proposed Rule: Applicability of IND Requirements, 52 Fed. Reg. 8798, 8803 (final rule Mar. 19, 1987) (codified at 21 CFR § 312.2) ("As noted in the preamble to the proposed rule, it was clearly the intent of Congress in passing the Federal Food, Drug, and Cosmetic Act that FDA not regulate the practice of medicine, which the agency has consistently viewed as including the use by physicians of marketed drugs for unlabeled indications in the 'day-to-day' treatment of patients. Once a drug product has been approved for marketing, a physician may, in treating patients, prescribe the drug for uses not included in the drug's approved labeling. Control of the practice of medicine in these cases is primarily exercised through State laws affecting medical licensing and practice and through products liability law").
[45] Dzuba IG, Grossman D, Schreiber CA. Off-label indications for mifepristone in gynecology and obstetrics. *Contraception,* 2015;92:203-05, doi: 10.1016/j.contraception.2015.06.021 (showing that data from around the world suggests mifepristone could be used to treat patients with a wide variety of cancers, tumors, and other hormone-sensitive conditions who have exhausted other standard treatments).
[46] Mifepristone Compassionate Use Program. Feminist Majority Foundation website (discussing a program that has been able to help treat a small cadre of eligible patients, but must contend with FDA-mandated paperwork that is onerous to most physicians and creates needless delays in quickly and effectively accessing a potentially life-saving treatment option). http://www feminist.org/rrights/compassionateuse.asp. Accessed December 21, 2015.