The National Abortion Federation and Planned Parenthood Federation of America have submitted comments to the Food and Drug Administration (FDA) demonstrating the safety and efficacy of Mifeprex, a medication used for early medical abortion. These comments show that the Petition submitted by the American Association of Pro-Life Obstetricians and Gynecologists, the Christian Medical Association, and Concerned Women for America ("Petitioners") seeking the withdrawal of Mifeprex's approval or restrictions on its use lacks any scientific basis and should be denied.

EXECUTIVE SUMMARY

In approving Mifeprex, FDA properly concluded that Mifeprex is safe and effective and that health care providers who meet the qualifications required by FDA in the Mifeprex Prescriber's Agreement can safely provide Mifeprex to their patients.

Mifeprex May Be Safely Provided Without Mandatory Routine Ultrasound.

The Petitioners claim that routine ultrasound prior to the administration of Mifeprex is necessary to date the pregnancy and to detect ectopic pregnancy. This would impose an unnecessary requirement that is inconsistent with the standard of care for managing early pregnancy, regardless of whether the patient is considering abortion. A variety of methods to confirm and date pregnancy are available to health care providers including patient history, physical examination, and pregnancy testing. Ultrasound is not necessary as a routine matter and is, rather, indicated when other assessments are discordant. This is the standard of care not only in the United States but also in other countries where Mifeprex has been approved and used safely.

Additionally, routine ultrasound is not necessary for detection of ectopic pregnancy. A number of tests, as well as physical exam and patient history, are available to clinicians for diagnosis. If these tests suggest an ectopic pregnancy, ultrasound may be indicated to confirm the diagnosis. Approved Mifeprex labeling reflects these standards and assures that a woman will receive or be referred for an ultrasound examination if indicated.

FDA's Requirements for Mifeprex Providers Assure Safe Use.

FDA requires health care providers to certify that they meet certain qualifications in order to provide Mifeprex:

- The ability to accurately date pregnancy;
- The ability to diagnose ectopic pregnancy;
- The ability to provide or arrange for surgical intervention in the event of an incomplete abortion or severe bleeding; and
- The ability to assure the patient access to medical facilities equipped to provide emergency care.

These standards safeguard women's health without intruding excessively into the practice of medicine.

The Petitioners argue that additional requirements are necessary and that only physicians trained in surgical abortion who have admitting privileges to emergency facilities within an "objective

geographical limitation" be allowed to prescribe Mifeprex. FDA properly rejected these unnecessary qualifications, which would interfere with standard medical practice and curtail women's ability to access safe and early medical abortion.

Health care providers need not be trained in surgical abortion to prescribe Mifeprex safely. Complications requiring surgical intervention are rare, and in the event that surgical intervention is necessary, the FDA-approved labeling assures that, if the Mifeprex provider does not provide surgical intervention himself or herself, the patient will be referred to another provider for that treatment. A geographical restriction is also unwarranted and is inconsistent with the standard of care. Medical abortions with Mifeprex are medically comparable to spontaneous abortions (i.e. miscarriages). Numerous facilities and health care providers that do not provide surgical abortion manage spontaneous abortions surgically, and can and do provide surgical intervention in the event of heavy bleeding or an incomplete medical abortion. Moreover, current standards of medical care do not mandate either that physicians treating other medical conditions have admitting privileges or that admitting privileges be within an "objective geographical limitation."

Mifeprex is Safe for Women.

Petitioners also contend that Mifeprex is unsafe. This contention is inconsistent with the studies that supported FDA's approval, other published medical studies, and the experience of medical practitioners who have provided Mifeprex to millions of patients world-wide. Indeed, since the FDA's approval of Mifeprex in 2000, more than 250,000 American women have used Mifeprex safely to terminate an early pregnancy.[*] Mifeprex is, in fact, safer and more effective than other abortion methods for some women, for instance women with vaginal scarring, large uterine fibroids, or certain abnormalities of the uterus or cervix, and many women have a clear preference for a non-surgical abortion.

Evidence-Based Alternative Regimens Do Not Contravene the FDA Approval.

The Petitioners also contend that offering the Mifeprex regimen through 63 days' gestation and permitting patients to administer the dose of misoprostol at home rather than requiring them to return to the medical office violates FDA's approval. Nothing in the FDA approval of Mifeprex, however, obligates providers to follow any specific dose or regimen for prescribing Mifeprex. The use of evidence-based, or "off-label," alternative regimens is an accepted part of standard medical practice if supported by published literature or other appropriate scientific evidence. Indeed, the published literature demonstrates that the alternative regimens about which the Petitioners complain are safe and effective. These alternatives may be more effective and have fewer side effects than the FDA-approved regimen.

Conclusion

FDA's approval of Mifeprex assures safe and effective use without unnecessary intrusions into the practice of medicine. The scientific data continues to support the drug's safety and effectiveness. Consequently, FDA should promptly deny the Petitioners' requests.

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[*] as of early 2004. For current usage numbers, see Danco Laboratories' website at www.earlyoptionpill.com.