AAPLOG Statement on FDA Approval of Mifeprex (RU 486)

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On September 28, 2000 the United States Food and Drug Administration (FDA) announced the approval of mifepristone, in combination with misoprostol, for early pregnancy termination.[1] This decision received the unqualified approval of the American College of Obstetricians and Gynecologists (ACOG). Mifepristone is also known as RU 486 and is marketed in the United States under the brand name Mifeprex. It is anticipated that 1/3 of future elective pregnancy terminations will be performed using this pharmaceutical regimen. Therefore, as many as 400,000 American women per year may be subject to this procedure, making it a significant health care issue. The American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) opposes the destruction of an unborn human being at any stage of development. Therefore, we oppose pharmaceutical abortion with the same vigor that we oppose surgical abortion. However, pharmaceutical abortion has now become a reality of American medical practice, sanctioned by the FDA and ACOG. A stipulation of the FDA's approval of Mifeprex is that its distribution be restricted to physicians able to meet certain qualifications. The American Association of Pro-Life Obstetricians and Gynecologists believes these qualifications are insufficiently circumscribed to adequately safeguard the health of American women. We therefore make the following statements regarding these qualifications: FDA Qualification: Physicians providing, or supervising the provision of, Mifeprex must be able to assess the duration of pregnancy accurately. Comment: Mifeprex is approved only for the termination of intrauterine pregnancy through 49 days' pregnancy, yet this guideline mentions no required standard for pregnancy dating. Relying on the onset of the last menstrual period to determine early gestational age is inadequate for the purpose of early pregnancy termination with mifepristone and misoprostol. According to the American study by Spitz et al,[2] complications of mifepristone/misoprostol abortions are doubled if the gestation is 56 to 63 days, rather than 49 days, at the time of treatment. This same dating discrepancy also resulted in a nine-fold increase in the "complication" of ongoing pregnancy. For purposes of distinguishing a 49 day gestation from a 56 or 63 day gestation, the menstrual history and physical examination will often be unreliable. An imprecise estimation of gestational age is not in the best interest of women using mifepristone since complication rates double with only a one to two week dating discrepancy. Transvaginal sonography is an established standard for dating in early pregnancy. There is almost a doubling of embryonic size between 49 and 56 days gestation. For the safety of the women involved it would have been prudent for the FDA to require sonographic dating for mifepristone abortions. The

diagnose ectopic pregnancies. Comment: Ectopic pregnancy occurs in 2% of clinically recognized pregnancies in the United States, and is one of the leading causes of maternal mortality in this country. Therefore, it is imperative that it be recognized and treated in a timely fashion. A woman with an ectopic pregnancy who is mistakenly subject to an attempted mifepristone abortion may have an ongoing ectopic pregnancy, as mifepristone does not effectively abort these pregnancies. She will undoubtedly interpret bleeding and pain as consistent with a pharmaceutical abortion, since these are nearly universal effects of mifepristone and misoprostol. This leaves her with the immediate threat of serious harm, or death, if the ectopic pregnancy ruptures. Ectopic pregnancy is a contraindication to the administration of mifepristone and the only practical and reliable way to assess for ectopic pregnancy in early gestation is with sonography. Any physician prescribing mifepristone and misoprostol to a pregnant woman without first confirming an intrauterine pregnancy by ultrasound is providing suboptimal care, in our view. Women are entitled to this common evaluation in order to minimize their risk of avoidable harm. Yet ACOG has not supported any standard that would require sonographic evaluation before the administration of mifepristone/misoprostol. FDA Qualification: Physicians providing, or supervising the provision of, Mifeprex must have the ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through other qualified physicians, and be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary. Comment: Currently, in many communities, it is status quo for providers of surgical abortions at freestanding facilities to abdicate responsibility for complications of their practice. In these communities, women experiencing a complication of an abortion procedure are left on their own to initiate follow-up with another provider or local hospital emergency department. Mifepristone abortions have an emergency dilatation and curettage (D&C) rate of 2% for excessive bleeding.2 This translates to an estimated 8,000 emergency D&Cs per year in the United States. What assurance do women have that complications of these abortions will be handled differently then in current practice? We urge ACOG to advocate a standard of full physician responsibility for obtaining appropriate consultation and follow-up care in abortion practice–a standard common to other arenas of medical care, but frequently not followed in current abortion practice. FDA Qualification: Physicians providing, or supervising the provision of, Mifeprex must provide each patient with a Medication Guide and 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 both the Medication Guide and the Patient Agreement, obtain her signature on the Patient Agreement and must sign it as well. Comment: The FDA's RU 486 approval letter indicates that application for the drug was approved under 21 CFR 314 Subpart H.1 Subpart H–Accelerated Approval of New Drugs for Serious or Life Threatening Illness–is FDA policy which was instituted to provide expedited approval of new treatments for acquired immunodeficiency syndrome

is termination of early pregnancy. This dishonest use of the FDA's protocol to approve Mifeprex slights American women. Drugs approved under this accelerated approval process can still be considered new and experimental, which generally means that manufacturers and sellers of the drug cannot be held strictly liable for injuries sustained from its use. Patients injured by mifepristone may have less legal recourse to a tort action. Yet there is no requirement that women be informed that they are using a medication not subjected to the usual testing requirements of the FDA and which may have unknown risks. Information about this is not included in the Medication Guide provided for patients, or in the Patient Agreement they sign. Nor is it acknowledged in the literature prepared for abortion providers. ACOG should insist that women be notified of this unique status of mifepristone as part of appropriate informed consent. Anything less is an abandonment of quality assurance and patient safety in favor of easy access to abortion. Further, in another unprecedented move, the FDA did not release the name of the Chinese pharmaceutical firm manufacturing the Mifeprex sold in the United States. This is particularly concerning as there have been recent quality control concerns related to other pharmaceuticals imported from this same manufacturer. It is not clear what warranted the withholding of this information from the American public, especially by a federal agency charged with protecting consumers and patients. With these actions the FDA has applied a lower standard for approving and overseeing the safety of this drug compared to other pharmaceuticals. Meanwhile, the American College of Obstetricians and Gynecologists, self-titled "Advocates for women's health in the 21st century," has been silent with regard to these matters.

The American College of Obstetricians and Gynecologists has been at the forefront of setting standards in reproductive health care for 50 years. Therefore, it is inexplicable to us, as a special interest group of ACOG, that our parent organization would champion the ready availability of mifepristone without simultaneously championing appropriately rigorous standards for the use of this agent. At this critical juncture ACOG appears to have relinquished its role as guardian of the highest standard of care for women by its refusal to explicitly address the numerous safety issues surrounding the use of this method of abortion. While reiterating our objection to the destruction of unborn human life at any stage of development, and while remaining opposed to both pharmaceutical and surgical abortions, we also recognize the new reality of mifepristone in American life. We urge ACOG to consider the potential harm done to American women if vigorous standards for its use are not developed and promulgated. This would include standards for pregnancy dating, for ruling out the presence of an ectopic gestation, for holding providers responsible for obtaining appropriate consultation and follow-up for their patients, and for ensuring that women are adequately apprised of mifepristone's experimental status and unknown risks. Without the promotion of such standards it will become increasingly clear that "access to abortion" has replaced "protection of women's health" in

Notes

1FDA Letter to Sandra P. Arnold, Vice President, Corporate Affairs, Population Council. September 28, 2000. 2 Spitz IM, Bardin CW, Benton L, Robbins A. Early pregnancy termination with mifepristone and misoprostol in the United States. N Engl J Med 1998;338:1241-1247.

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