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**Statement on Medical Abortion by Allan T. Sawyer, MD
In Regards to Arizona House Bill 2416**

Dear Committee Chairman and Committee Members,

Thank you for the opportunity to present my opinions regarding medically induced abortion as it relates to women's healthcare in the State of Arizona. Please accept my apology for being unable to present these opinions to you in person, as my practice obligations created an unavoidable conflict that prohibited my ability to speak with you directly.

The opinions that are presented below are based on my experience as a board certified obstetrician and gynecologist who has been licensed to practice medicine in the State of Arizona since 1989. In addition, I have served on numerous national committees with the American College of Obstetricians and Gynecologists (ACOG), including the Committee on Obstetric Practice and also on the Editorial Committee for the ACOG publication, Guidelines for Perinatal Care¹. Presently I serve as the Chairman of Bioethics and member of the Medical Executive Committee at Banner Thunderbird Medical Center in Glendale. I am also the Director of the Women's Health Division of HOPE Clinical Research, a clinical research organization, in Phoenix.

¹ Guidelines for Perinatal Care, American College of Obstetricians & Gynecologists, 4th Edition.



As a women's healthcare professional I am concerned about the potential for unsafe and unregulated access to medical abortion, especially as it relates to interstate, international, internet, and potential for unregulated access to these potent medications. I will present today data from published medical literature, the United States Food and Drug Administration (FDA) proceedings, and prior medical expert testimony to substantiate my concerns. As compared to surgical abortion, medical abortion with mifepristone (RU-486) increases the risk of life threatening hemorrhage, severe life threatening infections including sepsis and toxic shock syndrome, and an increased risk of subsequent ectopic pregnancy. Physician oversight in licensed and regulated clinic setting is necessary to insure minimal maternal morbidity and mortality associated with the administration of mifepristone as an abortifacient. I must also state the obvious, that the fetal mortality rate with abortion is 100%.

Medical abortion with mifepristone is only approved by the FDA for use during the first 49 days of pregnancy. ACOG has guidelines for physicians that carefully outline the counseling and selection of patients for the appropriate method of pregnancy termination. The availability of laboratory and ultrasound services under the supervision of a trained physician in a licensed facility is of paramount importance to reduce the risks of potentially life threatening complications. These issues are all addressed in the ACOG Practice Bulletin on the Medical Management of Abortion.² ACOG is careful to point out that prior to offering medical abortion to patients that the gestational age of the fetus should be confirmed by clinical evaluation or ultrasonography.

There are multiple medical contraindications to medical abortion, which include confirmed or suspected ectopic pregnancy or an undiagnosed adnexal (pelvic) mass, the presence of an intrauterine device, current long-term systemic corticosteroid therapy, chronic adrenal failure, severe anemia, known coagulopathy or anticoagulant (blood thinner) therapy, and mifepristone intolerance or allergy. Most clinical trials also excluded women as potential candidates for mifepristone if they had severe liver, renal or respiratory disease, hypertension, or cardiovascular diseases such as angina, valvular disease, arrhythmia or cardiac failure. Women who have uncontrolled seizure disorders should also not take mifepristone. Because of the risk of maternal morbidity or mortality, a complete medical history and physical examination of the patient is

² Medical Management of Abortion. ACOG Practice Bulletin, Number 67, October 2005. ACOG

paramount in order to assure correct patient selection as to the method of termination of pregnancy.

Increased Risk of Mifepristone Induced Life-Threatening Hemorrhage:

Mifepristone induced abortions are associated with more severe hemorrhage than found in surgical or spontaneous abortion. This is believed to be due to the excessive and prolonged levels of nitric oxide in the uterine tissues which stimulates dilation of the uterine blood vessels and relax the uterine muscles. This combination leads to a more severe hemorrhage which is not seen in surgical abortions.³ The FDA Adverse Event Reports (AERs) demonstrates that one of the most concerning risks of mifepristone administration for medical abortion is the risk of massive life-threatening hemorrhage.^{4 5} My experience has been that obstetric and gynecologic hemorrhage can be comparable to that seen in major trauma. Patients who potentially would receive mifepristone for a medically induced abortion should be under the care of a licensed physician in a licensed facility who is available to be able to anticipate and respond to the acute needs of these patients. Women who are considering elective abortion need appropriate counseling regarding the risks of medical versus surgical abortion in a licensed facility under the care of a licensed physician.

Increased Risk of Mifepristone Induced Sepsis and Toxic Shock Syndrome:

Mifepristone is associated with a drug-induced septic shock secondary to *clostridium sordellii*. This infection is atypical to the usual presentation of sepsis and may occur without the typical signs of infection, such as fever and tenderness. The FDA recognized that there is an atypical presentation of mifepristone induced sepsis and toxic shock syndrome and opines that if physicians and patients are properly informed of the manner in which mifepristone can cause this rapid onset of atypical sepsis, then both physicians and patients might be more aware of the atypical

³ Meich, R. Pathophysiology of Excessive Hemorrhage in Mifepristone Abortions *The Annals of Pharmacotherapy* 2007:41. www.theannals.com, DOI 10.1345/aph.1K351.

⁴ Margaret m. Gary, M.D., and Donna J. Harrison, M.D., "Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient," *Annals of Pharmacotherapy*, Dec. 27, 2005. (www.theannals.com)

⁵ Letter, David Boyer, Assistant Commissioner for Legislation, FDA, to Chairman Mark Souder, Subcommittee on Criminal Justice, Durg Policy and Human Resources, House Committee on Government Reform (May 2, 2006)("Boyer Letter")

presentation. It is essential, therefore, that mifepristone be dispensed only in a closely supervised clinical setting under the direction of a licensed physician who has the direct ability to counsel the patient regarding the risks, and also to examine the patient prior to and after administration of mifepristone. Physicians who might not be aware of the potential for an atypical presentation of life threatening sepsis and toxic shock syndrome in patients treated with mifepristone (e.g. an emergency room physician) would be at increased risk of missing the correct diagnosis of sepsis.^{6 7}

⁸ Delay in diagnosis of these serious infections will contribute to increased morbidity and mortality of women who choose medical abortion over surgical abortion. Dr. Michael Greene, a Harvard Professor of Perinatal Medicine (High Risk Obstetrics) at Massachusetts General Hospital noted a ten times higher rate of death from infection following mifepristone abortions than after surgical abortions.⁹ This finding was reported in the *New England Journal of Medicine*, of which Dr. Greene is an editor.

Increased risk of subsequent ectopic pregnancy

Medically induced abortions increase the risk of subsequent ectopic pregnancy, which is not noted with surgical abortion. Patients who are treated with medically induced abortions should be counseled by a licensed physician in a certified facility that offers both the option of medically induced abortion and surgically induced abortion, so that the patient can be given the option of which procedure she would rather have. She needs to be counseled as to the risks of both procedures so that she can make a true informed choice. Part of that informed consent process is to educate her as to the risks to subsequent pregnancy outcome caused by her choice of method of termination of pregnancy. The increased risk of ectopic pregnancy is 2.8 times higher with a history of a prior medically induced abortion, and no such association is observed for a surgical abortion.¹⁰

⁶ Sternberg, E. *Proceedings of the National Academy Sciences* 1989, 86, 2374-2378.

⁷ Fischer, M. Fatal Toxic Shock Syndrome Associated with *Clostridium sordellii* after Medical Abortion, *New England Journal of Medicine* 2005;353:2352-60.

⁸ Miech, RP. Pathophysiology of Mifepristone-Induced Septic Shock Due to *Clostridium sordellii*, *The Annals of Pharmacotherapy*, 2005; 39:xxxx. www.theannals.com DOI 10.1345/aph.1G189.

⁹ Greene, MF, Fatal Infections Associated with Mifepristone-Induced Abortion, *New England Journal of Medicine* 2005; 353.

¹⁰ Bouyer, J. et al, Risk Factors for Ectopic Pregnancy: A Comprehensive Analysis Based on a Large Case-Control, Population-based Study in France, *American Journal of Epidemiology*, 2003;157:185-194.

Summary:

The medical management of abortion requires close physician supervision in a licensed facility where patients who are considering termination of pregnancy may be counseled and cared for in order to reduce the risks of potentially life threatening complications. The risks of medical abortion are greater than surgical abortion. The infections associated with mifepristone use can present in an atypical fashion, and physicians who are experienced and knowledgeable of this presentation of sepsis and toxic shock syndrome need to be following these patients and evaluating them following the administration of these medications in order to reduce the potential maternal morbidity or mortality associated with medical abortion. Patients who attempt to take mifepristone who are not under the care of a physician have the additional risk of failure to diagnose an ectopic pregnancy, which is a fairly common complication of pregnancy, occurring in approximately one in two hundred pregnancies. Failure to recognize an ectopic pregnancy can lead to life threatening hemorrhage. Physician supervision and the availability of laboratory testing and ultrasound dramatically reduce the risk of failure to diagnose an ectopic pregnancy.

These medications should not be permitted to be dispensed across state borders, via the internet, or in any fashion that dispenses these medications without direct physician supervision in a licensed facility. If patients are able to obtain these medications without direct physician oversight, then they are at risk of consuming the medication beyond the first 49 days of gestation, which can further raise the risk of complications, hemorrhage and infection. Since there are numerous contraindications and complications related to mifepristone administration, direct physician supervision and examination of the patient is required. ¹¹

Respectfully submitted,



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¹¹ Medical Management of Abortion. ACOG Practice Bulletin, Number 67, October 2005. ACOG