Position on the Recent Judicial Challenge of U.S. Food and Drug Administration Approval of Mifepristone

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The position of the American College of Medical Toxicology (ACMT) is as follows:

ACMT supports the role of the U.S. Food and Drug Administration (FDA) to ensure the safety and effectiveness of drugs. Recently, there have been legal efforts to reverse the 2000 U.S. FDA approval of mifepristone, a medication with over two decades of established safety and efficacy. Revoking mifepristone approval would not only undermine the robust FDA approval process and overturn precedent on scientific regulation of drugs, but will limit access to the medication, which will have harmful consequences. This decision would prevent patients from having access to mifepristone for medication abortion and early pregnancy loss, leading to an increase in complications and unnecessary surgical procedures.

Background

Mifepristone is FDA-approved [1,2]. Many studies and over two decades of experience have demonstrated this drug to be safe, effective, and well tolerated. Adverse effects are typically not severe and include vaginal bleeding, pelvic cramping, gastrointestinal discomfort, headache, and dizziness [1,3]. FDA required implementation of a Risk Evaluation and Mitigation Strategy (REMS) with approval of the drug with the intent of preventing misdiagnosis of an ectopic pregnancy (which cannot be managed with mifepristone) not due to inherent toxicity of the drug [4].

Legal Context

Historically, regulation and approval of medications based on safety and efficacy have been a federal responsibility superseding state and local law. FDA was established and delegated this responsibility by Congress largely in two successive legislative acts in 1906 and 1938 [5]. On April 7, 2023, a federal district court in Texas issued a ruling in favor of the plaintiffs in a lawsuit against FDA and the U.S. Health and Human Services over the approval of mifepristone [6]. This ruling, which is currently under appeal, would effectively reverse FDA approval of the drug.

Public Health and Policy Implications

Overturning FDA's approval of mifepristone in the Courts would result in serious negative policy and public health consequences.

A ruling against the FDA undermines the agency's robust drug approval process. As part of the drug approval process, drug manufacturers send the FDA evidence from studies to determine the safety and effectiveness of the drug for its intended use. Experts at the FDA, with the help of external advisers, evaluate applications and approve the medication if a drug is safe and effective and that the drug's benefits outweigh the known and potential risks [7]. Not only has mifepristone undergone the appropriate approval process, but it has over two decades of clinical experience and FDA postmarketing surveillance that demonstrate it is safe and effective and that serious adverse effects are rare [8,9].

The American College of Obstetrics and Gynecology [10,11], the American Medical Association, the American Academy of Family Physicians, Society for Maternal-Fetal Medicine, recognize mifepristone as safe. Determination of a medication's safety and effectiveness should lie with the FDA and should be based on robust scientific evidence combined with clinical experience and not with the determination of a judge or tribunal that lacks the requisite expertise.

Summary

In summary, mifepristone has over two decades of safety and efficacy data supporting its use. We oppose this unprecedented abrogation of established FDA authority. A decision to overturn the FDA approval will undermine the FDA approval process and allow the robust body of scientific literature for this approval to be ignored. Moreover, it will result in harm to patients and to public health. ACMT supports the rigor of the FDA approval process and patient access to medications with a proven safety record and joins other medical societies in doing so.

References

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