



Crohn's & Colitis Foundation

Support of FDA Authority for Drug Approval

Mifepristone Decision Position Statement

On April 7, in an unprecedented decision, a Texas federal judge invalidated the Food and Drug Administration's (FDA) approval of a drug that was approved by the agency in 2000. The drug, mifepristone, is used for medical abortions, but the ruling has implications far greater than this drug.

Since 1938, Congress has given the FDA the sole authority to approve drugs in the U.S. For decades, the agency has rigorously tested and reviewed drug efficacy and safety through multiple phases of lab and clinical testing. The results are reviewed by scientists and medical experts at every stage of the testing and approval process, and then monitored for safety after the drug is on the market.

The Crohn's & Colitis Foundation, representing the millions of Americans who live with inflammatory bowel disease (IBD) and the professional health care providers and scientists who support them supports the scientific oversight of drugs and regulation by the FDA, and we are deeply concerned about the potential impact this decision will have on the FDA's approval and regulation of the medications our patients rely upon for treatment of IBD, including Crohn's disease and ulcerative colitis.

The precedent and repercussions of this decision may be far-reaching for drug research and development, and undermines the authority of the FDA and the scientific process that leads to safe and effective treatments for patients. This in turn will result in preventing patients from getting the medical care they need.

The Crohn's & Colitis Foundation urges the courts to overturn this ruling and stands in strong support of the current jurisdiction of the FDA.