

ONE HUNDRED EIGHTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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WASHINGTON, DC 20515-6115

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April 12, 2023

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Brett Guthrie
Chairman, Subcommittee on Health
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chair Rodgers and Chairman Guthrie,

We write to request that the Energy and Commerce Committee immediately schedule a hearing on the unprecedented decision by a federal court in the Northern District of Texas staying the approval of mifepristone, a drug that has been approved by the Food and Drug Administration (FDA) for more than 22 years.¹ On April 7, 2023, in *Alliance for Hippocratic Medicine v. FDA*, Judge Matthew Kacsmaryk stayed FDA's approval of the drug throughout the United States after April 14, 2023. This lawsuit is a blatant attempt to eradicate access for women to a safe medication for the termination of pregnancy and effectuate a nationwide abortion ban. Judge Kacsmaryk's decision willingly supplants FDA's scientific decision-making to the detriment of patients, our nation's public health, and all Americans who rely on FDA-approved medications.

We have grave concerns about the ongoing attacks to reproductive health care in the United States, and the implications for those who seek abortion care following the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, which overturned nearly 50 years of precedent protecting the Constitutional right to abortion. Unfortunately, *Alliance for Hippocratic Medicine* is one more example of ideologically driven litigation that is intended to restrict abortion access and block women from obtaining the care they need, while also turning back the clock on reproductive rights and bodily autonomy.

However, the District Court's ruling in *Alliance for Hippocratic Medicine* could also have far-reaching effects beyond abortion access, by second-guessing the expertise of our public health agencies and creating uncertainty for Americans who rely on life-saving medications approved by FDA every day.

¹ *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, No. 2:22-CV-00223-Z (N. Dist. Tx. Apr. 7, 2023) (order granting preliminary injunction in part).

As Members of the Committee of jurisdiction over FDA and our nation’s drug approval process, we have an important responsibility to review and consider any detrimental impacts or threats to FDA’s “Gold Standard” of review. Given the implications of this decision, we believe it is important for the Committee to hear from experts about how the outcome of this case attempts to undermine the drug approval process, restricts access to an FDA-approved medication, and places ideology, politics, and judicial activism above science.

More than a dozen renowned food and drug law scholars have noted that the outcome in this case could “profoundly undermine the well-established statutory and regulatory framework for the approval of new drugs and the due process accorded to drug marketing application holders by statute.”² These experts also emphasized that requiring FDA to suspend or withdraw the approval of mifepristone would “create harmful reverberations that would affect patients, healthcare providers, and the biopharmaceutical industry, all of whom rely on the expertise of FDA to make scientific determinations regarding the safety and effectiveness of our nation’s medical products.”³ Given the breadth of these stakeholders and implications, it is critical that we hear from those impacted on the effects of this decision.

The Committee, and the American people, must understand the impact of this decision and what is at stake for not only abortion care, but also for access to critical safe and effective medications more broadly. As such, we request that the Committee convene a hearing as soon as possible on this issue.

Thank you for your consideration.

Sincerely,



Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce



Anna G. Eshoo
Ranking Member
Subcommittee on Health

² Brief of Food and Drug Law Scholars as *Amici Curiae*, *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, No. 2:22-CV-00223-Z (N. Dist. Tx.) (filed Feb. 10, 2023).

³ *Id.*



Diana DeGette
Ranking Member
Subcommittee on Energy, Climate, and
Grid Security



Jan Schakowsky
Ranking Member
Subcommittee on Innovation, Data, and
Commerce



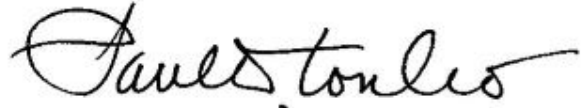
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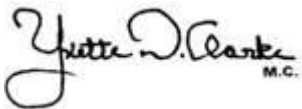
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