

In Support of FDA's Authority to Regulate Medicines

On Friday, April 7, a federal judge with no scientific training fundamentally undermined the bipartisan authority granted by Congress to the Food and Drug Administration to approve and regulate safe, effective medicines for every American.

District Judge Matthew Kacsmaryk issued a decision that overturns the FDA's 23-year old approval of mifepristone, the primary medicine used in abortion and miscarriage care, and which has been proven by decades of data to be safer than Tylenol, nearly all antibiotics and insulin.

The decision ignores decades of scientific evidence and legal precedent. Judge Kacsmaryk's act of judicial interference has set a precedent for diminishing FDA's authority over drug approvals, and in so doing, creates uncertainty for the entire biopharma industry. As an industry we count on the FDA's autonomy and authority to bring new medicines to patients under a reliable regulatory process for drug evaluation and approval. Adding regulatory uncertainty to the already inherently risky work of discovering and developing new medicines will likely have the effect of reducing incentives for investment, endangering the innovation that characterizes our industry.

Judicial activism will not stop here. If courts can overturn drug approvals without regard for science or evidence, or for the complexity required to fully vet the safety and efficacy of new drugs, any medicine is at risk for the same outcome as mifepristone. While the drug development, approval and monitoring process is not perfect, the Agency's framework has resulted in decades of unsurpassed medical innovation and in statutory mechanisms to remove drugs from the market if, among other reasons, they fail to maintain the anticipated safety and efficacy profile.

As an industry dedicated to improving human health, and as members of the biopharma industry, we add our signatures to [this letter](#) and stand together to unequivocally support the continued authority of the FDA to regulate new medicines.

In the face of laws and rulings that aim to undermine the evidence-based and legislatively sanctioned authority of federally mandated institutions such as FDA to protect public interests, and by putting an entire industry focused on medical innovation at risk, we cannot stay quiet. We call for the reversal of this decision to disregard science, and the appropriate restitution of the mandate for the safety and efficacy of medicines for all with the FDA, the agency entrusted to do so in the first place.

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