



Preparedness For When the Courts and Medicines Collide

The recent decision by a Texas judge to rescind the FDA's approval of mifepristone, a drug used for abortions, has created ripple effects across the life sciences sector, fueling concerns that future decisions on any therapy could be circumvented through the courts. The action has been seen by many as unprecedented, as it could reverse a 23-year-old market approval of the drug.¹

A cross-section of patient and provider groups – from the American Cancer Society to the American Medical Association to the National Health Council – [said in a joint statement](#) that, “the implications of this ruling go far beyond mifepristone. This decision risks emboldening other courts to block access to FDA-approved drugs and treatments for reasons having nothing to do with their safety or efficacy.”² Health and Human Services Secretary [Xavier Becerra suggested](#) insulin, vaccines and new Alzheimer's drugs could also come under scrutiny if the ruling is upheld.³

[A letter](#) signed by more than 400 life sciences executives representing a broad cross section of innovators⁴ extended the patient and provider community's alarm by affirming that, even though “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.”

Strategic Communications Considerations

While this legal process will continue playing out after the Supreme Court preserved access to mifepristone⁵, life science companies, with innovations and treatments that range from therapeutics and treatments of the rarest of diseases to the creation of generics, have an opportunity to outline how to protect their products, pipeline and patients through a strategic communications strategy. While not exhaustive, some areas to consider include:



Review existing legal and reputation challenges on the value of any medicines under an issues microscope. Outlining clear communications strategies for any of these products allows a company to be prepared to handle any potential short-term needs and allows for establishing a more enduring message strategy



Proactively build public awareness about your company's position as external stakeholders will continue looking to the life sciences industry for leadership as they have during other public health crises



Engage advocates and employees by providing opportunities, such as town halls, 1:1 discussions, or external roundtables to address questions and concerns, and to educate on the issue and solicit support for extending company messages

This latest legal decision has proven once again how extraordinary events can merge seemingly out of nowhere to create a marketplace moment for the healthcare industry. None of those are typically the daily focus of executives. Keeping that leadership group apprised is critical to supporting organizational readiness among the Legal, Medical Affairs, Communications and Public Affairs teams if the need to take action arises.

The term “unprecedented” has been used by numerous experts and news stories to describe this key health policy inflection point. It certainly will not be the last event likely to cause another national debate and prompt swift, sector-wide action. Organizations should now be evaluating how to navigate the next issue that challenges existing regulatory frameworks the industry and patients have come to rely on.

Endnotes

- ¹ ABC News. “Unprecedented Texas abortion pill ruling sparks debate about ‘judge shopping.’” April 13, 2023. <https://abcnews.go.com/Politics/unprecedented-texas-abortion-pill-ruling-sparks-debate-judge/story?id=98531203>
- ² National Health Council. “31 PATIENT AND PROVIDER GROUPS WARN THAT MIFEPRISTONE RULING THREATENS ALL FDA-APPROVED DRUGS.” April 11, 2023. https://nationalhealthcouncil.org/news-releases/31-patient-and-provider-groups-warn-that-mifepristone-ruling-threatens-all-fda-approved-drugs/?utm_source=rss&utm_medium=rss&utm_campaign=31-patient-and-provider-groups-warn-that-mifepristone-ruling-threatens-all-fda-approved-drugs
- ³ Politico. “The abortion pill rulings are scaring the FDA and drugmakers. Here’s why.” April 10 2023. <https://www.politico.com/news/2023/04/10/abortion-pill-rulings-fda-00091264>
- ⁴ New York Times. “Drug Company Leaders Condemn Ruling Invalidating F.D.A.’s Approval of Abortion Pill.” April 10, 2023. <https://www.nytimes.com/2023/04/10/health/abortion-ruling-pharma-executives.html#:~:text=The%20statement%20was%20signed%20by,case%20stretches%20far%20beyond%20abortion>
- ⁵ Washington Post. “Read the Supreme Court’s decision on abortion pill mifepristone.” April 21, 2023. <https://www.washingtonpost.com/politics/2023/04/21/supreme-court-mifepristone-ruling-decision/>

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