Legal Dispute Surrounding Abortion Pill Has Significant Implications for Broader Healthcare Industry

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On November 18, 2022, the Alliance for Hippocratic Medicine and several other plaintiffs ("Plaintiffs") filed suit in federal court against the Food and Drug Administration (the "FDA"), seeking to overturn the FDA's approval of mifepristone, a drug commonly used for medication abortions, as well as in the management of miscarriage and in the treatment of certain diseases (the "*AHM* Litigation"). After expedited briefing and a hearing, Northern District of Texas Judge Matthew Kacsmaryk issued a preliminary order that would effectively remove mifepristone from the market nationwide for use in the termination of pregnancy. The court signaled its belief that both the FDA's initial approval and its subsequent decision to eliminate certain restrictions on its use were arbitrary and capricious because the FDA had allegedly failed to consider relevant safety data.

While the merits of this case have yet to be fully litigated—and the Supreme Court has temporarily preserved the status quo—this case may have significant implications for the broader healthcare industry, including FDA-regulated entities as well as providers, insurers, and even companies that subsidize healthcare for their employees.

The Complaint

Plaintiffs allege that the FDA violated the Administrative Procedure Act (the "APA") when first approving mifepristone in 2000—and again when later removing certain restrictions on its use and approving a generic version—because the FDA lacked the legal authority to approve the drug in the first place, and because the FDA's decisions were not supported by the scientific evidence.

First, Plaintiffs allege that the FDA did not have the authority to approve mifepristone. In 2000, the FDA approved mifepristone pursuant to 21 C.F.R. § 314, Subpart H, which authorizes the FDA to grant accelerated approval to certain new drugs intended to treat serious or life-threatening illnesses. Plaintiffs claim that mifepristone did not meet the requirements for expedited approval and also allege that the FDA never required or reviewed safety studies involving pregnant persons under the age of 18.

Second, Plaintiffs allege that in 2016, the FDA improperly eliminated certain restrictions on prescribing mifepristone, including extending the window in which it may be prescribed for medication abortion from 49 to 70 days of gestation, reducing the number of required in-office visits from three to one, and eliminating certain adverse event reporting requirements.

Third, Plaintiffs argue that the FDA's announcement on December 16, 2021 that it had modified the Risk Evaluation and Mitigation Strategies ("REMS") for mifepristone to formally remove the in-person dispensing requirement was contrary to federal law. Plaintiffs also allege that certain changes violate federal law under the Comstock Act, even though the Department of Justice ("DOJ") published a memo in December 2022, concluding that the Comstock Act does not prohibit the mailing of mifepristone.

The Federal District Court Decision

On April 7, 2023, the District Court ruled on Plaintiffs' motion for a preliminary injunction and effectively enjoined: (i) the FDA's 2000 approval of mifepristone, (ii) the FDA's 2016 changes to the REMS, (iii) the 2019 generic approval, and (iv) the 2021 REMS changes. Judge Kacsmaryk's ruling would have halted the use of mifepristone nationwide pending a ruling on the merits.

The court concluded that Plaintiffs were likely to prevail on effectively every element of their complaint, finding that the FDA's decisions likely exceeded its statutory authority, were arbitrary and capricious, and violated federal law. The court adopted nearly all of Plaintiffs' arguments, including the theory that mifepristone is fundamentally unsafe and should never have been approved in the first place (by citing, among other things, statistics from studies authored by anti-abortion advocacy groups that have been widely criticized by medical and public health researchers for their methodological flaws). The order included a seven-day stay to allow the FDA and mifepristone manufacturer Danco Laboratories ("Danco"), who had intervened in the lawsuit as a defendant, time to appeal the ruling.

Competing Injunction from Federal Court in Washington

To further complicate matters, in February 2023, seventeen states[1] and the District of Columbia ("Plaintiff States") sued the FDA in the federal district court for the Eastern

[1] Plaintiff States are Arizona, Colorado, Connecticut, Delaware, Illinois, Michigan, Nevada, New Mexico, Oregon, Rhode Island, Vermont, Hawaii, Maine, Maryland, Minnesota, Pennsylvania and Washington.

District of Washington, challenging the remaining restrictions under the mifepristone REMS as medically unnecessary and seeking a declaration that mifepristone is safe and effective. Less than 30 minutes after the Northern District of Texas Court's ruling, the judge in the Eastern District of Washington issued a conflicting injunction ordering the FDA *not* to change the REMS currently in place for mifepristone in any of the Plaintiff States. The court preliminarily enjoined the FDA from "altering the status quo and rights as it relates to the availability of Mifepristone under the current operative 2023 [REMS]" in the Plaintiff States. However, the court declined to issue a nationwide injunction, finding it an unnecessary remedy to protect the interests of the Plaintiff States and citing the likelihood of competing litigation in this area.

The Appeals on the Stay

Following the Northern District of Texas Court's ruling, the FDA filed an emergency appeal to the Fifth Circuit Court of Appeals, arguing that the lower court's ruling "upended decades of reliance by blocking the FDA's approval of mifepristone and depriving patients of access to safe and effective treatment, based on the court's own misguided assessment of the drug's safety."

The Fifth Circuit granted the request in part—staying the District Court's order as to the FDA's initial approval of mifepristone in 2000, but declining to protect subsequent FDA decisions involving the drug from 2016 onward. While this would, in theory, have kept the drug legal, in practice it would likely cause regulatory chaos—with pharmaceutical companies, physicians, and patients needing to respond to significant policy changes that would occur overnight.

On April 14, 2023, the FDA and Danco, sought emergency relief from the United States Supreme Court, requesting a temporary stay of the District Court's order pending full appeal to the Fifth Circuit and, if necessary an application for further relief from the Supreme Court. With the seven-day administrative stay set to expire at midnight on April 14, the Supreme Court twice extended the stay by a few days to give the court additional time to consider the request.

On April 21, 2023, the Supreme Court ruled 7-2 (Justices Alito and Thomas dissenting) in favor of the FDA and Danco, staying the District Court's order until it could be heard in full by the Fifth Circuit on an expedited basis. The majority did not issue a written opinion—a common approach for emergency appeals—but Justice Alito issued a short dissent, effectively agreeing with the Fifth Circuit that reverting to the restrictions in place prior to 2016 would not cause irreparable harm.

Opening briefs were filed with the Fifth Circuit on April 26, 2023, and oral argument is set for May 17, 2023.

Implications for Abortion Access

Despite being approved by the FDA approximately 23 years ago, the use of mifepristone for medication abortion may ultimately be banned nationwide—including in states where abortion is legal. The Fifth Circuit is currently considering the District Court's preliminary order, which may end up before the Supreme Court a second time. After the second round of appeals is complete, the case is expected to return to the District Court for a hearing and decision on the merits—which would then likely be appealed.

At each stage of the litigation, Debevoise has filed *amicus curiae* briefs on behalf of our clients the American College of Obstetricians and Gynecologists, the American Medical Association, and many other leading medical and public health organizations. The *amicus* briefs describe in detail the extensive scientific evidence supporting mifepristone's safety and efficacy, as well as the substantial negative impact that removing or limiting access to mifepristone would have on patients across the country.

Broader Impact on Healthcare Industry

If the District Court's order is ultimately upheld, it would be the first time a court has applied its own medical judgment to assess drug safety and efficacy in order to reverse an FDA prescription drug approval. The District Court's decision represents an unprecedented encroachment by the judicial branch into complex scientific and medical determinations traditionally assessed by regulatory agencies with relevant expertise such as the FDA. Moreover, it would set a precedent that could disrupt the FDA approval process and potentially jeopardize other FDA drug (and device) approvals that may also be second-guessed by a federal judge.

While framed as a "stay of the effective date" of mifepristone's approval, it is, in effect, a judicially ordered withdrawal of an FDA-approved drug. The authority, however, to withdraw a prescription drug is statutorily delegated to the FDA, which has promulgated detailed rules governing the withdrawal process.

Affirming the decision to withdraw the approval of mifepristone would have a significant short-term and long-term impact on the healthcare industry. To begin with, it would put mifepristone in legal limbo. Because a court order overriding FDA approval is unprecedented, its practical function is not clear. Justice Alito raised the theoretical

possibility in his dissent that the FDA could exercise its enforcement discretion and allow mifepristone to remain on the market. Equally unclear is the impact of the competing injunction issued by the federal court in Washington.

Stakeholders across the healthcare landscape would also be impacted by the District Court's order. Any provider who historically prescribed mifepristone would suddenly be unable to prescribe the drug, which is widely prescribed off-label for miscarriage management and other conditions, not just abortion—impacting hospitals and physician practices. Any pharmacy or other retailer who sells mifepristone would also be put in the challenging position of having to interpret and navigate competing judicial orders and the FDA's own enforcement authority. Insurers (and private companies that provide insurance for their employees) would be faced with a similar uncertainty, and might need to reimburse for a potentially more expensive (and harder to obtain) procedural abortion.

Of additional concern to the healthcare sector is that the District Court's reasoning would create precedent for private plaintiffs to challenge any FDA risk-benefit determination for drugs, devices, or other FDA-regulated products. This in turn would cause widespread uncertainty for the pharmaceutical and medical device industries that could have a chilling effect on R&D and product development. While many are focused on the Supreme Court's May 1, 2023 decision to grant certiorari in *Loper Bright Enterprises, et al. v. Raimondo, et al*., to consider overruling the long-standing *Chevron* doctrine as heralding broader doctrinal changes to judicial deference to administrative agency action, the *AHM* litigation confirms that shift is already well underway.

This is an evolving issue of significant importance and we will continue to monitor these cases and provide updates as warranted.

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