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New Challenge to Abortion Access Takes on FDA Drug Approvals

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On November 18, 2022, a collection of organizations and providers that oppose abortion filed suit against the US Food and Drug Administration (FDA) and the US Department of Health and Human Services (HHS), seeking — among other things — a permanent injunction ordering the withdrawal of the FDA approvals for mifepristone and misoprostol for use in the provision of abortion.

- In this newly filed case, titled *Alliance for Hippocratic Medicine, et al. v. US Food and Drug Administration, et al.*, 2:22-cv-00223, in the US District Court for the Northern District of Texas, the plaintiffs challenge six FDA actions related to the Mifeprex approval, generic mifepristone approval, and Risk Evaluation and Mitigation Strategy (REMS) under the Administrative Procedure Act (5 USC § 706).

- Mifepristone is used together with misoprostol to end an early pregnancy. FDA first approved Mifeprex (mifepristone) in 2000 with a REMS, which was subsequently updated in 2016. To note, misoprostol is not independently approved by FDA for use in the provision of abortion. Rather, the agency included misoprostol as part of the regimen for terminating pregnancy with mifepristone.

- Ultimately, the plaintiffs seek a preliminary and permanent injunction ordering FDA and HHS to withdraw FDA's approval of both mifepristone and misoprostol for use in the provision of abortion and to withdraw FDA's actions "to deregulate" these drugs.

In the complaint, the plaintiffs challenge the following "six discrete [a]gency actions," spanning from the first FDA approval of Mifeprex in 2000 to the agency's 2021 response to a citizen petition regarding the drug's REMS:

1. FDA’s 2000 approval of the New Drug Application (NDA) for Mifeprex

2. FDA’s 2016 denial of a 2002 Citizen Petition raising concerns related to the approval and safety of Mifeprex

3. FDA’s 2016 approval of the updated REMS, which, among other things, expanded the gestational age for which mifepristone was approved and allowed for the administration of misoprostol at home rather than in a clinical setting

4. FDA’s 2019 approval of the Abbreviated New Drug Application (ANDA) for generic mifepristone

5. FDA’s 2021 decision to exercise enforcement discretion with respect to the in-person dispensing requirement under the REMS

6. FDA’s 2021 denial of a 2019 citizen petition raising concerns regarding the updated REMS and petitioning for further clinical studies

Plaintiffs allege that each of these actions (1) was in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, and (2) was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, and, as such, constitutes a violation of the Administrative Procedure Act.

In combination, and among other contentions, the complaint’s six claims for relief levy the following allegations:

- The accelerated approval pathway provided in 21 CFR. Part 314, Subpart H — under which FDA approved Mifeprex — applies only to drugs intended to treat serious or life?threatening illnesses, a category inapplicable to pregnancy.

- Both the 2000 Mifeprex approval and 2016 changes to the REMS were based upon flawed clinical trials, which failed to show that the drug is safe and effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling.

- Both the 2000 Mifeprex approval and 2016 changes to the REMS violated the Pediatric Research Equity Act (PREA) because (1) FDA waived the pediatric study requirement for the 2000 Mifeprex approval despite no qualifications for such waiver being met, and (2) during the 2016 REMS update, FDA reached its conclusion regarding the safety and effectiveness of mifepristone use in pediatrics by impermissibly extrapolating from studies conducted on adults.

- FDA impermissibly mandated the use of misoprostol as part of the 2000 Mifeprex approval, despite the fact that no supplemental NDA was submitted for this new use of misoprostol.

- A 2002 citizen petition submitted to FDA provided the agency “with substantial legal arguments that [the 2000 approval of Mifeprex] exceeded [FDA’s] authority and was not in accordance with law,” yet the agency denied the petition in 2016.

- FDA’s 2019 approval of the ANDA for mifepristone relied upon the “unlawful” 2000 Mifeprex

approval, rendering the 2019 ANDA approval itself unlawful for the same reasons described above.

- FDA's actions in allowing the mailing of mifepristone were expressly prohibited by federal law under 18 USC §§ 1461-62.

- A 2019 citizen petition submitted to FDA provided the agency with "significant data" to justify reverting to the pre-2016 REMS, strengthening the REMS generally, and requiring a formal study of outcomes for certain populations, including girls under 18 years of age. The agency denied the petition in 2021.

- FDA's "illegal and unreasonable rationales" for several of the actions above — including the 2000 Mifeprex approval and the 2016 changes to the REMS — especially "in light of the political context of the [a]gency's actions," indicate that the stated reasons for the actions are mere "pretext."

As the case is still in its infancy, it remains to be seen how it will progress. ArentFox Schiff will be closely monitoring the docket and providing updates as the case continues forward.

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