FDA's Recent Litigation Records Are Strong, But Imperfect

By **Jonathan Berman and Colleen Heisey** (December 14, 2023)

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Litigating against the U.S. Food and Drug Administration can be a daunting task.

Depending on the circumstances, courts might defer to the FDA's positions due to the FDA's scientific expertise, its authority to administer the governing statutes and its discretion when setting its own agenda.

Administrative law principles relating to ripeness create additional barriers, particularly for litigants who want to resolve their disputes quickly. It is therefore no surprise that over the past two years, the FDA has notched its share of litigation wins, due in large part to these advantages.

But we do not live in ordinary times. The FDA has found itself litigating some highly visible, hot-button issues, and has been considerably less successful in these arenas.

Mifepristone

In 2023, the most widely publicized cases involving the FDA centered on the drug mifepristone. Mifepristone was approved by the FDA in 2000 "for the medical termination of intrauterine pregnancy through 49 days' pregnancy," and was more recently characterized by the U.S. Court of Appeals for the Fifth Circuit as "a drug used to cause abortion," in *Alliance for Hippocratic Medicine v. FDA*.[1]

Challenges regarding this approval, and regarding changes to the drug's Risk Evaluation and Mitigation Strategy,[2] or REMS, safety program, have resulted in a thicket of conflicting decisions.

On April 7, the U.S. District Court for the Eastern District of Washington entered a preliminary injunction in *State of Washington v. FDA*, enjoining the FDA from changing the REMS for mifepristone, as applicable in 17 states and Washington, D.C.[3]

That same day, the U.S. District Court for the Northern District of Texas entered a preliminary injunction in *Alliance for Hippocratic Medicine v. FDA*, staying the original approval of mifepristone, finding that the FDA was arbitrary and capricious in approving the drug, in approving generic versions of the drug, and in making changes to the REMS in 2016.[4]

The U.S. Supreme Court stayed the Texas order pending appeal and pending disposition of petitions for writ of certiorari.[5] The Fifth Circuit then issued a lengthy opinion that vacated in part and affirmed in part the Texas order, noting that "all of this relief is subject to the Supreme Court's prior [stay] order."[6]

Meanwhile, in Whole Woman's Health Alliance v. FDA, the U.S. District Court for the Western District of Virginia denied a motion for a preliminary injunction that would have enjoined any attempt at "altering the status quo," finding such relief unwarranted in light of

the orders already in place.[7]

All of these cases remain pending. On Dec. 13, the Supreme Court agreed to review the Fifth Circuit's decision, granting cert petitions filed by the FDA and a drug manufacturer, although denying the petition for certiorari filed by the plaintiffs.[8]

The importance of these cases extends well beyond the scope of this article. Of note to the development of administrative law, however, is the willingness of courts to delve into areas implicating the core of the FDA's technical expertise.

The merits portion of the Fifth Circuit's decision, for example, turned on that court's conclusion that data in the FDA Adverse Event Reporting System did not support the FDA's decision to relax the requirements of the REMS safety program.[9]

The Washington court reached an inconsistent decision — that the existence of any REMS program was likely arbitrary and capricious — finding that the FDA failed to properly consider the need for such a program in light of "potentially internally inconsistent FDA findings regarding mifepristone's safety profile."[10]

Treatments for COVID-19 and Public Warnings

For many years, the FDA has issued public warnings in a variety of settings.

In September, the Fifth Circuit narrowed the FDA's ability to do so, holding: "FDA is not a physician. It has authority to inform, announce, and apprise — but not to endorse, denounce, or advise."[11] This holding was issued in *Apter v. U.S. Department of Health and Human Services*, a lawsuit brought by doctors who prescribe ivermectin as a treatment for COVID-19.

Ivermectin is the active ingredient in a variety of FDA-approved drugs, including both human drugs and animal drugs. These products are approved as anti-parasitic agents. The FDA has not approved ivermectin for the treatment of COVID-19.

Seeing that ivermectin was nonetheless frequently used to treat COVID-19, the FDA launched a publicity campaign to discourage this use. The FDA argued that its publicity campaign was authorized under the FDA's inherent authority, under its statutory mission to "promote the public health," and under express authority to "cause to be disseminated information regarding … drugs … in situations involving … imminent danger to health or gross deception of the consumer."[12]

The Fifth Circuit disagreed, holding that the anti-ivermectin publicity campaign was ultra vires: "FDA can inform, but it has identified no authority allowing it to recommend consumers 'stop' taking medicine."[13]

The FDA fared better in a pair of cases brought by an organization that sought to revoke approvals and emergency use authorizations for vaccines intended to prevent COVID-19. In both cases, the courts found that the organization and its members lacked standing in the absence of any mandate requiring them to be vaccinated with these products.[14]

General Litigation

The FDA fared best in litigation that was conducted far from the limelight. Multiple courts viewed as decisive the deference owed to the FDA.

- In *Vanda Pharmaceuticals Inc. v. FDA* in August, the U.S. District Court for the District of Columbia held that the FDA's refusal to grant a fast-track designation to an investigational drug intended to treat gastroparesis was not arbitrary or capricious: "Defining an unmet medical need is a scientific judgment within the agency's area of expertise, and the Court gives it a high level of deference."[15]

- In *McAfee v. FDA* last year, the U.S. Court of Appeals for the District of Columbia Circuit held that the FDA had the discretion to refuse to engage in a rulemaking proceeding to redefine the standard of identity for butter: "An agency decision to deny a petition for rulemaking is subject to only extremely limited and highly deferential review."[16]

- In *Natural Resources Defense Council Inc. v. FDA* last year, the U.S. District Court for the Southern District of New York held that the FDA's decision to exempt from regulation a chemical used in food packaging, at low levels of exposure, was not arbitrary and capricious: "Courts should be particularly reluctant to second-guess agency choices involving scientific disputes that are in the agency's province of expertise. Deference is desirable."[17]

The FDA also won cases that courts deemed premature.

In two cases last year — *Arrow Reliance Inc. v. Woodcock* in the U.S. District Court for the Western District of Washington and *Wedgewood Village Pharmacy v. FDA* in the U.S. District Court for the District of New Jersey — manufacturers anticipated that the FDA would soon make damaging public statements relating to inspections of the manufacturers' facilities. The courts refused to enjoin the FDA from doing so, finding that the disputes were not ripe because the FDA had not yet issued any such public statement.[18]

Also last year, the D.C. district court ruled in *Nostrum Pharmaeuticals LLC v. FDA* that a complete response letter denying approval of a drug was an interim step, not final agency action, and was therefore not immediately appealable.[19]

The FDA lost a case that was tangentially related to COVID-19. As part of the Hatch-Waxman mechanism for resolving patent disputes, manufacturers applying for authorization of a generic drug may need to give certain notices to the manufacturer of the branded drug.

The manufacturer of a generic alternative to Minocin attempted such a notification by sending written materials by overnight service. The delivery company provided a contactless delivery, which apparently meant leaving the package outside an unattended office without obtaining the recipient's signature.

Although the FDA viewed this delivery as sufficient, the court disagreed. The court gave no deference to the FDA's determination that contactless delivery satisfied a regulation requiring "signature proof of delivery by a designated delivery service."[20]

FOIA Litigation

A similar pattern emerged in litigation regarding requests for information under the Freedom of Information Act. The FDA won its share of cases, with courts:

- Rejecting a demand for the disclosure of trade secrets;[21]

- Rejecting a demand to expedite certain FOIA requests above others in the queue;[22]

- Agreeing with the FDA that a request for records lacked the requisite specificity;[23]

- Denying a request to take a deposition of an FDA official regarding its refusal to produce information;[24] and

- Holding that a new FOIA request could not be litigated in a years-old lawsuit that related to different FOIA requests.[25]

However, in a pair of related cases last year and this year, both called *Public Health and Medical Professionals for Transparency v. FDA*, the Northern District of Texas found a compelling need for public disclosure of information relating to the approvals of COVID-19 vaccines.

In both cases, the court ordered the expedited production of responsive documents, under schedules that also took into account the massive volumes of the materials in question and the resulting burden upon the FDA.[26]

The FDA also lost a FOIA case in which the plaintiff sought disclosure of reviews by an interdisciplinary team of FDA experts regarding a supplemental new drug application. In *Vanda Pharmaceuticals Inc. v. FDA*, the D.C. district court found that the materials were created without an expectation that they would be shielded from public view, and that disclosure would not chill intra-agency communications related to drug approvals.[27]

Conclusion

The FDA has many advantages in litigation, including in particular the various administrative law doctrines that can lead courts to defer to the FDA's expertise and discretion.

As a result, and as in previous years, the FDA was largely successful in court. But the FDA's advantages can sometimes be overcome, particularly where the limelight shines brightest.

The FDA was thus markedly less successful in cases involving mifepristone or treatments for COVID-19. In 2024, it will be worth watching whether the skepticism courts have shown in high-profile cases will lead to a broader reluctance to defer to the FDA.

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[1] See Approval letter for Mifeprex (Sept. 28, 2000) (available from "Drugs@FDA" website); *Alliance for Hippocratic Medicine, et al. v. U.S. Food and Drug Admin., et al.*, 78 F.4th 210, 222 (5th Cir. 2023).

[2] "REMS" is the abbreviation for a Risk Evaluation and Mitigation Strategy. The FDA will mandate a REMS program for drugs where "necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. §355-1(a)(1).

[3] *State of Washington, et al. v. U.S. Food and Drug Admin., et al.*, No. 1:23-CV-3026-TOR, 2023 WL 2825861 (E.D. Wash. Apr. 7, 2023), order modified 2023 WL 2941567 (Apr. 13, 2023).

[4] *Alliance for Hippocratic Medicine, et al. v. U.S. Food and Drug Admin., et al.*, No. 2:22-cv-223-Z, 2023 WL 2825871 (N.D. Tex. Apr. 7, 2023).

[5] *Danco Labs., LLC v. Alliance for Hippocratic Medicine, et al.*, 143 S.Ct. 1075 (Apr. 21, 2023).

[6] *Alliance for Hippocratic Medicine*, 78 F.4th at 256.

[7] *Whole Woman's Health Alliance v. U.S. Food and Drug Admin.*, No. 3:23-cv-00019, 2023 WL 5401885, at *3 (W.D. Va. Aug. 21, 2023).

[8] In 2020, a federal court in Maryland had entered a preliminary injunction, enjoining the enforcement of some of the REMS requirements. *Am. College of Obstetricians and Gynecologists v. U.S. Food and Drug Administration*, 472 F. Supp. 3d 183 (D. Md. 2020). That case was voluntarily dismissed in 2021.

[9] *Alliance for Hippocratic Medicine*, 78 F.4th at 250-251.

[10] *State of Washington*, 2023 WL 2825861, at *8.

[11] *Apter v. Department of Health and Human Servs., et al.*, 80 F.4th 579, 595 (5th Cir. 2023).

[12] *See* 21 U.S.C. §§375(b), 393(b)(1).

[13] *Apter*, 80 F.4th at 587.

[14] *Children's Health Defense, et al. v. U.S. Food and Drug Admin., et. al.*, No. 21-6203, 2022 WL 2704554 (6th Cir. 2022); *Children's Health Defense, et al. v. U.S. Food and Drug Admin.*, et. al., 650 F.Supp.3d 547 (W.D. Tex. 2023).

[15] *Vanda Pharmaceuticals, Inc. v. Food and Drug Admin., et al.*, No. 1:22-cv-01432, 2023

WL 6035663, at *9 (D.D.C. Aug. 2, 2023) (internal citations omitted).

[16] *McAfee v. U.S. Food and Drug Admin.*, 36 F.4th 272, 274 (D.C. Cir. 2022) (internal citations omitted).

[17] *Natural Resources Defense Council, Inc., et al. v. U.S. Food and Drug Admin.*, 598 F.Supp.3d 98, 107 (S.D. N.Y. 2022) (internal citations omitted).

[18] *Arrow Reliance, Inc. v. Woodcock*, No. 22-1057, 2022 WL 3104102 (W.D. Wash. Aug. 4, 2022); *Wedgewood Village Pharmacy, LLC v. U.S. Food and Drug Admin.*, No. 22-cv-02649, 2022 WL 1591787 (D. N.J. May 19, 2022).

[19] *Nostrum Pharmaeuticals, LLC v. U.S. Food and Drug Admin.*, 35 F.4th 820 (D.C. Cir. 2022).

[20] *Melinta Therapeutics, LLC, et al. v. U.S. Food and Drug Admin., et al.*, No. 22-2190, 2022 WL 6100188, at *4 (D.D.C. Oct. 7, 2022) (interpreting 21 C.F.R. §314.95(e)).

[21] *Seife v. U.S. Food and Drug Admin., et al.*, 43 F.4th 231 (2d Cir. 2022).

[22] *Harrington v. Food and Drug Admin., et al.*, 581 F.Supp.3d 145 (D.D.C. 2022).

[23] *Informed Consent Action Network v. U.S. Food and Drug Admin.*, No. 20-cv-689, 2022 WL 902083 (S.D. N.Y. Mar. 28, 2022).

[24] *Vanda Pharmaceuticals, Inc. v. Food and Drug Admin.*, No. 1:22-cv-938, 2022 WL 17976504 (D.D.C. Oct. 27, 2022).

[25] *Judge Rotenberg Educ. Center, Inc. v. U.S. Food and Drug Admin., et al.*, No. 1:17-cv-02092-BAH, 2022 WL 16845801 (D.D.C. Nov. 1, 2022).

[26] *Public Health and Medical Professionals for Transparency, et al. v. Food and Drug Admin.*, No. 4:22-cv-0915-P, 2023 WL 3335071, at *2 (N.D. Tex. May 9, 2023); *Public Health and Medical Professionals for Transparency v. Food and Drug Admin.*, No. 4:21-cv-1058-P, 2022 WL 90237 (N.D. Tex. Jan. 6, 2022).

[27] *Vanda Pharmaceuticals, Inc. v. Food and Drug Admin.,* No. 22-cv-938, 2023 WL 2645714 (D.D.C. Mar. 27, 2023).