Apter v. Department of Health and Human Services

JONATHAN BERMAN & COLLEEN M. HEISEY*

You are not a horse, and FDA is not a physician.

I. WHY IT MADE THE LIST

FDA frequently issues statements and warnings about matters of public health. FDA was held to have exceeded its authority to do so in *Apter v. Department of Health and Human Services*.[1]

During the COVID pandemic, increasing numbers of people took drugs containing ivermectin—including drugs intended for livestock—to treat COVID. FDA advised against this, reminding us that "you are not a horse." The Fifth Circuit shot back: "FDA is not a physician."[2] The *Apter* court held that FDA did not have general authority to make pronouncements regarding public health, and that statements made without specific statutory authority were *ultra vires*, and unlawful. FDA can disseminate information, but not medical recommendations.

Case law is sparse regarding the limits of FDA's authority to comment on public health. *Apter* breaks new ground and provides a new avenue for challenging FDA.

II. DISCUSSION

A. Factual Background

Ivermectin is the active ingredient in a number of FDA-approved drugs. FDA has approved ivermectin-containing tablets, creams, and lotions for human use, as well as dozens of products intended for animals. Approved indications include the treatment and prevention of parasites—but not COVID-19.

Despite the lack of a COVID indication, ivermectin products became increasingly popular for the treatment or prevention of COVID. In response, FDA launched a

---

* Jonathan Berman is a partner at Jones Day with almost thirty years of experience litigating and trying antitrust cases, class actions, and other complex litigation matters, focusing on the interplay between civil litigation and the laws administered by the Food and Drug Administration (FDA). Jonathan also has advised clients, on dozens of matters, regarding FDA law and practice and has represented, in major litigation, pharmaceutical companies, a drug wholesaler, an insurer, and hospitals. Colleen Heisey is a partner at Jones Day, where she directs her more than twenty years of experience toward helping clients navigate FDA regulation. Her practice involves strategic counsel to clients navigating near-market and post-market opportunities and obligations, including matters related to product jurisdiction, pathways to market, regulatory exclusivities, accelerated approvals, orphan drug status, product promotion, adverse event reporting, recalls, and managing federal agency inquiries and enforcement actions. The views and opinions set forth herein are the personal views or opinions of the author; they do not necessarily reflect views or opinions of the law firm with which they are associated.

[1] Apter v. U.S. Dep't of Health & Hum. Servs., 80 F.4th 579 (5th Cir. 2023).

[2] *Id.* at 595.

publicity campaign in an attempt to discourage this use. FDA viewed ivermectin as ineffective against COVID. Moreover, FDA identified that high doses of ivermectin, such as the doses found in products intended for livestock, are dangerous to humans.

FDA issued a number of statements on this subject. The punchiest, and the ones that gathered the greatest public attention, focused on the danger of taking drugs intended for livestock. FDA tweeted:

> "You are not a horse. You are not a cow. Seriously, y'all. Stop it."

This tweet is still on FDA's "X" account, where it has gathered 46,179 reposts and 105,892 "likes."[3] The tweet links to a long article on the FDA website titled "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19."[4]

Similarly, FDA posted on Instagram: "You are not a horse. Stop it with the #Ivermectin. It's not authorized for treating #COVID."[5]

Three doctors who commonly prescribed ivermectin to treat COVID, including Dr. Robert Apter, sued FDA. They alleged that the above statements (and other similar social media postings) exceeded FDA's authority. They further alleged that these "Posts" interfered with their ability to practice medicine and caused pharmacies to refuse to fill ivermectin prescriptions. Additional alleged harms vary among the plaintiffs, but include harm to reputation, the loss of admitting privileges, and the loss of positions at a medical school and a hospital.[6]

The district court found that sovereign immunity barred these claims, and dismissed the lawsuit. While a government officer does not have sovereign immunity for *ultra vires* acts—acts taken "without any authority whatsoever, or without any colorable basis for the exercise of authority," the district court held that FDA had "at least a colorable basis in authority—and there is no statute saying otherwise."[7] The Administrative Procedure Act (APA) sometimes supplies a waiver of sovereign immunity, but the Posts were not "final agency action" within the meaning of the APA and were therefore not reviewable under that statute.[8] An appeal ensued.

B. The Fifth Circuit's Ruling

The Fifth Circuit reversed in part. It agreed with the district court that the Posts were not final agency action, and that therefore the plaintiffs failed to state a claim under the APA. However, the Fifth Circuit held that the Posts were *ultra vires*, and therefore actionable notwithstanding the assertion of sovereign immunity.[9]

FDA had argued that it had an inherent authority to speak on behalf of its statutory mission "to promote the public health."[10] FDA also cited to statutory authority to

---

[3] https://twitter.com/US_FDA/status/1429050070243192839?lang=en (last visited March 6, 2024).

[4] https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19.

[5] https://www.instagram.com/fda/p/CS1giIfJ0sa/.

[6] *See Apter*, 80 F.4th at 585.

[7] Apter v. U.S. Dep't of Health & Hum. Servs., et al., 644 F.Supp.3d 361, 367, 369 (S.D. Tex. 2022).

[8] *Id.* at 369–72.

[9] *See Apter*, 80 F.4th.

[10] 21 U.S.C. §§ 393(b)(1), (b)(2)(B).

utilize publicity to "disseminate[] information regarding . . . drugs . . . in situations involving . . . imminent danger to health or gross deception of the consumer."[11]

The Fifth Circuit held that this authority was inapplicable to the Posts. The Posts "offer advice, not mere information."[12] "[A]ll six of the Posts contain syntax that is imperative rather than declaratory . . . ."[13] Although "FDA cites plenty of statutory authority allowing it to issue *information*, it never identifies even colorable authority allowing it to make medical *recommendations* . . . ."[14] In sum, the Fifth Circuit held:

> FDA is not a physician. It has authority to inform, announce, and apprise—but not to endorse, denounce, or advise. The [plaintiffs] have plausibly alleged that FDA's Posts fell on the wrong side of the line between telling *about* and telling *to*.[15]

III. IMPACT

The *Apter* decision is significant for several reasons.

First, the decision opens up a new (or at least seldom-used) pathway for challenging FDA's public statements: arguing that they are *ultra vires*.

Second, proceeding on an *ultra vires* theory potentially avoids an inquiry into the accuracy of the challenged statements. The *Apter* decision does not discuss whether patients should in fact use ivermectin as a COVID treatment, nor whether FDA is owed deference in a matter of scientific opinion. The apparent holding of *Apter* is that an *ultra vires* action is unlawful, pure and simple.

Third, FDA issues recommendations and warnings in any number of contexts, including where it discerns "imminent danger[s] to health or gross deception[s] of the consumer."[16] For example, FDA maintains on its website a page titled "Health Fraud Scams," designed to warn against "products that claim to prevent, treat, or cure diseases or other health conditions, but are not proven safe and effective for those uses."[17] *Apter* calls into question FDA's ability to issue these warnings, many of which arguably do not merely "inform," but also make medical recommendations, denounce, and advise.

An important question that was litigated in *Apter*, but expressly left unresolved,[18] is whether FDA violated a prohibition on interfering with the practice of medicine by advising against a specific off-label use of an approved medicine. A section of the Federal Food, Drug, and Cosmetic Act (FDCA) states that it shall not "be construed to limit or interfere with the authority of a . . . practitioner to prescribe or administer

---

[11] 21 U.S.C. § 375(b). *See also* 42 U.S.C. § 242o(b) (permitting HHS to "issue information related to public health").

[12] *Apter*, 80 F.4th at 589.

[13] *Id.* at 588.

[14] *Id.* at 589 (emphasis original); *accord id.* ("Nothing in the [FDCA's] plain text authorizes FDA to issue medical advice or recommendations.").

[15] *Id.* at 595 (emphasis in original).

[16] 21 U.S.C. § 375(b).

[17] *Health Fraud Scams*, U.S. FOOD & DRUG ADMIN. (Feb. 6, 2024), https://www.fda.gov/consumers/health-fraud-scams.

[18] *Apter*, 80 F.4th at 589 & n. 31.

any legally marketed ***device*** . . . ."[19] The parties debated, but *Apter* did not resolve, whether the principle of noninterference extends to off-label prescriptions of ***drugs***.[20]

Nor did *Apter* resolve what it means to "interfere" with a practitioner's authority. FDA's Posts about ivermectin did not order anyone to do, or not do, anything: plaintiffs failed "to show that FDA's actions determined rights, produced obligations, or caused legal consequences."[21] But FDA certainly intended the real-world consequence of convincing people that treating COVID with ivermectin was bad medicine. And the plaintiffs alleged the real-world consequence of harm to their professional reputations and positions. Particularly in light of FDA's unique ability to influence debates on medical issues, does the principle of noninterference place a check on FDA's authority to do so?

We can expect continued litigation as courts more fully define the line between government overreach and FDA's power to inform the public.

---

[19] 21 U.S.C. § 396 (emphasis added).

[20] There is no code section comparable to 21 U.S.C. § 396 that explicitly references drugs. However, it is commonly said that FDA does not regulate the practice of medicine, including with regard to off-label uses of drugs.

[21] *Apter*, 80 F.4th at 593.