

# RESPONSE TO LISTENING TO MIFEPRISTONE

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In *Alliance for Hippocratic Medicine v. FDA*, a group of plaintiffs sued the Food & Drug Administration (FDA) over its regulation of the first drug in the medication abortion regimen: mifepristone.<sup>1</sup> Plaintiffs claim mifepristone is unsafe and seek to invalidate certain regulatory actions, including the drug's approval.<sup>2</sup> This case has been widely publicized as one of the most developed attempts in the post-*Roe* era to curtail abortion access across the country, particularly in states where abortion remains legal.<sup>3</sup> In response to this lawsuit, nineteen prominent food and drug law scholars submitted an amicus brief to the district court explaining why, regardless of one's views on abortion, the plaintiffs "gravely mischaracterized" FDA law.<sup>4</sup> We are the two lead amici in that brief.

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1. Complaint, *All. for Hippocratic Med. v. FDA*, No. 2:22-cv-00223-Z, 2023 WL 2825871 (N.D. Tex. Apr. 7, 2023) [hereinafter AHM Complaint].

2. *Id.* at 15–17.

3. See, e.g., Haley Weiss, *The Most Common Abortion Method Is in Danger in Every State*, TIME (Feb. 15, 2023, 10:59 AM), <https://time.com/6255625/abortion-pills-mifepristone-texas-lawsuit/> [https://perma.cc/P3VA-67KM].

4. Brief of Food and Drug Law Scholars as *Amici Curiae* in Support of Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction at 1, *All. for Hippocratic Med. v. FDA*, No. 2:22-cv-00223-Z, 2023 WL 2825871 (N.D. Tex. Apr. 7, 2023) [https://perma.cc/SV4N-VFRJ] [hereinafter District Court FDA Law Scholars Brief]. The scholars added another signatory (twenty total) and subsequently submitted an amicus brief to the Supreme Court in April 2023. See Brief for Food and Drug Law Scholars as *Amici Curiae* in Support of Applicants, *Danco Labs., LLC v. All. For Hippocratic Med.*, 143 S. Ct. 1075 (2023) (Nos. 22A902 & 22A901) [https://perma.cc/9HMS-RD5Z] [hereinafter Supreme Court FDA Law Scholars Brief]. The scholars added another signatory (twenty-one total) and submitted an amicus brief to the Fifth Circuit in May 2023. See Brief for Food and Drug Law

Professor Lars Noah wrote an essay responding in part to this brief, entitled *Listening to Mifepristone*.<sup>5</sup> His essay argues, among other things, that amici overstated our case.<sup>6</sup> We write to briefly explain how Noah misrepresents both our argument and the case law. Nothing in his essay weakens any of the brief's assertions.

## I.

### BACKGROUND AND NOAH'S CRITIQUE

On November 18, 2022, plaintiffs filed a lawsuit in Amarillo, Texas challenging FDA's approval and regulation of mifepristone.<sup>7</sup> The plaintiffs make many claims, among them that FDA used an improper regulatory mechanism to approve mifepristone, that the drug is unsafe both generally and particularly through telehealth and mail-order dispensing, and that a century-old, unenforced ban on shipping abortion pills prohibited many of FDA's actions.<sup>8</sup> In April 2023, the district court issued a preliminary injunction to "stay" FDA's approval of mifepristone and the agency's subsequent regulatory actions related to that approval.<sup>9</sup> The Supreme Court quickly stepped in to stay the preliminary injunction until it reviews the case or denies a petition for certiorari, referring it back to the U.S. Court of Appeals for the Fifth Circuit. In August 2023, the Fifth Circuit vacated the portion of the district court's order that would have stayed the initial approval, but affirmed the portions that would have stayed FDA's subsequent regulatory actions.<sup>10</sup> The resolution of this and other issues await input from the Supreme Court.<sup>11</sup>

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Scholars as *Amici Curiae* Supporting Appellants and Reversal, All. for Hippocratic Med. v. FDA, 78 F.4th 210 (5th Cir. 2023) (No. 23-10362) [<https://perma.cc/ZT82-WMH5>] [hereinafter Fifth Circuit FDA Law Scholars Brief].

5. Lars Noah, *Listening to Mifepristone*, 80 N.Y.U. ANN. SURV. AM. L. 33 (2023). Professor Noah initially posted a version of the essay, dated July 4, 2023, on SSRN, which prompted our response.

6. *Id.*

7. See AHM Complaint, *supra* note 1.

8. *Id.* at 15–17, 83.

9. All. for Hippocratic Med. v. FDA, No. 2:22-cv-223-Z, 2023 WL 2825871, at \*32 (N.D. Tex. Apr. 7, 2023).

10. All. for Hippocratic Med. v. FDA, 78 F.4th 210, 222–23 (5th Cir. 2023).

11. Danco Labs., LLC v. All. for Hippocratic Med., 143 S. Ct. 1075 (2023). The government reportedly plans to seek Supreme Court review of the Fifth Circuit's August 2023 ruling. See, e.g., Brendan Pierson, *US Appeals Court Backs Abortion Pill Restrictions; Supreme Court Appeal Planned*, REUTERS (Aug. 16, 2023, 7:09 PM), <https://www.reuters.com/world/us/us-appeals-court-rules-restrict-abortion-pill-use-2023-08-16/> [<https://perma.cc/BG6K-7X2K>].

As scholars who have written about FDA law and the regulation of mifepristone,<sup>12</sup> we helped organize a group of food and drug law scholars to file an amicus brief in the U.S. District Court for the Northern District of Texas that highlighted the serious flaws in the plaintiffs' arguments regarding FDA law. We invited professors who teach and write about FDA law to join our brief, and seventeen others agreed.<sup>13</sup> (Noah quotes the district court brief, but the group also submitted briefs to the Supreme Court and the Fifth Circuit with a few additional signatories.<sup>14</sup>) Noah was invited to join the amicus effort but did not respond to that invitation.

Instead, Noah penned a sensationalized<sup>15</sup> essay, which he posted online on July 19, 2023.<sup>16</sup> Among his chief complaints is a portion of a sentence in our brief that states: "We are not aware of any case in which a court has removed a drug from the market over FDA's objection."<sup>17</sup> Noah claims this line is "readily disproven."<sup>18</sup>

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12. See, e.g., PETER BARTON HUTT, RICHARD A. MERRILL, LEWIS A. GROSSMAN, NATHAN CORTEZ, ERIKA FISHER LIETZAN & PATRICIA J. ZETTLER, *FOOD AND DRUG LAW: CASES AND MATERIALS* (5th ed. 2022); David S. Cohen, Greer Donley & Rachel Rebouché, *Abortion Pills*, 76 STAN. L. REV. (forthcoming 2024); Patricia J. Zettler, Eli Y. Adashi & I. Glenn Cohen, *Alliance for Hippocratic Medicine v. FDA — Dobbs's Collateral Consequences for Pharmaceutical Regulation*, 388 NEW ENG. J. MED. E29(1) (2023); David S. Cohen, Greer Donley & Rachel Rebouché, *The New Abortion Battleground*, 123 COLUM. L. REV. 1 (2023); Patricia J. Zettler, Annamarie Beckmeyer, Beatrice L. Brown & Ameet Sarpatwari, *Mifepristone, Preemption, and Public Health Federalism*, 9 J.L. & BIOSCIENCES 1 (2022); Patricia J. Zettler & Ameet Sarpatwari, *State Restrictions on Mifepristone Access — The Case for Federal Preemption*, 386 NEW ENG. J. MED. 705 (2022); Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L. REV. 627 (2022); Patricia J. Zettler, Margaret Foster Riley & Aaron S. Kesselheim, *Implementing a Public Health Perspective in FDA Drug Regulation*, 73 FOOD & DRUG L.J. 221 (2018); Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L.J. 845 (2017).

13. District Court FDA Law Scholars Brief, *supra* note 4.

14. The Supreme Court and Fifth Circuit briefs included twenty and twenty-one amici, respectively, as explained *supra* note 4. See Supreme Court FDA Law Scholars Brief, *supra* note 4; Fifth Circuit FDA Law Scholars Brief, *supra* note 4.

15. Though not the point of this essay, it is worth noting that Noah disparaged amici as "self-anointed 'FDA law scholars'" who had "egg on [our] face," comparing the brief to one with blatant fabrications written by a "chatbot." Noah, *supra* note 5, at 33, 50 n.61, 59.

16. Lars Noah, *Listening to Mifepristone*, 80 N.Y.U. ANN. SURV. AM. L. (forthcoming 2023), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=4489364](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4489364) [<https://perma.cc/8YE8-94RF>].

17. District Court FDA Law Scholars Brief, *supra* note 4, at 19.

18. Noah, *supra* note 5, at 50.

## II. OUR RESPONSE

Our amicus brief made many arguments rebutting the plaintiffs' claims. One of them carefully described why a court order suspending or revoking mifepristone's approval would be unprecedented. We did not assert, as Noah misrepresents, that judges should not or cannot review FDA decisions, including drug approvals.<sup>19</sup> Indeed, our prior published work describes the necessity of such review.<sup>20</sup> Rather, the brief asserts that the amici were not aware of cases involving a court revoking a drug approval for a product already on the market based on a differing opinion about the drug's safety and effectiveness. The text containing the partial sentence that Noah reads out of context states:

Plaintiffs ask the Court to override FDA's safety and effectiveness determinations and force it to withdraw an approved application for a drug that has been on the market for more than 20 years. Such an order would "seismically disrupt the agency's governing authority as to whether drugs are safe and effective." Danco's Opp'n 1. It would also be unprecedented: We are not aware of any case in which a court has removed a drug from the market over FDA's objection.

The effects could extend beyond mifepristone. No drug is without risk, and a ruling for Plaintiffs could lead to challenges to FDA's benefit-risk determinations for drugs it has approved to treat other diseases and conditions.<sup>21</sup>

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19. *Id.* ("[J]udicial review of agency licensing happens with some regularity, and that includes FDA drug approval decisions . . ."); *id.* at 52 ("The APA did regard certain agency decisions as unreviewable, but nothing in that statute or the FDA's enabling act would place drug approval decisions entirely beyond judicial scrutiny."); *id.* at 56 ("Federal judges do not, however, dismiss such challenges as unreviewable, and every once in a while these efforts succeed even if only on some technicality.").

20. *See, e.g.,* Zettler, Adashi & Cohen, *supra* note 12, at E29(3) ("Although we believe it is clear no error was made in approving mifepristone, the FDA, like any agency, sometimes makes errors. Its decisions should be subject to scrutiny by the public, including by means of litigation. But there is a difference between using litigation to ensure that regulatory decisions are grounded in scientific evidence and suggesting — contrary to statutory text, regulatory authority, and longstanding practice — that an agency isn't empowered to do its job."); Donley, *supra* note 12, at 680–86 (arguing that "the FDA irrationally departed from its standards when it issued the mifepristone REMS" and that "[t]here is a strong case to be made . . . that the agency acted arbitrarily and capriciously" in requiring a REMS for mifepristone).

21. District Court FDA Law Scholars Brief, *supra* note 4, at 19.

The cases Noah catalogs in which courts have reviewed FDA decision-making are inapposite.<sup>22</sup> We never claimed such FDA action is unreviewable.

Furthermore, Noah cites to several<sup>23</sup> cases that “readily disprove[]”<sup>24</sup> our point on the unprecedented nature of plaintiff’s theory including: *Institute for Fisheries Resources v. FDA*,<sup>25</sup> *Genus Lifesciences, Inc. v. Azar*,<sup>26</sup> and *Serono Laboratories, Inc. v. Shalala*.<sup>27</sup> However, none of them involves a court revoking the approval of a drug already on the market by substituting its own judgment about safety and effectiveness in place of FDA’s. Notably, though the *Institute for Fisheries Resources* Court found flaws in the agency’s environmental assessment and remanded to FDA to cure those deficiencies, it *refused* to revoke the animal drug approval at issue during remand, in part because of possible market disruptions.<sup>28</sup> Similarly, in *Genus*, which involved an interpretation of the Hatch-Waxman Act, not a challenge to FDA’s safety and effectiveness determinations,<sup>29</sup> the court refused to immediately vacate the approval because pulling the drug from the market would “affect the consumers and healthcare providers who rely on [the drug] for medical treatment.”<sup>30</sup> In other words, in both

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22. Noah, *supra* note 5, at 49–59.

23. This Essay was substantially completed in July and August 2023, in response to a version of Noah’s Essay, which cited the three cases we discuss in the above-the-line text. During the editing process, Noah added a fourth case in support of his statement, *American Bioscience Inc. v. Thompson*, 269 F.3d 1077 (D.C. Cir. 2001). Like the others, this case does not involve a court removing a drug from the market due to a differing view about safety or effectiveness. There, the court found FDA’s approval of an abbreviated new drug application (ANDA) for a generic drug contrary to relevant provisions of the Hatch-Waxman Act because of a patent listing issue—the case did not involve a challenge to FDA’s safety and effectiveness determinations. *Id.* at 1079 (“This dispute arises out of the complex relationship between the FDA’s approval process for generic drugs and patent law.”). Notably, FDA has a “longstanding policy” of administering the patent-listing provisions of the Hatch-Waxman Act in a merely “ministerial fashion”—a far different kind of decision-making from its safety and effectiveness determinations. *Id.* at 1084. *See also* Jacob S. Sherkow & Patricia J. Zettler, *Epipen, Patents, and Life and Death*, 96 N.Y.U. L. REV. ONLINE 164, 176 (2021) (“The FDA has long claimed its authority to police the Orange Book is ‘purely ministerial.’” (quoting *AaiPharma Inc. v. Thompson*, 296 F.3d 227, 237 (4th Cir. 2002))).

24. Noah, *supra* note 5, at 50.

25. 499 F. Supp. 3d 657 (N.D. Cal. 2020).

26. 486 F. Supp. 3d 450 (D.D.C. 2020).

27. 974 F. Supp. 29 (D.D.C. 1997).

28. The court found that revoking the approval would lead to a significant loss of property and “would be wasteful given the real possibility that the FDA will be able to cure the NEPA . . . errors on remand.” *Inst. for Fisheries Res.*, 499 F. Supp. 3d at 669–70.

29. *Genus*, 486 F. Supp. 3d at 458.

30. This issue of vacating the approval was considered after the summary judgment decision. There, upon considering the possibility of market disruptions when it

*Institute For Fisheries Resources* and *Genus*, the courts took special pains to ensure that an approved, marketed drug was *not* removed from the market. Finally, the preliminary injunction in *Serono*—which had prevented a generic drug from entering the market, as opposed to removing a product already on the market—was vacated on appeal out of deference to FDA.<sup>31</sup>

Is it possible that Noah will be able to unearth a case where a court revoked an approval for a drug already on the market over a different view on safety and effectiveness? Sure. Our statement led with “we are not aware of” language for a reason. But Noah has not yet cited any such case.<sup>32</sup> And given the number of scholars with decades of experience in FDA law who agreed with that statement (several of whom have served in roles at FDA), we are confident that any such case will not be obvious or impactful.<sup>33</sup>

Noah also misrepresents a few other points in our amicus brief. Some of note: he claims that the agency’s “[s]NDA approval hardly amounts to reissuing the original license.”<sup>34</sup> The brief never suggests it does. Rather, we argue that “any alleged defects in the original approval of mifepristone in 2000 were cured in 2011 when, at the direction of Congress, FDA approved a risk evaluation and mitigation strategy

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vacated the approval, the court gave FDA sixty days to cure its deficiencies before the order would go into effect. *Genus Lifesciences, Inc. v. Azar*, No. 1:20-cv-00211, 2021 WL 270409, at \*4 (D.D.C. Jan. 27, 2021) (“Here vacatur would dissolve FDA’s approval of Numbrino, meaning Lannett would have to pull the drug from the market until at least 2022. Genus does not dispute these facts but suggests that any harm would be ‘economic harm’ restricted to Lannett. Not so, as it would also affect the consumers and healthcare providers who rely on Numbrino for medical treatment.”).

31. *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1321–27 (D.C. Cir. 1998).

32. For that matter, plaintiffs conceded during oral argument that they could not point to an instance where a court has vacated a drug’s approval after the drug had been on the market for a significant period of time. *See* Transcript of Hearing on Plaintiffs’ Motion for Preliminary Injunction at 51–52, *All. for Hippocratic Med. v. FDA*, No. 2:22-cv-223-Z, 2023 WL 2825871 (N.D. Texas Apr. 7, 2023), [https://fm.cnn.com/applications/cnn.com/resources/editorial-files/2023/03/17/2023MAR15-HIPPOCRATIC\\_MEDICINE-PI\\_HRG.pdf](https://fm.cnn.com/applications/cnn.com/resources/editorial-files/2023/03/17/2023MAR15-HIPPOCRATIC_MEDICINE-PI_HRG.pdf) [<https://perma.cc/T6R9-RLZM>] (“THE COURT: . . . Can you point the Court to analogue cases where other drugs on the shelf for similar periods of time have been subject to court intervention and either suspended, withdrawn, set aside, vacated—whatever remedy, which we’ll discuss next, can you point to analogues where courts have intervened in such a way where a drug has been in use for so long? MR. BAPTIST: My answer to your question is, no, I can’t.”).

33. Although Noah did not cite it, we also note that the Eleventh Circuit’s decision in *Catalyst* similarly did not involve a court second guessing FDA’s safety and effectiveness determinations. Rather, it concerned an interpretation of the exclusivity provision of the Orphan Drug Act. *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299, 1306 (11th Cir. 2021).

34. Noah, *supra* note 5, at 59–60.



(REMS) for mifepristone . . . ”<sup>35</sup> In other words, we do not suggest that subsequent regulatory action replaced the original approval, but that it cured any defects that a court might find there. Nor do we argue, as Noah misrepresents, that “the agency had not in fact relied upon the accelerated approval rule, [Subpart H].”<sup>36</sup> We explain that the agency did not use the section of Subpart H that allowed approvals based on a surrogate endpoint.<sup>37</sup> Instead, the agency relied on the section in Subpart H that allowed approval with restrictions to assure safe use.<sup>38</sup>

Finally, Noah casts doubt on a claim from “some observers” that a victory for plaintiffs “would unsettle research and development investments in the pharmaceutical industry.”<sup>39</sup> Our brief made a point along these lines,<sup>40</sup> and we have individually written elsewhere about how the public health and innovation stakes of this case are not limited to the abortion context.<sup>41</sup> We are not alone in this view. For

35. District Court FDA Law Scholars Brief, *supra* note 4, at 3.

36. Noah, *supra* note 5, at 59 n.102.

37. The brief states:

Although Plaintiffs call the approval of mifepristone an “accelerated approval,” FDA uses that term to refer to a separate provision of Subpart H (21 C.F.R. § 314.510), which provides for the accelerated approval of a drug product based on a surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity. FDA did not use that provision in connection with the approval of mifepristone.

District Court FDA Law Scholars Brief, *supra* note 4, at 5 n.6. The clinical trials supporting the approval of mifepristone looked at whether the drug achieved its clinical objective.

38. *Id.* A 2008 Government Accountability Office report on the approval of mifepristone made a similar point. *See, e.g.*, U.S. GOV’T ACCOUNTABILITY OFFICE GAO-08-751, FOOD AND DRUG ADMINISTRATION: APPROVAL AND OVERSIGHT OF THE DRUG MIFEPREX, at 1 n.2 (2008), (“The [Subpart H] regulations contain two approval provisions. One provides a process through which FDA may restrict the distribution or use of a drug to assure its safe use. The other provides FDA with flexibilities that allow the agency to accelerate the approval process for certain drugs on the basis of clinical trial endpoints that are considered reasonably likely to predict clinical benefit.”); *Id.* at 10 (“As of February 2007, nine drugs—Actiq, Accutane, Lotronex, Mifeprex, Plenaxis, Revlimid, Thalomid, Tracleer, and Xyrem—had either an NDA or supplemental NDA approved under the *restricted distribution provision* of Subpart H.” (emphasis added)); *Id.* at 14 (“FDA Approved Mifeprex under the Subpart H *Restricted Distribution Provision* After Concluding That Clinical Evidence Supported Its Safety and Efficacy” (emphasis added)).

39. Noah, *supra* note 5, at 58.

40. District Court FDA Law Scholars Brief, *supra* note 4, at 19.

41. *See, e.g.*, Zettler, Adashi & Cohen, *supra* note 12; Greer Donley & Rachel Sachs, *The Stakes in the Texas Abortion Medication Suit Are Broader than Just One Pill*, WASH. POST (March 3, 2023, 7:45 AM), <https://www.washingtonpost.com/opinions/2023/03/03/antiabortion-pill-suit-drug-development-access/> [<https://perma.cc/Q25B-7HBN>]; Greer Donley & Patricia Zettler, *The Case Against Medical Abortion Rejects Science and Embraces Falsehoods*, THE HILL (Nov. 27, 2022, 1:00 PM), <https://thehill.com/opinion/healthcare/3751672-the-case-against-medical-abortion->

example, an amicus brief to the Fifth Circuit signed by an extensive list of pharmaceutical executives and industry groups criticized the original district court injunction, arguing:

[T]he district court's lawless opinion will empower any plaintiff to grind drug approvals to a halt, disrupting patients' access to critical medicines. That outcome would chill crucial research and development, undermine the viability of investments in this important sector, and wreak havoc on drug development and approval generally, causing widespread harm to patients, providers, and the entire pharmaceutical industry.<sup>42</sup>

Particularly given the large cohort of experts making similar arguments,<sup>43</sup> we disagree with Noah's view that it is "entirely hyperbolic" to suggest the case could impact pharmaceutical innovation.<sup>44</sup>

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rejects-science-and-embraces-falsehoods/ [https://perma.cc/AEN6-LL82]; cf. Zettler, Beckmeyer, Brown & Sarpatwari, *supra* note 12, at 25–31 (considering the public health implications that preemption challenges to state mifepristone restrictions may have beyond the context of abortion).

42. Brief of Pharmaceutical Companies, Executives, and Investors as *Amici Curiae* In Support of Appellants' Motion For Stay Pending Appeal at 3, All. for Hippocratic Med. v. FDA, 78 F.4th 210 (5th Cir. 2023) (No. 23-10362) [https://perma.cc/44G7-2MYN].

43. See, e.g., Abbe R. Gluck, *The Mifepristone Case and the Legitimacy of the FDA*, 329 JAMA 2121, 2121 (2023) ("The case creates a precedent that could allow almost anyone, no matter their relationship to the drug competitors, ideological opponents, political actors—to challenge the settled approval of a drug decades later, creating an atmosphere of perpetual uncertainty for manufacturers."); Wendy K. Mariner, *Science v. Ideology in Court: Mifepristone and the U.S. Food and Drug Administration*, 176 ANNALS OF INTERNAL MED. 857, 857 (2023) ("If anyone can challenge the FDA's approval of a drug or device they dislike, and if judges can make up facts to take it off the market, regardless of its safety and effectiveness, then developing any drug may be risky."); Margaret Hamburg & Joshua Sharfstein, *Judicial Interference with Mifepristone*, 380 SCIENCE 223 (2023) ("As the former commissioner and principal deputy commissioner of the FDA, we couldn't have said it better [than the industry amicus brief] ourselves. The FDA is a unique institution, bringing together intellectual resources from inside and outside government to make decisions on thousands of products each year. Once courts dismiss core scientific judgments by the agency, there is no reason to believe they will limit themselves to this one medication."); Letter from Industry Leaders, In Support of FDA's Authority to Regulate Medicines, https://docsend.com/view/2ahvmwy8djzxax3g [https://perma.cc/LAVQ-UNGU] ("Judge Kacsmaryk's [decision] has set a precedent for diminishing FDA's authority over drug approvals, and in so doing, creates uncertainty for the entire biopharma industry. As an industry we count on the FDA's autonomy and authority to bring new medicines to patients under a reliable regulatory process for drug evaluation and approval. Adding regulatory uncertainty to the already inherently risky work of discovering and developing new medicines will likely have the effect of reducing incentives for investment, endangering the innovation that characterizes our industry.").

44. Noah, *supra* note 5, at 58.



### III. CONCLUSION

Noah's essay, *Listening to Mifepristone*, picks at one argument from the Food and Drug Law Scholars brief, misrepresents it, and then attacks that misrepresentation. His essay fails to raise any argument or cite to any case that undermines the substance of our brief. Although this scholarly debate may seem narrow—concerning one part of one sentence of an amicus brief—the stakes of this case are not. We stand behind the brief.



# LISTENING TO MIFEPRISTONE

LARS NOAH\*

## ABSTRACT

*In April 2023, a federal court in Texas preliminarily invalidated the license for mifepristone, the abortion drug approved by the FDA more than two decades earlier. Two weeks later, the U.S. Supreme Court issued an emergency stay pending appeal, so mifepristone remains available for now, but this consequential litigation has several more rounds to go. Judge Kacsmaryk’s opinion richly deserves criticism at any number of levels, but one of the most fundamental objections to it misses the mark: although rare, judges before him have found fault with FDA drug approval decisions, so what happened in this particular case hardly qualifies as unprecedented, and the affiliated policy arguments offered by some of his critics strike me as largely misplaced as well. The lawyers for the government—and the group of self-anointed “FDA scholars” eager to offer their insights to the courts and the media—should know that overstating your case can end up leaving egg on your face.*

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## I. INTRODUCTION

In the fall of 2000, the U.S. Food and Drug Administration (FDA) approved the abortion drug mifepristone. As I explained at the time, the agency took some peculiar steps during this process,<sup>1</sup> though these struck me as rendering the special restrictions imposed on its distribution—rather than the underlying approval—vulnerable to second-guessing.<sup>2</sup> Earlier this year, Matthew Kacsmayk, a federal judge sitting in Amarillo, Texas, tentatively decided to invalidate that license in its entirety.<sup>3</sup> I was mortified to see that his opinion twice quoted from my old article.<sup>4</sup> Evidently, he missed my all-important

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1. See Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics*, 36 WAKE FOREST L. REV. 571, 573–90 (2001); see also *id.* at 603 (“The final chapter in the mifepristone story has not been written, and, given its convoluted path to approval, it would be foolhardy to predict how it will end.”).

2. See *id.* at 582 (“Accelerated approval may have simplified the sponsor’s task of generating evidence of safety and effectiveness, but the clinical data submitted for mifepristone clearly would have satisfied the FDA’s regular requirements.”); *id.* at 592–93 (doubting that the agency would have any defensible grounds for withdrawing approval); see also *id.* at 584–86 (elaborating on questions about the FDA’s power to limit access); *id.* at 593 n.102 (“[T]he sponsor might assail the distribution restrictions . . . established under the accelerated approval regulations as inconsistent with the statute.”). I did, however, recognize some unintended consequences of using this specialized approval pathway:

[T]his speedier process came at the price of granting the FDA the right to extract concessions that Congress did not authorize until a few years after the filing of this NDA [new drug application]. Apparently the agency took this route so that it could better justify imposing otherwise unauthorized restrictions on the use and distribution of the drug, but it also unwittingly gave critics the opportunity to suggest that the FDA had approved the drug on the basis of weaker evidence of safety and effectiveness than it would normally demand. The accelerated approval mechanism also, of course, purports to allow the FDA to withdraw the NDA using more truncated procedures, which unintentionally may have made mifepristone more vulnerable to the contrary preferences of the new administration.

*Id.* at 582 (footnotes omitted). Given what has now happened, you might say that the agency was too clever by half.

3. See *All. for Hippocratic Med. v. FDA*, No. 22-CV-223-Z, 2023 WL 2825871, at \*32 (N.D. Tex. Apr. 7, 2023), *aff’d in part, vacated in part*, No. 23-10362, 2023 WL 5266026, at \*32 (5th Cir. Aug. 16, 2023).

4. See *id.* at \*27 n.62 (“The Clinton administration went to great lengths to bring mifepristone into the United States. From pressuring the hesitant manufacturer to apply for approval, and utilizing a specialized review procedure normally reserved for life-saving drugs, to imposing unusual restrictions on distribution, and promising to keep the identity of the manufacturer a secret, the FDA’s approval process deviated from the norm in several respects.” (quoting Noah, *supra* note 1, at 576)); *id.* at \*28 n.63 (“[T]he agency took this route so that it could better

concluding sentence: “[B]y virtue of the approval decision, the other branches of government cannot now blithely disregard the agency’s judgment without encountering significant constitutional obstacles.”<sup>5</sup> The constitutional landscape—and much else—has, of course, changed in the meantime, and my 2001 article had focused on the prospects of an override coming (quickly) from the White House, Congress, or (indirectly) the states;<sup>6</sup> I briefly noted the mechanics for triggering judicial intervention, never imagining that such an effort would get taken seriously.<sup>7</sup>

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justify imposing otherwise unauthorized restrictions on the use and distribution of the drug.” (quoting Noah, *supra* note 1, at 582)). Indeed, I enjoyed the dubious distinction of being the sole legal “scholar” referenced with regard to the particulars of the drug’s approval; then again, Kacsmaryk also quoted from *Sesame Street* (among other even less compelling authorities). See *id.* at \*20 (“One of these things is not like the others, one of these things just doesn’t belong.”); see also Ann E. Marimow et al., *Dueling Rulings on Abortion Pill Tee up Collision*, WASH. POST, Apr. 8, 2023, at A1 (“Nathan Cortez, a law professor and FDA scholar at Southern Methodist University, said the judge’s ruling was ‘about as out-there as you can imagine.’”); *id.* (“The sources he cites and the terminology he uses also read very much like the opinion of an antiabortion crusader rather than an impartial judge,” said Cortez . . .”).

5. Noah, *supra* note 1, at 603; see also *id.* at 590 (“[M]ifepristone shares one crucial similarity with every other pharmaceutical product that has successfully run the gauntlet of the approval process: the federal government has now issued a license authorizing its sale in the United States.”). It is hardly the first time that a court entirely missed my gist. See, e.g., Lars Noah, *Does the U.S. Constitution Constrain State Products Liability Doctrine?*, 92 TEMP. L. REV. 189, 203 n.80 (2019) [hereinafter Noah, *Constitution Constrain*] (In *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245 (N.J. 1999), “the majority quoted several passages from my earlier article on the subject, see *id.* at 1251–52, 1255–56, 1258, but evidently failed to notice that I had concluded that the [direct-to-consumer advertising] exception made no sense . . . . Indeed, immediately after quoting my summary of the rationales underlying the learned intermediary rule, the majority offered a brief synopsis that blatantly mischaracterized some of these . . . .”); see also Marcantonio v. Moen, 937 A.2d 861, 882–85 (Md. Ct. Spec. App. 2007) (Meredith, J., dissenting) (explaining that the majority fundamentally misunderstood the calculations offered in Lars Noah, *An Inventory of Mathematical Blunders in Applying the Loss-of-a-Chance Doctrine*, 24 REV. LITIG. 369 (2005) [hereinafter Noah, *Mathematical Blunders*]), *rev’d*, 959 A.2d 764, 776 (Md. 2008) (making an even more profound mathematical mistake by holding that traditional causation requirements are satisfied any time that the antecedent probability of survival exceeds 50% without regard to how much or little the alleged medical malpractice reduced a patient’s chances of survival).

6. See Noah, *supra* note 1, at 590–603; *id.* at 573 (“Critics of the agency’s decision have suggested that the new administration, Congress, or individual states could take steps to either revoke the approval or impose significant restrictions on the distribution of mifepristone, though each of these strategies would pose difficult statutory and constitutional questions.”).

7. See *id.* at 593 n.104; see also Caroline Kitchener & Perry Stein, *Abortion Rights Backers Fear Ruling in Pills Case*, WASH. POST, Feb. 6, 2023, at A5 (“The [Texas] suit has been widely ridiculed by legal experts as rooted in baseless and debunked arguments. . . . [The plaintiffs] have struggled to get people to take the case seriously.”).

Two decades before they brought their Texas lawsuit, a couple of the plaintiff organizations filed a citizen petition with the FDA that sought to unravel its approval of mifepristone,<sup>8</sup> and this just happened to get sent to me at the time. One year after the publication of my mifepristone article, I took a call from Leonard Leo, then the executive vice president of the Federalist Society. If memory serves, Mr. Leo said that he liked my piece and wondered whether I would consider turning it into an op-ed that he could place in the *Wall Street Journal* or similar outlet.<sup>9</sup> He also offered to send me a hard copy of a citizen petition just filed by the American Association of Pro-Life Obstetricians & Gynecologists, Concerned Women for America, and the Christian Medical Association, hoping that I would give it a plug. Before that arrived, I prepared and emailed to Mr. Leo a column that I hoped a leading newspaper would accept for publication.<sup>10</sup> One week later, he emailed back an edited version of my draft to “reflect a greater degree of skepticism about the FDA process.”<sup>11</sup> I responded later that same afternoon, explaining that I didn’t care for his seemingly presumptuous approach,<sup>12</sup> shared my misgivings

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8. See *All. for Hippocratic Med.*, 2023 WL 2825871, at \*2; see also *id.* at \*1 (adding that the FDA had missed its 180-day deadline for ruling on the petition filed in 2002 by more than thirteen years). The third organization on the original petition, Concerned Women for America, participated in the case only as an amicus. See *id.* In contrast, the lead plaintiff came into the picture much later and engaged in some masterful forum shopping, ensuring that Judge Kacsmaryk would hear their case. See Caroline Kitchener & Ann E. Marimow, *The Texas Judge Who Could Take Down the Abortion Pill*, WASH. POST, Feb. 26, 2023, at A1 (“The lead plaintiff in the abortion pills case, the Alliance for Hippocratic Medicine, incorporated in Texas—with a ‘registered agent’ in Amarillo—several months before the lawsuit was filed. . . . [R]ecords filed with the Texas secretary of state’s office show that the group’s mailing address is in Tennessee.”); see also Lauren Weber et al., *Documents Show Reach of Doctors Association*, WASH. POST, June 16, 2023, at A1 (painting an unflattering portrait of one of the other plaintiffs, the American College of Pediatricians).

9. Plainly he had the clout to make good on such a promise. See Katie Robertson, *Justice’s Reply to ProPublica in Rival Paper Stirs Criticism*, N.Y. TIMES, June 22, 2023, at A14 (describing criticism of the *Wall Street Journal* for allowing Justice Alito to use its opinion pages to clear his name of not-yet-published charges of unethical conduct); see also Adam Liptak, *Alito Defends Using Billionaire’s Jet, Then Judging Cases Involving Him*, N.Y. TIMES, June 22, 2023, at A14 (elaborating on the nature of those charges as well as Mr. Leo’s involvement and reaction).

10. See E-mail from author to Leonard A. Leo, Exec. Vice President, Federalist Soc’y (Jan. 28, 2003, 10:57 AM) (on file with author).

11. See E-mail from Leonard A. Leo, Exec. Vice President, Federalist Soc’y to author (Feb. 4, 2003, 2:36 PM) (on file with author).

12. See E-mail from author to Leonard A. Leo, Exec. Vice President, Federalist Soc’y (Feb. 4, 2003, 3:50 PM) (on file with author) (“I had invited you to draw my attention to problems of length, tone, or emphasis that I would take care of—I certainly did not intend for you to edit (or ghost co-author) it.”).



about the poor caliber of the petition,<sup>13</sup> and effectively told him to get lost,<sup>14</sup> which successfully put an end to that opportunity for me. Mr. Leo's grander project of refashioning the federal courts had a far more consequential impact, of course, and in a small way helped to set the stage for Judge Kacsmaryk to endorse that same citizen petition two decades later.<sup>15</sup>

In fairness, my 2001 article had expressed agnosticism about the endpoint, admitting to "a calculated indifference about where the analysis ultimately points."<sup>16</sup> That does not, however, excuse a failure to appreciate the fact that my objections had related to the unjustified limitations on access rather than the base approval of the drug,<sup>17</sup> and that hardly amounts to a revisionist account of what I had written at the time—as one commentator recently put it

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13. *See id.* ("[T]he citizen petition was of surprisingly poor quality (esp. in suggesting that the FDA acted at all unusually in failing to demand pivotal RCTs of absolutely impeccable quality for both safety and effectiveness, abiding by all Phase IV commitments, etc.—if that were enough to w/d an NDA, half of all drugs on the market today would disappear)."). Ever the pack rat, I still have that lengthy document (with my marginal notations) in a file cabinet.

14. *See id.* ("If that's not acceptable, please just forget the whole damn thing. . . . [I'm] uncomfortable w/ the idea of saying anything terribly complimentary about [the citizen petition]. Good luck.").

15. Mr. Leo's behind-the-scenes machinations have hardly gone unnoticed in the media. *See, e.g.,* Shawn Boburg et al., *Activist Leo Aided Drive to Lionize Thomas*, WASH. POST, July 21, 2023, at A1 ("The resources available to Leo expanded vastly in 2020, when a nonprofit organization he chairs received a \$1.6 billion contribution . . ."); Steve Eder & Jo Becker, *As a Law School Grows, So Do Perks for Justices*, N.Y. TIMES, Apr. 30, 2023, at A1 (calling him the "prime architect of a grand project then [in 2016] gathering force to transform the federal judiciary and further the legal imperatives of the right"); Kenneth P. Vogel, *The Hidden Hand Guiding Conservative Causes*, N.Y. TIMES, Oct. 13, 2022, at A1 (detailing "how he has built that network, with relatively little public attention, into one of the best-funded and most sophisticated operations in American politics, giving him extraordinary influence as he pushes a broad array of hot-button conservative causes"); *see also* Beth Reinhard & Josh Dawsey, *DeSantis Used Panel to Flip Fla. High Court*, WASH. POST, June 27, 2023, at A1 (reporting that Florida's Governor and now presidential candidate had enlisted Mr. Leo's help to shift the state supreme court hard to the right, while he praised Justice Alito and "called Justice Clarence Thomas 'our greatest living justice' and pledged to move the U.S. Supreme Court even further to the right than President Donald Trump did"); *cf.* LARS NOAH, LAW AND THE PUBLIC'S HEALTH: CASES, CONTROVERSIES, AND COVID-19, at 878 (2023) ("Cynical politicians may come and go, but the rightward drift of our federal and state courts poses a far more serious challenge.").

16. Noah, *supra* note 1, at 573 ("Although abortion politics provide the necessary backdrop for this story, I have intentionally side-stepped this broader debate. Some of my claims will appeal to the pro-choice crowd, while others will gladden the hearts of those opposed to abortion . . .").

17. *See supra* note 2 and accompanying text.

immediately before quoting from my article, “[t]he FDA’s distribution restrictions were seen as problematic from the outset.”<sup>18</sup> Indeed, in a rollicking paper that I published just three years after the piece on mifepristone, all hesitation about sharing my personal inclinations on the broader subject had evaporated.<sup>19</sup> Apart from trying to set the record straight about where I stand, this Article attempts to assess the merits of a frequently raised objection to the “unprecedented” nature of what Judge Kacsmaryk did. Although I find much to criticize in his legal analysis,<sup>20</sup> it turns out that little justifies the

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18. Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L. REV. 627, 639 (2022); see also *id.* at 643–66 (arguing persuasively that even the subsequently watered-down limitations on access lacked justification and conflicted with the FDA’s enabling statute as amended in 2007). Instead, the defendants in this case have tried to rewrite the story of what happened by denying that the agency had used its accelerated approval pathway. See *infra* note 102.

19. See Lars Noah, *A Postmodernist Take on the Human Embryo Research Debate*, 36 CONN. L. REV. 1133, 1139 (2004) (wondering in jest whether an embryo “had the same moral status as an inflamed appendix”); *id.* at 1140 n.26 (“A billboard along the road to Disney World helpfully proclaims that ‘life begins at conception.’”). It now seems positively quaint to think that the second President Bush had so gotten my dander up:

Religious fundamentalism represents a serious threat to democratic values the world over, no more so than in the United States. It makes little sense to engage in this dialogue as if it were an honest debate or as if it turned on issues of science. Our emerging theocracy is decidedly antideliberative and antiscientific.

*Id.* at 1160 (footnote omitted); see also *id.* at 1150 (“In addition to selecting ideologies to help shape federal science policy, the Bush administration has established a pattern of selective invocation of science to suit its views on policy—akin to ‘cooking the intel’ in order to justify military objectives—on issues ranging from reproductive medicine . . . .”); cf. Michael M. Grynbaum, *Fox Trades Motto of “Fair and Balanced” for “Most Watched, Most Trusted,”* N.Y. TIMES, June 15, 2017, at B8 (reporting that this right-wing television network dropped its ridiculous old slogan in the midst of the 2016 presidential election campaign).

20. For instance, the court concluded that the FDA had dialed back its originally proposed restrictions too readily at the time of initial approval even while deciding that the one arguable basis for mandating them did not apply to the drug in the first place. See, e.g., *All. for Hippocratic Med. v. FDA*, No. 22-CV-223-Z, 2023 WL 2825871, at \*28 (N.D. Tex. Apr. 7, 2023), *aff’d in part, vacated in part*, No. 23-10362, 2023 WL 5266026, at \*32 (5th Cir. Aug. 16, 2023). Which is it?! As I had recounted the maneuvering that happened in the run up to approval, the FDA proposed absolutely no restrictions on access at first, shifted course a few years later solely to secure some newly needed political cover, and ultimately softened these unjustified conditions because the sponsor refused to cave in to those ridiculous demands. See Noah, *supra* note 1, at 583 (“In short, when the sponsor restarted the FDA’s interrupted review process by filing the requested information in August 1999, it faced an agency that may have lost some of its earlier enthusiasm for the drug.”); *id.* at 584 (“Apparently without the emergence of any new information casting doubt on the original safety and effectiveness data reviewed by the agency under Dr. Kessler’s watch, the FDA now [after his departure as Commissioner] suggested a variety of

more fundamental charge lodged by others that he has improperly broken new ground.

## II. SITUATING THE CASE IN THE BROADER BATTLES OVER ABORTION

When mifepristone first came to market in this country, it had seemed that Congress might attempt an override, or that newly installed leaders at the agency might revisit an approval decision made in the waning days of the Clinton administration, but neither of those things happened.<sup>21</sup> Perhaps the product would have fared less well if the FDA originally had done nothing other than require a prescription; instead, the cumbersome limitations on access worked to slow the initial uptake of the drug and mute some of the political backlash. Mifepristone could only be used during the first seven weeks of pregnancy, it had to be dispensed in person and only by specially certified physicians, and patients had to sign a consent form supplied by the manufacturer, which obligated them to visit twice more: within forty-eight hours to receive misoprostol and then a couple of weeks later for a follow-up exam to confirm that it worked.<sup>22</sup> As time passed and reassuring experience in more widespread use accumulated, the FDA gradually loosened its original

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unusual distribution restrictions . . . .”); *id.* at 584 n.59 (“Some commentators speculated that Vice President Gore may have urged the FDA to go slow on mifepristone in order to avoid providing a flash point during the campaign that would galvanize opposition to his candidacy by pro-life activists.”); *id.* at 585 (explaining why the NDA’s sponsor “seemingly had nothing to lose by resisting the agency’s belated request”); *see also* U.S. GOV’T ACCOUNTABILITY OFF., GAO-08-751, FOOD AND DRUG ADMINISTRATION: APPROVAL AND OVERSIGHT OF THE DRUG MIFEPREX (2008) (elaborating on what happened in the lead up to and immediate aftermath of approval).

21. For instance, a bill first introduced in November 2003 and then again a couple of years later sought to do so but never gained much traction. *See* Marc Kaufman, *Abortion Foes Want RU-486 Pill Pulled; Deaths of Several Women Are Cited*, WASH. POST, May 17, 2006, at A3; Marie McCullough, *Bacteria Blamed in Deaths of 4 Who Used Abortion Pill; A Rare Infection Killed the Young California Women*, PHILA. INQUIRER, Dec. 1, 2005, at A5 (“In March, U.S. Sen. Jim DeMint (R., S.C.) introduced the RU-486 Suspension and Review Act, commonly known as ‘Holly’s Law’ . . . .”); *see also* William Cummings, *Cruz Tweet on Pregnancy Risks Draws Ire*, USA TODAY, Sept. 4, 2020, at 3A (“In their letter [to the FDA], the 20 GOP senators said ‘this deadly pill should never have been approved’ and objected to it being approved through ‘an accelerated approval process normally reserved for high-risk drugs that address life-threatening illnesses like AIDS.’”).

22. *See* Noah, *supra* note 1, at 585.

restrictions on distribution,<sup>23</sup> and it did so in each instance by approving a supplemental new drug application (SNDA).<sup>24</sup> When the agency failed to waive some of the remaining access requirements early in the pandemic, however, litigation sought to force its hand.<sup>25</sup> The current administration eventually rolled back the restrictions still further without, however, dropping them altogether, as some had urged.<sup>26</sup>

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23. See Miriam Berger, *Abortion Pill Facing Restrictions in U.S. Has Been Approved by over 90 Nations*, WASH. POST, Apr. 21, 2023, at A15 (“The FDA has broadened access to mifepristone over the years as evidence of its efficacy and safety has increased . . . . Regulatory agencies abroad have done the same, and the WHO [World Health Organization] has come to recommend it and list it as an essential drug.”). In 2016, for instance, the agency revised the drug’s labeling in order to facilitate readier access. See Sabrina Tavernise, *New F.D.A. Rules Will Ease Access to Abortion Pill*, N.Y. TIMES, Mar. 31, 2016, at A1; see also Elizabeth G. Raymond et al., *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 376 NEW ENG. J. MED. 790 (2017) (applauding the labeling changes but concluding that the agency should discontinue the distribution restrictions as well). Some thought that the shift in allowable use from seven to ten weeks of gestation had not gone far enough. See Donley, *supra* note 18, at 691 n.440 (preferring twelve weeks); Pam Belluck, *Pressing Limits to Ease Delivery of Abortion Pill*, N.Y. TIMES, Sept. 4, 2022, at A1.

24. The first major SNDA, approved in 2011, had converted the distribution restrictions issued under its 1992 accelerated approval regulation to align with the Risk Evaluation and Mitigation Strategies (REMS) authority granted by Congress in 2007. See 21 U.S.C. § 355-1 (f); see also Donley, *supra* note 18, at 640 n.88. The second major SNDA for mifepristone, approved in 2016, dialed some of these back, see *id.* at 641, and then a third one reviewed in 2022 loosened still more of these, see *id.* at 642, 687. For the full regulatory history of Danco’s license for mifepristone (sold under the brand name Mifeprex®), see *Drugs@FDA: FDA-Approved Drugs*, <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020687> [<https://perma.cc/5K7X-C9S2>].

25. See *Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183, 212–33 (D. Md. 2020) (issuing a preliminary injunction ordering the suspension of the in-person dispensing requirement for the duration of the declared public health emergency), *stay granted pending appeal*, 141 S. Ct. 578 (2021). The lawsuit became moot after the new administration announced that the FDA would grant the requested waiver. See Pam Belluck, *By-Mail Abortion Pills Permitted During Pandemic*, N.Y. TIMES, Apr. 14, 2021, at A28; see also Sheryl Gay Stolberg, *Administration Tells Pharmacists Not to Withhold Abortion Pills*, N.Y. TIMES, July 14, 2022, at A14 (reporting that the Department of Health & Human Services (HHS) issued guidance to remind conscientious objectors of their obligations under federal law).

26. See Laurie McGinley & Katie Shepherd, *FDA Relaxes Restriction to Obtain Abortion Pill*, WASH. POST, Dec. 17, 2021, at A1 (reporting that the agency would permanently drop the in-person dispensing requirement but had retained prescriber certification and patient consent rules and added a separate certification requirement for pharmacists); see also Pam Belluck, *Pharmacies to Dispense Abortion Pill*, N.Y. TIMES, Jan. 4, 2023, at B1 (reporting that it took a year to formalize this change after negotiations with the two license holders). Major pharmacy chains caught some flak after announcing that they would not stock the drug in twenty-one red states that had threatened to take legal action otherwise. See Christopher Rowland, *In Drawing*

In the two decades since the FDA's original approval of mifepristone, collateral questions have arisen about various state efforts to stand in the way of medication abortion:

- Requirements that prescribers strictly adhere to the protocol specified by the FDA;<sup>27</sup>
- Restrictions on access to the drug that imposed greater burdens than the FDA did;<sup>28</sup>
- Requirements that prescribers disseminate misinformation about the drug to patients;<sup>29</sup>
- Prohibitions on all use of the drug: whether directly, by explicitly barring its distribution,<sup>30</sup> or indirectly, by making its sole approved use unlawful.<sup>31</sup>

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*a Line on Abortion Pills, Walgreens Seems to Satisfy Neither Side*, WASH. POST, Mar. 9, 2023, at A17.

27. See Laurah J. Samuels, Note, *Mifepristone Protocol Legislation—The Anti-Choice Movement's Disingenuous Method of Attack on the Reproductive Rights of Women and How Courts Should Respond*, 26 COLUM. J. GENDER & L. 316, 325–30 (2014) (discussing statutes from Arizona, North Dakota, Ohio, Oklahoma, and Texas that mandated strict adherence to the directions for use specified in the labeling approved by the FDA); see also Lars Noah, *State Affronts to Federal Primacy in the Licensure of Pharmaceutical Products*, 2016 MICH. ST. L. REV. 1, 18 n.69 (citing split decisions among the various lower federal courts and one state supreme court that have confronted this issue).

28. See, e.g., Laurie McGinley & Katie Shepherd, *FDA Relaxes Restriction to Obtain Abortion Pill*, WASH. POST, Dec. 17, 2021, at A1 (“The highest-profile limitations were enacted in Texas, where lawmakers made it a felony to provide abortion pills after seven weeks of pregnancy and outlawed sending the drugs through the mail.”); see also Donley, *supra* note 18, at 689–90 (counting nineteen states that still require in-person dispensing or prescribing); Pam Belluck, *F.D.A. Allows Abortion Pills Through Mail*, N.Y. TIMES, Dec. 17, 2021, at A1 (reporting that in 2021 “six states banned the mailing of pills, seven states passed laws requiring pills to be obtained in person from a provider, and four states passed laws to set the limit on medication abortion at earlier than 10 weeks’ gestation”); cf. Erik Eckholm, *Arizona Governor Signs Abortion Bill That Skirts F.D.A. Decision*, N.Y. TIMES, Apr. 2, 2016, at A8 (reporting that one state had mandated continued adherence to the FDA’s obsolete older protocol); *infra* note 40 (discussing the fate of such a law in Oklahoma).

29. See Lars Noah, *Censorship Is So Last Century: Therapeutic Products, Propaganda, and Compelled Speech*, 66 ST. LOUIS U. L.J. 79, 92–93 (2021) (questioning the constitutionality of laws adopted in almost a dozen states that had obligated health care professionals to advise their patients about the purported reversibility of medication abortions); Kate Zernike, *Pills Are New Target in 50-Year Abortion Battle*, N.Y. TIMES, Apr. 6, 2022, at A1 (“[G]roups have obtained preliminary injunctions against abortion reversal laws in three states, arguing that they violate the free speech of doctors by forcing them to provide what one judge called ‘misleading’ information to patients.”).

30. See David W. Chen & Pam Belluck, *Wyoming Becomes the First State to Outlaw Pills for Medical Abortion*, N.Y. TIMES, Mar. 18, 2023, at A18.

31. See *id.* (“Medication abortion is already outlawed in states that have total bans, since those bans already prohibit all forms of abortion.”). This represents

These pose potentially difficult constitutional questions, however, only so long as the FDA's approval remains in place.

Before the U.S. Supreme Court decided in 2022 to no longer recognize a constitutional right protecting a woman's choice about terminating a pregnancy before viability,<sup>32</sup> challenges to state restrictions on the use of mifepristone never bothered to raise federal preemption arguments.<sup>33</sup> After *Dobbs*, and with more aggressive state efforts to limit access to medication abortion in particular,<sup>34</sup> attention has increasingly turned to the possibility of using the Supremacy Clause.<sup>35</sup> That avenue for trumping restrictive state laws would disappear if mifepristone lost its federal license.

Mifepristone does not represent the only drug used in medication abortions. The FDA's protocol had called for providing misoprostol (Cytotec®), which it previously had approved for treating

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a subtle but potentially consequential distinction between interdicting supply of the drug and interdicting demand for it. Older time limits on securing any type of abortion (e.g., fifteen weeks) had no real impact given the first trimester window for use of the drug, but newer ones (e.g., six weeks) would dramatically curtail its use. Separately, some states resisted coverage obligations under public insurance programs. See Robert Pear, *States, Required to Cover Some Abortions, Flout Law*, N.Y. TIMES, Feb. 18, 2019, at A14 ("Federal law does not explicitly require Medicaid coverage of the prescription drugs used to terminate a pregnancy. But states are generally required to cover the drugs of any companies that agree to give deep discounts to Medicaid through its drug rebate program, and the manufacturer of Mifeprex, Danco Laboratories, is among those companies."); *id.* (explaining that this means "states are supposed to cover the drug when it is used in abortions eligible for federal funding under the Hyde Amendment"—namely, in cases of rape, incest or life-threatening circumstances—but that thirteen states had failed to do so).

32. See *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2284 (2022); see also Caroline Kitchener et al., *A Fragile New Phase*, WASH. POST, June 23, 2023, at A1 (cataloging the abortion access landscape one year later).

33. See Noah, *supra* note 27, at 19 n.69 ("These challenges claimed an undue burden on the abortion decision but did not raise any preemption arguments.").

34. See Pam Belluck & Sheryl Gay Stolberg, *In Abortion Fight, Pills Could Be the Next Focus*, N.Y. TIMES, May 6, 2022, at A1; Caroline Kitchener, *Abortion Foes Aim to Cut Pill Access*, WASH. POST, Dec. 15, 2022, at A1.

35. See, e.g., *GenBioPro, Inc. v. Sorsaia*, No. 23-0058, 2023 WL 5490179 (S.D. W. Va. Aug. 24, 2023) (dismissing claims by the generic manufacturer of mifepristone that FDA approval preempted state restrictions as applied to medication abortion); David S. Cohen et al., *The New Abortion Battleground*, 123 COLUM. L. REV. 1, 53–71 (2023); Pam Belluck, *Lawsuit Challenges State Abortion Pill Ban*, N.Y. TIMES, Jan. 26, 2023, at A19; David G. Savage, *Abortion-Fueled Battle Between FDA and Red States*, L.A. TIMES, July 17, 2022, at A1; see also Lars Noah, *State Regulatory Responses to the Prescription Opioid Crisis: Too Much to Bear?*, 124 DICK. L. REV. 633, 665 n.136 (2020) (noting that, if "the U.S. Supreme Court backpedals on women's freedom to terminate a pregnancy, then the Supremacy Clause may become an increasingly important tool in the face of growing restrictions imposed by the states").



ulcers, a couple of days after taking mifepristone,<sup>36</sup> and misoprostol alone could serve this purpose though somewhat less effectively.<sup>37</sup> Entirely apart from triggering an abortion, misoprostol has long enjoyed a recognized off-label use in managing miscarriages, which explains the FDA's decision to call for its use in tandem with mifepristone. Some have now urged the agency to formally approve a supplemental indication for use of both drugs after miscarriage, which would allow off-label use as a potential end run around the spread of broadly applicable abortion restrictions at the state level.<sup>38</sup>

Before mifepristone became available, some physicians also induced abortions with a more powerful drug, methotrexate, which the FDA had approved to treat rheumatoid and juvenile arthritis, psoriasis, and certain blood cancers.<sup>39</sup> State restrictions on abortion accomplished by any means would bar such off-label uses and without the prospect that the agency's older approval decisions would

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36. See Noah, *supra* note 1, at 585; see also *id.* at 588–90 (explaining that the manufacturer of Cytotec initially resisted getting drawn into this use).

37. See Pam Belluck, *Pill in Series Can Be Used on Its Own*, N.Y. TIMES, Apr. 12, 2023, at A15; Rachel Roubein & Caroline Kitchener, *Abortion Providers Grapple with Conflicting Rulings on Drug Mifepristone*, WASH. POST, Apr. 9, 2023, at A10; see also Roni Caryn Rabin, *Abortion Using Pills May Be Safe After 12 Weeks*, N.Y. TIMES, July 7, 2023, at A11 (discussing newly published research documenting successful use of misoprostol alone to terminate pregnancies even after the first trimester).

38. See Pam Belluck, *CVS and Walgreens Plan to Offer Abortion Pills*, N.Y. TIMES, Jan. 6, 2023, at B5 (“Recently, dozens of groups, including the American College of Obstetricians and Gynecologists and the American Medical Association, filed a citizen petition asking the F.D.A. to take action to make it easier for mifepristone to be used for miscarriages.”); Laura Ungar, *Lawsuit Threatens Miscarriage Care; One of the Most Widely Used Treatments for Miscarriage Is in Jeopardy*, BOS. GLOBE, May 7, 2023, at A15 (“[I]t is often used ‘off label’ to treat early pregnancy loss or to speed up delivery when a fetus dies later in pregnancy. These uses are so common that US senators urged manufacturer Danco to apply to the FDA to add miscarriage to the label of its drug, Mifeprex.”); see also Courtney A. Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 NEW ENG. J. MED. 2161, 2169 (2018) (finding it superior to the use of misoprostol alone in a randomized clinical trial); cf. Sarah Jane Tribble, *Abortion Drug Also Treats a Rare Disease*, WASH. POST, Apr. 10, 2018, at E6 (reporting that the agency approved a 300 mg mifepristone product (Korlym®) from Corcept to treat hyperglycemia associated with Cushing’s syndrome accompanied by a black box warning about its capacity to end pregnancy but not subject to any access restrictions).

39. See Katie Shepherd & Frances Stead Sellers, *For the Chronically Ill, a Domino Effect from Abortion Bans*, WASH. POST, Aug. 11, 2022, at A1; see also Noah, *supra* note 1, at 576 (discussing the off-label use of methotrexate as an abortifacient prior to the approval of mifepristone); cf. *id.* at 575 n.11 (“The Upjohn Company once sold a prostaglandin product that physicians could use to induce an abortion, but it ceased marketing the drug in 1985 in response to boycotts against its other products.”).

trigger implied preemption,<sup>40</sup> although the Supremacy Clause arguably would stand in the way of direct state prohibitions on any (even approved) uses of those other drugs just as federal preemption should imperil state efforts to ban the sale of mifepristone.<sup>41</sup> By invalidating the FDA's original approval of mifepristone, which also had authorized the concomitant use of misoprostol in terminating a pregnancy (though still not separately labeled for that purpose), Judge Kacsmaryk's sweeping decision threatened to pull the rug out from under these sorts of tricky questions.

The district court's decision to grant preliminary relief hardly represents the last word on the merits of this particular lawsuit.<sup>42</sup> First, on the very same day that Judge Kacsmaryk issued his order, another federal court directed the agency to keep the drug on the

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40. *Cf. Cline v. Okla. Coal. for Reprod. Just.*, 313 P.3d 253, 257–60, 262 (Okla. 2013) (construing a state law that had required strict adherence to the FDA's approved labeling whenever using an "abortion-inducing drug" as not only a prohibition on different methods of using mifepristone but also any use of misoprostol, even in conjunction with mifepristone as called for by the agency, and the off-label use of methotrexate to manage ectopic pregnancies). After the state legislature amended this law, another constitutional challenge succeeded because it mandated strict adherence to the labeling for mifepristone originally approved by the FDA, which became obsolete after the agency approved substantial revisions in 2016. *See Okla. Coal. for Reprod. Just. v. Cline*, 441 P.3d 1145, 1153–61 (Okla. 2019) (invalidating this law as posing an undue burden on the federal constitutional right to abortion).

41. *See* E-mail from author to Lorie Chaiten, Senior Staff Att'y, ACLU Reprod. Freedom Project (Jan. 28, 2022, 3:22 PM) (on file with author) ("[A] state ban of mifepristone would make the implied preemption argument so much more straightforward than a more nuanced restriction imposed on the means of access through state-regulated intermediaries . . . [W]hether or not REMS/ETASU applies (which I think is why you figured a more nuanced state restriction was more rather than less likely to face preemption), FDA approval of a drug invariably should trump a state's contrary (non-approval) preference."); *see also* Noah, *supra* note 27, at 7–14, 28–35 (elaborating on the application of implied preemption to state prohibitions on the sale of all sorts of FDA-approved drugs); Noah, *supra* note 35, at 644–45 & n.42 (asking whether state restrictions on the use by health professionals of an FDA-approved prescription drug might amount to a de facto prohibition so as to trigger implied federal preemption); Patricia J. Zettler & Ameet Sarpatwari, *State Restrictions on Mifepristone Access: The Case for Federal Preemption*, 386 NEW ENG. J. MED. 705 (2022).

42. Technically, it issued a stay of the original approval (and all subsequent actions by the agency related to that approval) rather than grant a preliminary injunction ordering suspension of that approval, but it comes to the same thing (and if the court ultimately decides to issue such relief on a permanent basis, then it would plainly amount to an order that the FDA withdraw the drug's approval). *See All. for Hippocratic Med. v. FDA*, No. 23-10362, 2023 WL 5266026, at \*30–32 (5th Cir. Aug. 16, 2023) (rejecting objections to the district court framing its preliminary relief in this manner).

market, though it declined to grant the preliminary relief sought by the attorneys general representing more than a dozen blue states that had challenged the FDA's failure to drop all of its special restrictions.<sup>43</sup> Second, the government immediately appealed Judge Kacsmaryk's order, prompting the Fifth Circuit to narrow its scope pending resolution of the appeal.<sup>44</sup> Although it left the original approval in place, this modified preliminary relief still operated to roll back the agency's more recent easing of access limitations.<sup>45</sup>

The appellate court's slightly more nuanced initial decision drew attention to the fact that this litigation threatened to unravel a separate license to sell mifepristone as an abortifacient. In 2009, the FDA received an abbreviated new drug application (ANDA) to sell a generic version of the drug, which it took the agency a full decade to approve.<sup>46</sup> Thus, generic approval came only after the FDA had lowered the recommended dose, modified the professional labeling, and loosened some of the distribution restrictions originally imposed on the brand-name drug produced by Danco Laboratories.<sup>47</sup> Because the Fifth Circuit's modified preliminary relief jeopardized every one of these post-2016 changes, the approved ANDA held by GenBioPro,

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43. See *Washington v. FDA*, No. 23-CV-3026, 2023 WL 2825861, at \*9–11 (E.D. Wash. Apr. 7, 2023) (issuing relief that covered approximately half of the country), *clarified*, No. 23-cv-3026, 2023 WL 2941567 (E.D. Wash. Apr. 13, 2023); see also Pam Belluck, *A Dozen States Sue the F.D.A., Seeking the Removal of Special Restrictions on an Abortion Pill*, N.Y. TIMES, Feb. 25, 2023, at A13 (explaining it as an effort to create a counterweight to the Texas litigation); Aaron Gregg & Christopher Rowland, *Abortion Pill Companies Struggle to Make Sense of Conflicting Court Rulings*, WASH. POST, Apr. 11, 2023, at A2.

44. See *All. for Hippocratic Med. v. FDA*, No. 23-cv-10362, 2023 WL 2913725, at \*21 (5th Cir. Apr. 12, 2023).

45. See Pam Belluck & Adam Liptak, *2 New Rulings Muddy Waters over Abortion*, N.Y. TIMES, Apr. 14, 2023, at A1.

Even after labels are rewritten to comply with the new, 5th Circuit-ordered regime, a process that could take months, women would only be able to obtain mifepristone for abortions up to seven weeks, not the 10 weeks currently approved by the FDA. Only doctors would be allowed to prescribe mifepristone. Women would have had to make not one but three separate visits to health facilities; the medication would no longer be available by mail. The approved dosage of mifepristone would have been triple what is currently used. Ruth Marcus, *Opinion, The Abortion Pill Ruling Is as Good as It Gets for This Court*, WASH. POST, Apr. 23, 2023, at A25. As individual tablets always have contained 200 mg, reverting to the original dosage would not require any reformulation but only relabeling to call for the ingestion of three tablets at once rather than just taking a single tablet.

46. See FDA, *Approval Letter for Mifepristone Tablets, 200 mg*, ANDA No. 091178 (Apr. 11, 2019), [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2019/091178Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/091178Orig1s000ltr.pdf) [<https://perma.cc/5UGP-VVAH>].

47. See *supra* notes 23–24 and accompanying text.

Inc. seemingly would evaporate, which prompted the company to file a separate lawsuit against the FDA in an effort to protect its rights to continue selling the sole generic form of mifepristone.<sup>48</sup> Judge Kacsmaryk's more sweeping suspension of the original approval in its entirety would, of course, also have invalidated GenBioPro's license.

Nine days after the Fifth Circuit issued its preliminary order, the U.S. Supreme Court granted an emergency stay of even that modified injunction,<sup>49</sup> so both the brand-name and generic versions of mifepristone would remain available on the same terms as before Judge Kacsmaryk got involved. A few weeks later, a different panel of the Fifth Circuit, composed entirely of staunchly anti-abortion judges, heard oral arguments in the case.<sup>50</sup> Meanwhile, officials in the Biden

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48. See Christopher Rowland, *U.S. Manufacturer of Abortion Pill Sues FDA to Save Generic Mifepristone*, WASH. POST, Apr. 20, 2023, at A15 (reporting that the company filed its action in the Maryland federal district court).

49. See Danco Labs., LLC v. All. for Hippocratic Med., 143 S. Ct. 1075 (2023) (per curiam); see also Abbie VanSickle, *Justices, for Now, Safeguard Access to Abortion Pills*, N.Y. TIMES, Apr. 22, 2023, at A1 (reporting that Justice Alito alone filed a dissenting opinion while Justice Thomas simply noted that he too dissented). Just a couple of years earlier, when the Supreme Court initially declined to intervene in a lawsuit brought by liberal groups seeking a waiver of the in-person dispensing requirement early in the pandemic, Justices Alito and Thomas complained in dissent that a federal judge "took it upon himself to overrule the FDA on a question of drug safety." *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 10, 12 (2020) (Alito, J., dissenting). Talk about rank hypocrisy!

50. See Ann E. Marimow et al., *Appeals Court Appears Likely to Restrict Access to Abortion Pill Mifepristone*, WASH. POST, May 18, 2023, at A18; see also Abbie VanSickle, *Abortion Pill Case Will Be Heard by "Most Conservative" Court in U.S.*, N.Y. TIMES, May 17, 2023, at A14 (reporting that the three judges assigned to the panel hearing the case had previously revealed their staunch opposition to abortion). Within just three months, the panel announced its decision to affirm the district court's order in part, agreeing that the plaintiffs were likely to succeed on the merits of their claim that the agency had acted arbitrarily and capriciously when in 2016 it started to remove the original restrictions on distribution. See *All. for Hippocratic Med. v. FDA*, No. 23-10362, 2023 WL 5266026, at \*23-27 (5th Cir. Aug. 16, 2023); see also *id.* at \*2, 29, 32 (recognizing that the Supreme Court's earlier stay remained in effect and thereby would hold this latest order in abeyance). The panel split on the statute of limitations question, with the majority holding that the plaintiffs' delay barred it from considering objections to the denial of their earlier citizen petition challenging the original approval. See *id.* at \*20-22. But see *id.* at \*36-42 (Ho, J., concurring in part and dissenting in part) (disagreeing on this score, and also finding merit in the objections to the FDA's initial approval). Strangely, even though GenBioPro had not intervened in the case, the court explicitly preserved the company's license but made it subject to the pre-2016 restrictions even though the FDA had already dropped some of those when it first approved this ANDA. See *id.* at \*2, 18-19, 31 (majority opinion) (premising this part of its decision on a conclusion that the plaintiffs lacked standing to challenge agency approval of the generic). Absent this peculiar court-ordered modification in the terms of the approved ANDA, and in

administration urged the FDA to prepare contingency plans in the event that the government ended up losing the case,<sup>51</sup> and some states decided to stockpile supplies of the drugs that should last for a few years.<sup>52</sup>

### III. ASSAILING AN FDA-ISSUED LICENSE HARDLY BREAKS NEW GROUND

Although some in the media could not resist the temptation to demonize Judge Kacsmaryk, let us put to one side his shoddy fact-finding,<sup>53</sup> outlandish rhetoric,<sup>54</sup> peculiar delays in releasing

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contrast to the much older license for the brand-name drug, the generic license could not simply revert to the nonexistent conditions imposed on GenBioPro three years before it had secured approval in 2019.

51. See Pam Belluck, *Uncertainties Abound After Conflicting Rulings*, N.Y. TIMES, Apr. 10, 2023, at A13 (explaining different ways that the FDA might choose to exercise its nonenforcement discretion); Meryl Kornfield et al., *White House Prepares for Legal and Political Battle on Abortion Medication*, WASH. POST, Apr. 13, 2023, at A3 (discussing the likely delays involved in starting the approval process anew). In the immediate aftermath of the *Dobbs* decision, some had urged the White House to issue an emergency declaration. See Nancy Northup, Opinion, *Biden Must Declare a Public Health Emergency for Abortion—Immediately*, WASH. POST, July 1, 2022, at A17; Tarini Parti, *Democrats Press Biden on Emergency Powers*, WALL ST. J., July 21, 2022, at A4 (reporting that officials had considered declaring “a public-health emergency on abortion”). Among other things, such a move might facilitate the rapid reissuance of the license through an emergency use authorization (EUA). See 21 U.S.C. § 360bbb-3; see also Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders; Availability, 82 Fed. Reg. 4362 (Jan. 13, 2017).

52. See Reis Thebault et al., *Democratic States Stockpile Abortion Pills as Access Rests in Courts*, WASH. POST, Apr. 22, 2023, at A6.

53. See Amy Schoenfeld Walker et al., *Are Abortion Pills Safe? Here’s the Evidence*, N.Y. TIMES, Apr. 10, 2023, at A12; Lauren Weber et al., *Tex. Abortion Pill Ruling Built on Shaky Science*, WASH. POST, Apr. 14, 2023, at A1.

54. See Caroline Kitchener, *Judge “Was Made for” Antiabortion Ruling on Pill*, WASH. POST, Apr. 9, 2023, at A1 (“The judge referred to fetuses as ‘unborn humans’ or ‘unborn children’ and doctors who provide abortions as ‘abortionists’—terms often invoked by the antiabortion movement. He implied that abortion is a form of social Darwinism, a theory used to justify the discredited and racist practice of eugenics . . . .”); Ruth Marcus, Opinion, *The Worst Federal Judge in America Now Has a Name*, WASH. POST, Apr. 9, 2023, at A25 (“What really distinguishes Kacsmaryk is the loaded content of his rhetoric—not the language of a sober-minded, impartial jurist but of a zealot, committed more to promoting a cause than applying the law.”); see also Abbie VanSickle, *For Texas Judge in Abortion Case, a Life Shaped by Conservative Causes*, N.Y. TIMES, Apr. 8, 2023, at A17.

information to the public,<sup>55</sup> and the subsequently uncovered ethical lapses that evidently occurred during his confirmation process.<sup>56</sup> Instead, we need to examine whether Judge Kacsmaryk's legal analysis withstands close scrutiny. Even then, let us dispense with some striking though largely collateral questions, such as the applicability of a six-year statute of limitations.<sup>57</sup> The court plainly did break new ground in relying on the terribly antiquated Comstock Act to invalidate the agency's recent willingness to tolerate dispensing by mail,<sup>58</sup> but that only comes into play if the original approval remains

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55. See Katie Benner & Pam Belluck, *Judge in Abortion Pill Case Is Said to Delay Public Notice for Hearing*, N.Y. TIMES, Mar. 13, 2023, at A11 (reporting that "it was unusual to hold the status conference under seal and to keep the public from knowing about the hearing"); Ann E. Marimow, *Judge Cited Threats in Delaying Abortion-Pill Hearing Notice*, WASH. POST, Mar. 15, 2023, at A5 ("In recent years, the number of threats tracked by the U.S. Marshals Service, which protects judges and courthouses, has dramatically increased. But public access to legal proceedings remains a basic tenet of the U.S. judicial system, and it is rare for judges to delay public notice of hearings or ask lawyers not to discuss scheduled hearings."); see also Kitchener, *supra* note 54 ("Friends said they weren't sure why Kacsmaryk had chosen to issue his ruling on Good Friday. Maybe he was trying to limit his media coverage, one said—or maybe he was trying to make a point.").

56. See Caroline Kitchener et al., *Texas Judge Didn't Reveal Piece on Abortion, Gender*, WASH. POST, Apr. 17, 2023, at A1 (reporting that, as soon as his judicial nomination process got started, Mr. Kacsmaryk removed his name from a strident soon-to-be-published law review article); see also Ann E. Marimow, *In Unusual Redaction, Kacsmaryk Omits Single Stock in Financial Disclosures*, WASH. POST, Apr. 22, 2023, at A5 (suggesting that the holding worth at least \$5 million related to the Publix grocery store chain). Contrast a glowing piece about the drug's inventor published a few months earlier. See Pam Belluck, *Father of the Abortion Pill*, N.Y. TIMES, Jan. 17, 2023, at D1 (profiling Dr. Étienne-Émile Baulieu, age 96).

57. See *All. for Hippocratic Med. v. FDA*, No. 22-CV-223-Z, 2023 WL 2825871, at \*9–12 (N.D. Tex. Apr. 7, 2023), *aff'd in part, vacated in part*, No. 23-10362, 2023 WL 5266026, at \*32 (5th Cir. Aug. 16, 2023). In fact, his resolution of various other justiciability questions (e.g., standing, preclusion of review) might well merit criticism and even condemnation or ridicule. See Adam Liptak, *For Conservative Justices, Upholding Abortion Pill Ruling Is No Sure Thing*, N.Y. TIMES, Apr. 11, 2023, at A13; Ruth Marcus, Opinion, *Another Misguided Ruling on Abortion Meds*, WASH. POST, Apr. 14, 2023, at A21 (criticizing the "contortions" in the standing analysis used by the lower courts). In the course of later partly affirming the district court's order, the Fifth Circuit fully concurred in the standing analysis. See *All. for Hippocratic Med.*, 2023 WL 5266026, at \*12–18; *id.* at \*33–36 (Ho, J., concurring in relevant part). I will, however, jump over those threshold inquiries as well as the factors (apart from the likelihood of success on the merits) relevant when deciding whether to grant preliminary relief.

58. See *All. for Hippocratic Med.*, 2023 WL 2825871, at \*16–19; see also Emily Bazelon, *Why a 150-Year-Old Lewdness Law Is Key to the Abortion Pill Battle*, N.Y. TIMES, May 17, 2023, at A14; Dan Diamond & Ann E. Marimow, *Long-Idle 1873 Law Finds Traction in Abortion Case*, WASH. POST, May 18, 2023, at A1. On appeal to the Fifth Circuit, the majority found it unnecessary to reach this issue. See *All. for Hippocratic*



in place after all.<sup>59</sup> Instead, this Part will focus on the nugget at the center of the case that would only interest administrative law aficionados, while the more vocal results-oriented scholars on either side of this hottest of hot button issues seem to have already made up their minds.

The national press repeatedly emphasized the unprecedented nature of the decision to hold unlawful a license issued by the FDA, quoting various experts opining as much.<sup>60</sup> Indeed, “an amicus brief filed by 19 FDA scholars stated they were ‘not aware of any case in

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*Med.*, 2023 WL 5266026, at \*27 n.8; *cf. id.* at \*42–45 (Ho, J., concurring in part and dissenting in part) (finding merit in the objections under the Comstock Act to the FDA’s decision in 2021 to allow for dispensing by mail).

59. Indeed, it could become extremely consequential if the courts ultimately decide against invalidating the original approval. Although raised as an objection only to the FDA’s more recent willingness to allow for mail-order dispensing, such a holding could also impact upstream transfers from manufacturers to wholesalers and distributors, at least if done using the mails (defined as including any express common carriers)—companies involved in getting mifepristone to clinics for in-person dispensing as contemplated by the original license (or to retail pharmacies as later modified) would, at least upon a change in control of the White House, have to fear the prospect of federal prosecution for distributing their FDA-approved drug even in states where its use would violate no local laws. *See* Liz Essley Whyte & Laura Kusisto, *Abortion Opponents Invoke 19th-Century Law in Legal Strategy*, WALL ST. J., May 23, 2023, at A3 (“Republican elected officials have warned pharmacies and drug distributors that they could one day be prosecuted under the act.”); *cf.* Caroline Kitchener, *A New Pipeline for Abortion Pills*, WASH. POST, July 21, 2023, at A1 (“[O]ne of the largest abortion pill suppliers, Europe-based Aid Access, allows U.S. medical professionals in certain Democratic-led states that have passed abortion ‘shield’ laws to prescribe and mail pills directly to patients in antiabortion states.”); Allison McCann, *A Pipeline of Abortion Pills Flowing to the U.S.*, N.Y. TIMES, Apr. 19, 2023, at A1 (“Experts say a federal crackdown on patients ordering abortion pills—even those [now unlawfully] arriving from overseas—is unlikely.”).

60. *See, e.g.*, Pam Belluck & Christina Jewett, *Drug Executives Condemn Ruling on Abortion Pill*, N.Y. TIMES, Apr. 11, 2023, at A1 (“Legal scholars said the Texas ruling appeared to be the first time a court had tried to invalidate the approval of a drug over the objection of the F.D.A.”); Perry Stein et al., *What the Ruling Means and What Comes Next*, WASH. POST, Apr. 22, 2023, at A4 (“Kacsmarky’s ruling marks the first time a judge has ordered the FDA to revoke the approval of a drug, and experts say that it could politicize the agency and undermine its ability to approve medication that Americans rely on every day.”); Leana S. Wen, Opinion, *The FDA’s Review Process Is Now at Risk*, WASH. POST, Apr. 19, 2023, at A21 (quoting Dr. Jane E. Henney, FDA Commissioner at the time of mifepristone’s original approval: “This would be the first revocation of an FDA-approved product by the courts.”); *see also* Susan Jaffe, *Drug Developers Caution Against US Mifepristone Ban*, 401 LANCET 1325, 1325 (2023) (“This is the first time that a federal court has overturned the FDA’s approval of a drug.”); Joshua M. Sharfstein, Opinion, *The Abortion Pill Decision Is Dangerous*, N.Y. TIMES, Apr. 11, 2023, at A21 (“For what appears to be the first time, a court has invalidated an agency drug approval . . . .”); *infra* note 97 (identifying more of the same types of claims made by experts in the field).

which a court has removed a drug from the market over FDA's objection."<sup>61</sup> Putting aside the caveat about a lack of awareness, they should know better than to make such a sweeping claim, especially one that is so readily disproven.<sup>62</sup> Sacrificing accuracy in order to grab headlines with glib pronouncements risks making it too easy for your opponents to dismiss more serious (and subtle) objections.<sup>63</sup> Although I find much to dislike about what Judge Kacsmaryk wrote, especially his punch line, judicial review of agency licensing happens with some regularity, and that includes FDA drug approval decisions; instead, judges rarely invalidate the latter because of the tremendous deference traditionally shown to this agency,<sup>64</sup> a stance of judicial humility that seems to have fallen altogether out of fashion.<sup>65</sup>

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61. Daniel G. Aaron et al., *Court Intrusion into Science and Medicine—The Mifepristone Decisions*, 329 JAMA 1735, 1735 (2023). This brief can be found at <https://perma.cc/2D73-AYJ8>. I was asked to join that brief, see E-mail from Lewis Grossman, Of Counsel, Covington & Burling, to author (Jan. 31, 2023, 2:31 PM) (on file with author), but purposely neglected to respond to this invitation, and not simply because my employer has previously frowned upon letting faculty engage in such extracurricular activities (at least when staking out positions that fail to align with the reactionary views of our elected state officials!). Cf. Michael Wines, *Ruling on Free Speech a Victory for Florida Professors*, N.Y. TIMES, Jan. 22, 2022, at A16 (reporting that a federal judge had preliminarily enjoined some of these restrictions). Nor do I imagine that they can blame a chatbot for leading them astray in this way. Cf. Benjamin Weiser, *So, Have You Heard the One About the Lawyer Using A.I.?*, N.Y. TIMES, May 29, 2023, at A1 (reporting blatant fabrications after a lawyer relied on ChatGPT to produce a brief in federal district court).

62. See *infra* notes 83 & 90 and accompanying text (identifying four contrary illustrations, including a pair decided in just the last three years). Although one might well quibble with aspects of each one of these examples, they powerfully contribute to a broader picture that differs markedly from the one painted by those aligned with the defendants in this case.

63. For instance, during oral argument in the Fifth Circuit, the DOJ lawyer reportedly made the following statement in connection with the FDA's drug approval decisions: "It's not a court's role to come in and second-guess that expertise, and no court has ever done that." Abbie VanSickle & Pam Belluck, *Appeals Court Seems Ready to Curtail Access to Abortion Pill*, N.Y. TIMES, May 18, 2023, at A1 (quoting Sarah Harrington). This came after "Judge [James C.] Ho interrupted to criticize her description of the case . . . 'I hate to cut you off so early, but you've said unprecedented,' he said, adding that the appeals court had heard other cases against the F.D.A." *Id.*; see also *All. for Hippocratic Med. v. FDA*, No. 23-10362, 2023 WL 5266026, at \*45-47 (5th Cir. Aug. 16, 2023) (Ho, J., concurring in part and dissenting in part) (elaborating on this point in the course of urging that the district court's order get affirmed in its entirety).

64. See Lars Noah, *The Little Agency That Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901, 902 (2008) ("[T]he FDA has had an enviable record of success in the courts because judges have shown tremendous deference to its expertise in implementing its public health mission.").

65. See NOAH, *supra* note 15, at 167-68, 417-18, 465-66, 478-79 (documenting multiple recent instances of this shift); see also *id.* at 327-28, 417, 449, 687 (excerpting

Although agency rulemaking gets the lion's share of attention nowadays,<sup>66</sup> the Administrative Procedure Act (APA) plainly governs licensing. That statute defines "licensing" as including an "agency process respecting the grant, renewal, denial, revocation, suspension, annulment, withdrawal, limitation, amendment, modification, or conditioning of a license."<sup>67</sup> It defines "license" as including "the whole or a part of an agency permit, certificate, approval, registration, charter, membership, statutory exemption or other form of permission."<sup>68</sup> Furthermore, in defining the term "order,"<sup>69</sup> the APA unmistakably treats licensing as a form of adjudication rather than rulemaking.<sup>70</sup> Although subsequent provisions have fairly little to say about licensing as such,<sup>71</sup> and the degrees of procedural formality that attend adjudication will vary depending on cues from an agency's particular enabling statute,<sup>72</sup> section 558(c) of the APA demands

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dissenting opinions in recent decisions of the U.S. Supreme Court accusing the other justices of disregarding expert agency judgments); *cf.* Philip Bump, Opinion, *A Ruling Concerning Misinformation . . . That Includes Some of Its Own*, WASH. POST, July 7, 2023, at A6 (skewering a new decision by a Trump-appointed district court judge in Louisiana that credulously found merit in objections to alleged pressure exerted by the Biden administration against social media companies).

66. See Eric Biber & J.B. Ruhl, *The Permit Power Revisited: The Theory and Practice of Regulatory Permits in the Administrative State*, 64 DUKE L.J. 133, 142 (2014) (bemoaning "how little attention legal scholars have paid to the permit power"); *id.* at 149 ("[P]ermits are largely absent from academic teaching and scholarship."). Although that pair of authors focused almost entirely on environmental regulation (and what they called "general permits"), individual product licenses of the sort issued by the FDA would amount to a type of "specific permits" in their typology. See *id.* at 165–72; see also *id.* at 190 (contrasting the agency's approval requirements for innovator and generic drugs); *id.* at 195 n.217 (referencing over-the-counter drug monographs as well); *id.* at 154 n.82 (citing scholarship on cancer drugs).

67. 5 U.S.C. § 551(9).

68. *Id.* § 551(8).

69. See *id.* § 551(6) (defining "order" as "the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but including licensing").

70. See *id.* § 551(7) (defining "adjudication" as the "agency process for the formulation of an order"); see also *Air N. Am. v. DOT*, 937 F.2d 1427, 1436–37 (9th Cir. 1991); *City of W. Chi. v. NRC*, 701 F.2d 632, 643 (7th Cir. 1983). Later subsections defining "sanction," "relief," and "agency action" include references to "license," see 5 U.S.C. §§ 551(10)(F), (11)(A), (13), which can have consequences for purposes of later defining the availability of judicial review.

71. Several sections make an exception from formal procedural requirements in the case of initial decisions on a licensing application. See 5 U.S.C. § 554(d)(A) (separation of functions); *id.* § 556(d) (taking evidence in person); *id.* § 557(b) (form of initial decision).

72. See *id.* § 554(a) (applying "in every case of adjudication required by statute to be determined on the record after opportunity for an agency hearing"); see also *Seacoast Anti-Pollution League v. Costle*, 572 F.2d 872, 875–80 (1st Cir. 1978).

prompt review of applications and specifies the rights of license holders before adverse agency action.<sup>73</sup> The APA did regard certain agency decisions as unreviewable,<sup>74</sup> but nothing in that statute or the FDA's enabling act would place drug approval decisions entirely beyond judicial scrutiny.<sup>75</sup>

I have long railed against the FDA's seemingly lawless behavior.<sup>76</sup> Nonetheless, in the course of documenting that phenomenon, the approval of mifepristone hardly gets mentioned as an illustration, in part because the licensing power brings with it some freedom to impose conditions.<sup>77</sup> That does not, however, mean that licensing decisions by the agency altogether escape review by the courts, nor should they given several notable missteps over the years,<sup>78</sup> but many

73. See 5 U.S.C. § 558(c); see also Lars Noah, *Sham Petitioning as a Threat to the Integrity of the Regulatory Process*, 74 N.C. L. REV. 1, 67 (1995) (“[I]n what appears to be a little-noticed provision, the APA itself directs agencies to take action on license applications with dispatch.”); Delcianna J. Winders, *Administrative License Renewal and Due Process—A Case Study*, 45 FLA. ST. U. L. REV. 539, 545–52 (2018).

74. See 5 U.S.C. § 701(a) (when “(1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law”).

75. See Noah, *supra* note 73, at 3 (referring to disputes over agency licensing “in the pharmaceutical, transportation, communications, and energy industries”). Indeed, the recent litigation over mifepristone prompted some commentators to suggest amending the statute to preclude judicial review of drug approval decisions. See Aaron et al., *supra* note 61, at 1736 (“To reduce the uncertainty that these courts have created, Congress could explicitly give the FDA the final say in approving abortion drugs—or drugs more generally.”). That strikes me as unduly strong medicine for a process that is far from unimpeachable. See *infra* note 78 and accompanying text.

76. See, e.g., Lars Noah, *Governance by the Backdoor: Administrative Law(lessness?) at the FDA*, 93 NEB. L. REV. 89, 122–24, 138 (2014); Noah, *supra* note 64, at 924 (“[O]ver the course of a century of struggling to protect the public health with its limited statutory powers and often inadequate resources, the FDA evidently has institutionalized a practice of cavalierly ignoring legal constraints.”). Instead, efforts to restrict mifepristone offered a striking illustration of the occasional competition between federal and state officials over the use of products supplied for use by health professionals. See Noah, *supra* note 27, at 18–19; see also *id.* at 2 (focusing instead on one state’s effort to ban “a drug that lacked any of the special baggage associated with mifepristone, thereby presenting the constitutional questions in a fairly straightforward fashion”).

77. See, e.g., Lars Noah, *Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority*, 1997 WIS. L. REV. 873, 931 (“Perhaps the power to license implies a power to impose conditions on approval . . . Congress has, for instance, invited the FDA to impose such other conditions on product approvals as it may deem necessary in certain limited circumstances.”).

78. See, e.g., Pam Belluck et al., *Alzheimer Drug Approved Despite Doubts It Worked*, N.Y. TIMES, July 21, 2021, at A1 (discussing unusual controversy over the FDA’s decision to license Biogen’s monoclonal antibody Aduhelm® (aducanumab)); Christina Jewett, *Do Fast-Track Drugs Need More Scrutiny?*, N.Y. TIMES, Mar. 29, 2022, at D1

of the illustrations that follow involve largely misplaced challenges prompting judges to find fault only infrequently.

In 1993, for instance, the FDA approved the new animal drug application (NADA)<sup>79</sup> for Posilac<sup>®</sup> (recombinant bovine somatotropin (rbST)), a synthetic growth hormone intended for use in promoting milk production in dairy cattle.<sup>80</sup> It took little time for opponents to lodge a judicial challenge, but the federal district court in Wisconsin found no merit to their objections—not because FDA licensing enjoys immunity, but in light of the deference accorded to the agency’s expertise in making such judgments.<sup>81</sup> More recently, the NADA for a transgenic salmon prompted similar efforts at obstruction, and it took two full decades before the FDA finally granted approval.<sup>82</sup>

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(focusing on questions about the efficacy of Makena<sup>®</sup> for preterm labor); *see also* Lars Noah, *Federal Regulatory Responses to the Prescription Opioid Crisis: Too Little, Too Late?*, 2019 UTAH L. REV. 757, 773 (explaining that “the FDA’s profligacy in approving new opioids has hardly abated”); Noah, *supra* note 27, at 4 (observing that the agency’s approval of the long-acting hydrocodone product Zohydro<sup>®</sup> “drew howls of protest from public health experts and law enforcement officials”); *cf.* Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51, 67 (D.D.C. 1998) (“In asserting that any and all scientific claims about . . . prescription drugs are presumptively untruthful or misleading until [it] has had the opportunity to evaluate them, FDA exaggerates its overall place in the universe.”); *id.* (quoting my still earlier work for the proposition that the agency “is not a peer review mechanism for the scientific community”).

79. NADAs differ somewhat from NDAs insofar as approval leads to the issuance of a regulation available (subject only to any remaining patents) to any firm wishing to manufacture and sell the drug, which most closely resembles the “monograph” process that the FDA has used to authorize the marketing of many (typically older) over-the-counter drug products. *See* Lars Noah, *Reversal of Fortune: Moving Pharmaceuticals from Over-the-Counter to Prescription Status?*, 63 VILL. L. REV. 355, 363–66 (2018); *cf.* Lars Noah & Richard A. Merrill, *Starting from Scratch?: Reinventing the Food Additive Approval Process*, 78 B.U. L. REV. 329, 420 & n.405 (1998) (making the same point about FDA approval of food additive petitions, and focusing on unusual conditions that it had imposed on a controversial fat substitute); *id.* at 373–74 (explaining that anyone with objections has a statutory right to request a public hearing before the agency).

80. *See* Animal Drugs, Feeds, and Related Products; Sterile Sometribove Zinc Suspension, 58 Fed. Reg. 59,946, 59,947 (Nov. 12, 1993) (codified at 21 C.F.R. § 522.2112 (2023)).

81. *See* Stauber v. Shalala, 895 F. Supp. 1178, 1189–97 (W.D. Wis. 1995) (rejecting a challenge lodged by a group of consumer activists claiming that the FDA’s decision to approve the drug was arbitrary and capricious); *see also* Lars Noah, *Giving Personal Injury Attorneys Who Run Misleading Drug Ads a Dose of Their Own Medicine*, 2019 U. ILL. L. REV. 701, 736–40 (discussing the broader battle unleashed by the agency’s decision).

82. *See* New Animal Drugs in Genetically Engineered Animals; opAFP-GHc2 Recombinant Deoxyribonucleic Acid Construct, 80 Fed. Reg. 73,104 (Nov. 24, 2015) (codified at 21 C.F.R. § 528.1092 (2023)); *see also* Pub. L. No. 114-113, § 761, 129 Stat. 2242, 2285 (2015) (appropriations rider adopted one month after FDA

In fact, when challenged on various grounds, a federal district court in California found merit to some of the objections, ordering the agency to complete its environmental assessment but declining to vacate the approval in the meantime.<sup>83</sup>

On occasion, courts also have entertained legal challenges to revised licenses that attempt to reopen issues previously resolved by the agency, though again a posture of deference—as opposed to some basic defect in justiciability—accounts for the fact that these ultimately fail. For instance, after the FDA expanded the permitted uses of aspartame (NutraSweet®), a previously approved food additive, to include carbonated beverages (“wet use”), a consumer interest group filed a judicial challenge, but the court held among other things that the agency had already addressed more general issues surrounding this artificial sweetener’s safety at the time of original approval (for “dry use”).<sup>84</sup>

In the case of drugs, only disappointed applicants can seek judicial review of adverse agency action related to licensing, and they rarely do so.<sup>85</sup> Interested third parties can involve themselves only

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approval that mandated disclosure in labeling); Lars Noah, *Whatever Happened to the “Frankenfish”? The FDA’s Foot-Dragging on Transgenic Salmon*, 65 ME. L. REV. 606, 623 n.105 (2013) (noting that the company first sought permission in 1995); *id.* at 623–25 (criticizing the extent to which this license application got held hostage to politics).

83. *See* Inst. for Fisheries Res. v. FDA, 499 F. Supp. 3d 657, 665–70 (N.D. Cal. 2020), *appeal dismissed*, No. 21-15640, 2021 WL 4807198 (9th Cir. 2021); *see also* Request for Comments, Draft Amended Environmental Assessment for Production of AquAdvantage Salmon at the Bay Fortune and Rollo Bay Facilities on Prince Edward Island, Canada, 87 Fed. Reg. 69,032, 69,034 (Nov. 17, 2022).

84. *See* Cmty. Nutrition Inst. v. Young, 773 F.2d 1356, 1362–63 (D.C. Cir. 1985) (“The agency’s conclusions concerning the safety of the dry use of aspartame, except to the extent that new evidence suggests that the FDA may not rely on these prior findings in its deliberations on wet use, may not be raised again in this proceeding in the interests of administrative finality and judicial economy.”). As to wet use, the court deferred to the FDA’s expert judgment that there were no material issues warranting a hearing on the petitioners’ various objections. *See id.* at 1363–67; *see also id.* at 1364 (“Appellants have not introduced any new evidence suggesting that the FDA, in its approval of aspartame for wet use, abused its discretion in relying on tests and studies conducted previously in connection with the effects of consuming aspartame in dry uses.”); Noah & Merrill, *supra* note 79, at 401–05 (elaborating on the regulation of aspartame); Christina Jewett, *Aspartame Could Cause Cancer*, W.H.O. Agency Says, N.Y. TIMES, July 14, 2023, at A10.

85. *See* Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1864 (1996) (“Nor are FDA’s decisions—to grant, withhold, or delay approval—commonly challenged in court. . . . The FDA product approval system is, in short, remarkably free from conventional legal constraint.”); Lars Noah, *Deputizing Institutional Review Boards to Police (Audit?) Biomedical Research*, 25 J. LEGAL MED. 267, 284 (2004) (“[T]hese agency decisions are largely inscrutable;



by filing a citizen petition and then challenging the FDA's rejection of their request in court.<sup>86</sup> Public interest groups routinely file such petitions urging the withdrawal of an approved drug,<sup>87</sup> though it appears that they typically do not bother seeking judicial review when these efforts fail. Competitors also file such petitions,<sup>88</sup> and they seem more willing to involve the courts even if the traditional deference that judges show the agency ultimately makes such efforts

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the FDA offers very little in the way of an official explanation. . . . Patients, physicians, and other interested persons generally have no direct opportunity to ask a court to review an agency decision to approve or reject an NDA.”). Thus, Judge Kacsmaryk's repeated puzzlement about the lack of any cogent agency explanation about choices that it made at the time of original approval or thereafter (much as his demand that it account for shifts from predecisional internal proposals) makes little sense. *See* *Cumberland Pharms. Inc. v. FDA*, 981 F. Supp. 2d 38, 52 (D.D.C. 2013) (“[D]isagreement among agency staff during the decisionmaking process does not fatally undermine the agency's final determination, nor does it alone justify according the agency's final decision less deference than usual.”); *see also* *Jud. Watch, Inc. v. FDA*, 449 F.3d 141, 151 (D.C. Cir. 2006) (“[D]ocuments dated after mifepristone's approval for abortion may still be predecisional and deliberative [under the Freedom of Information Act] with respect to other, nonfinal agency policies, including uses of the drug that the agency has not approved.”).

86. *See* Noah, *supra* note 1, at 593 n.104.

87. *See, e.g.*, *Determination That Serzone (Nefazodone Hydrochloride) Was Not Withdrawn from Sale for Reasons of Safety or Effectiveness*, 69 Fed. Reg. 62,447 (Oct. 26, 2004) (explaining that the agency had denied a petition filed by the Public Citizen Health Research Group requesting the withdrawal of the license issued for an antidepressant). For a couple of older examples of petitions from that same organization seeking license withdrawals, which each happened to involve non-steroidal anti-inflammatory drugs (NSAIDs) indicated for use in patients with arthritis, *see* Notice of Public Hearing, 51 Fed. Reg. 3658, 3659 (Jan. 29, 1986) (piroxicam (Feldene®)); and Notice of Public Hearing, 49 Fed. Reg. 1939, 1940 (Jan. 16, 1984) (phenylbutazone (e.g., Butazolidin®) and oxyphenbutazone (Tandearil®)).

88. *See* Amendments to Regulations on Citizen Petitions, Petitions for Stay of Action, and Submission of Documents to Dockets, 81 Fed. Reg. 78,500, 78,501 (Nov. 8, 2016) (“Over the years, FDA has received numerous petitions asking the agency not to approve a particular ANDA . . . . [W]hen petitions are submitted late in the review process for challenged applications and do not raise valid scientific and/or legal issues, they may have the effect of improperly delaying the approval of an application.”); Marc Kaufman, *Petitions to FDA Sometimes Delay Generic Drugs: Critics Say Companies Misusing Process*, WASH. POST, July 3, 2006, at A1 (reporting an official estimate that, of the 170 citizen petitions pending before the agency, approximately 30% are “blocking petitions”); *see also* Matthew Avery et al., *The Antitrust Implications of Filing Sham Citizen Petitions with the FDA*, 65 HASTINGS L.J. 113 (2013). Indeed, when it promulgated rules governing orphan drugs, the FDA rejected suggestions that it create a preapproval challenge procedure, explaining that incumbent firms could file citizen petitions to challenge approvals that allegedly impinged on their own exclusivity rights. *See* Orphan Drug Regulations, 57 Fed. Reg. 62,076, 62,083 (Dec. 29, 1992).

futile.<sup>89</sup> Federal judges do not, however, dismiss such challenges as unreviewable, and every once in a while these efforts succeed, even if only on some technicality.<sup>90</sup>

Moreover, as persons conversant about products liability litigation know all too well, courts routinely entertain collateral attacks

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89. See Lars Noah, *Banning Off-Label Drug Promotion Offends the U.S. Constitution: Making the Strongest Case*, 83 ALB. L. REV. 301, 311 (2020) (“[Market] exclusivities operate to prevent the agency from issuing licenses to competitors, and the failure to honor this restriction would trigger a right of judicial review against the FDA rather than against the competitor.”). The pattern has become all too predictable: incumbent firms challenge approval of ANDAs by filing citizen petitions and then seek judicial review when the agency denies their petitions, which ends in summary judgment granted to the FDA (and invariably gets affirmed when appealed). See, e.g., *Hill Dermaceuticals, Inc. v. FDA*, 709 F.3d 44, 47–48 (D.C. Cir. 2013); *Upjohn Mfg. Co. v. Schweiker*, 681 F.2d 480, 482–84 (6th Cir. 1982); *Cumberland Pharms. Inc. v. FDA*, 981 F. Supp. 2d 38, 48–54 (D.D.C. 2013); *ISTA Pharms., Inc. v. FDA*, 898 F. Supp. 2d 227, 231–33 (D.D.C. 2012); *Sanofi-Aventis U.S. LLC v. FDA*, 842 F. Supp. 2d 195, 209–15 (D.D.C. 2012); see also *Schering Corp. v. Sullivan*, 782 F. Supp. 645, 651–53 (D.D.C. 1992) (explaining that judicial review of particular ANDA approvals would remain available to address disputes about FDA findings of bio-equivalence), *vacated as moot*, *Schering Corp. v. Shalala*, 995 F.2d 1103, 1106 (D.C. Cir. 1993); Linda A. Johnson, *Wyeth Sues FDA to Block Generic Rival of Antibiotic Zosyn*, BOS. GLOBE, Sept. 24, 2009, at B10 (summarizing ultimately unsuccessful objections lodged in federal court to the agency’s approval of a generic version of an older formulation that the brand-name manufacturer had previously discontinued selling on safety grounds). Although routinely unsuccessful, and nothing would prevent generic drug sales during the pendency of such litigation, some brand-name manufacturers evidently still find utility in pursuing this course of action. Cf. Lars Noah, *Product Hopping 2.0: Getting the FDA to Yank Your Original License Beats Stacking Patents*, 19 MARQ. INTELL. PROP. L. REV. 161, 165 (2015) (“[M]anufacturers routinely introduce new and improved versions of successful drugs as their patents on older products wind down and generic rivals prepare to enter the market . . .”).

90. See, e.g., *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1078, 1086 (D.C. Cir. 2001) (directing the district court to vacate an FDA order approving the ANDA for a generic version of the cancer drug Taxol® (paclitaxel) as arbitrary and capricious); *Genus Lifesciences, Inc. v. Azar*, 486 F. Supp. 3d 450, 468 (D.D.C. 2020) (holding in part for the plaintiff in a challenge to the FDA’s approval of a competitor’s topical cocaine hydrochloride solution used in sinus surgery, deciding that the agency should not have approved Lannett’s Numbrino® because it had failed to include any patent certification), *further proceedings*, No. 20-cv-00211, 2021 WL 270409, at \*4–5 (D.D.C. Jan. 27, 2021) (vacating the approval of Numbrino but staying its order for sixty days to allow the FDA to try and cure deficiencies in the application on remand); see also *Serono Labs., Inc. v. Shalala*, 974 F. Supp. 29, 37 (D.D.C. 1997) (preliminarily enjoining the sale of a generic version of an injectable protein-based drug to treat infertility approved by the FDA), *vacated*, 158 F.3d 1313, 1321–27 (D.C. Cir. 1998) (deferring to the judgments of officials responsible for approving the ANDA notwithstanding some disagreements expressed by lower-level FDA staff).

on the FDA's approval decisions.<sup>91</sup> Indeed, on rare occasions, the federal government may face tort liability for allegedly mistaken pharmaceutical licensing judgments.<sup>92</sup> More typically, victims seek to hold sellers of FDA-approved drugs responsible for their injuries.<sup>93</sup> Even after the U.S. Supreme Court broadly preempted design defect claims a decade ago,<sup>94</sup> so-called parallel claims may allow plaintiffs to establish some regulatory infraction in securing or retaining a license.<sup>95</sup> At the extreme, a few courts continue to recognize liability for the sale of harmful drugs on the theory that a manufacturer

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91. See Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2157 (2000) ("Courts still routinely ignore the agency's regulations and approval decisions in products liability litigation.").

92. See *Berkovitz v. United States*, 486 U.S. 531, 536–37 (1988) (holding that the discretionary functions exception to the waiver of sovereign immunity in the Federal Tort Claims Act (FTCA) would not cover the licensing of a polio vaccine—and the FDA's decision to release a particular lot—if the plaintiffs managed to prove their allegations that these actions had violated standards governing such decisions); see also *In re Sabin Oral Polio Vaccine Prods. Liab. Litig.*, 984 F.2d 124, 125–28 (4th Cir. 1993) (affirming the conclusion that the agency had unjustifiably failed to implement the applicable requirements). Typically, however, courts hold that sovereign immunity shields the FDA's product approval decisions. See, e.g., *Forsyth v. Eli Lilly & Co.*, 904 F. Supp. 1153, 1159–61 (D. Haw. 1995) (involving the approval of the antidepressant Prozac® (fluoxetine)); see also Deborah F. Buckman, Annotation, *Liability of United States, Under Federal Tort Claims Act, for Damages Caused by Ingestion or Administration of Government-Approved Drugs, Vaccines, and Medications*, 173 A.L.R. Fed. 431, § 8 (2001 & 2023 Supp.).

93. See Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 BROOK. L. REV. 839, 840 (2009) ("Lawsuits against the manufacturers of drugs and medical devices have become increasingly important in the last few decades, both in their volume and in the conceptual challenges that they have presented . . .").

94. See *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 484, 490 (2013); see also *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 298–300 (6th Cir. 2015); *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1139–41 (8th Cir. 2014) (explaining that a number of courts have interpreted *Bartlett* as preempting design defect claims); Noah, *supra* note 27, at 34 (explaining that the decision "seemingly would apply with equal force to sellers of brand-name drug products").

95. See *Bartlett*, 570 U.S. at 487 n.4; cf. *Morris v. PLIVA, Inc.*, 713 F.3d 774, 776–78 (5th Cir. 2013) (declining to allow such allegations against generic drug manufacturers to escape the more sweeping implied preemption of failure-to-warn claims involving products with approved ANDAs); Arlen W. Langvardt, *Generic Pharmaceuticals and the "Unfortunate Hand" Dealt to Harmed Consumers: The Emerging State Court Resistance*, 17 MINN. J.L. SCI. & TECH. 565, 619–35 (2016) (discussing judicial willingness to recognize certain parallel claims in such cases). Courts have more often confronted this exception in cases involving FDA-approved medical devices. See J. David Prince, *The Puzzle of Parallel Claims, Preemption, and Pleading the Particulars*, 39 WM. MITCHELL L. REV. 1034 (2013); Hannah Rodgers, Note, *The Presumption Against Implied Preemption: How State Law Fraud-on-the-FDA Claims Complement, Rather Than Conflict with, Federal Law*, 45 FLA. ST. U. L. REV. 861 (2018).

should never have introduced a product even after getting a green light from the FDA.<sup>96</sup>

Some observers expressed fear that Judge Kacsmaryk's decision would unsettle research and development investments in the pharmaceutical industry.<sup>97</sup> That strikes me as entirely hyperbolic. There is

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96. See *Holley v. Gilead Scis., Inc.*, 379 F. Supp. 3d 809, 814–15, 824–25 (N.D. Cal. 2019) (declining to dismiss the design defect claim of plaintiffs injured by HIV drugs with the active ingredient tenofovir disoproxil fumarate); *id.* at 822 (“The Supreme Court has not addressed whether federal law preempts design-defect claims against a brand-name manufacturer on grounds that, prior to initial FDA approval, the drug should have had a different composition.”); *Guidry v. Janssen Pharm., Inc.*, 206 F. Supp. 3d 1187, 1203–09 (E.D. La. 2016) (distinguishing between preempted “stop selling” claims and “never start selling” claims); *id.* at 1198 (declining to dismiss allegations that the Type 2 diabetes drug Invokana® caused kidney failure while offering only marginal improvements in blood sugar control); see also *Wimbush v. Wyeth*, 619 F.3d 632, 641–46 (6th Cir. 2010) (reversing summary judgment granted to the defendant on the basis of implied preemption, though predating *Bartlett*, of a negligence claim brought on behalf of a patient who died from primary pulmonary hypertension asserting that the manufacturer should never have brought the diet drug Redux® (dexfenfluramine) to market notwithstanding its receipt of FDA approval with labeling that warned of precisely this risk); *id.* at 645 (calling it a case of “pre-approval design defect”); cf. *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1009–10 (7th Cir. 2020) (“Federal law did not stop Ethicon from satisfying its state-law duties regarding Prolift’s design *before* it filed its premarket notification seeking substantial-equivalence clearance. It lost independent control over Prolift’s design only after it received § 510(k) clearance from the FDA.”).

97. See Margaret Hamburg & Joshua Sharfstein, Editorial, *Judicial Interference with Mifepristone*, 380 SCIENCE 223 (2023); Wendy K. Mariner, *Science v. Ideology in Court: Mifepristone and the U.S. Food and Drug Administration*, 176 ANNALS INTERNAL MED. 857, 857 (2023) (“More than 400 biopharma and investment executives issued a statement condemning the *Alliance* decision, noting, ‘If courts can overturn drug approvals without regard for science or evidence, or for the complexity required to fully vet the safety and efficacy of new drugs, any medicine is at risk for the same outcome as mifepristone.’”); Christina Jewett & Pam Belluck, *Abortion Drug Ruling Could Bring “Chaos” to F.D.A.’s Authority*, N.Y. TIMES, Apr. 10, 2023, at A13 (“[I]f upheld, the Texas decision would shake the very framework of the pharmaceutical industry’s reliance on the F.D.A.’s pathways for developing new drugs, legal experts said.”); David Ovalle et al., *Abortion Pill Rulings Put FDA Approval Authority in Peril*, WASH. POST, Apr. 10, 2023, at A4; Christopher Rowland, *Abortion Rulings Could Undermine the FDA’s Authority, Drug Companies Say*, WASH. POST, Apr. 19, 2023, at A17 (“Investments in cutting-edge biotechnology fields aimed at cancer and other serious diseases could be subject to attacks in the courts if FDA’s rulemaking [sic] is thrown open to court challenges, said executives who are urging the Supreme Court to put the orders on hold.”); *id.* (“Without confidence that the FDA’s actions can withstand attacks from people dissatisfied with the outcome, tens of billions of dollars of investments a year could be in jeopardy, the industry said.”); see also Christine Coughlin, Opinion, *An Unsettling Challenge to FDA’s Authority; The Mifepristone Case Is Unprecedented in Contesting Oversight*, PHILA. INQUIRER, May 7, 2023, at G2 (“The effects of this lawsuit could reach far beyond mifepristone—undermining the agency’s authority could threaten its entire drug approval process and change access to

nothing new about FDA licensing decisions getting held hostage to politics, though affected parties normally seek judicial intervention to guard against the intrusion of extraneous considerations, whereas in this case it served the opposite purpose. Moreover, as recognized in other domains that come into contact with the pitched battle over abortion,<sup>98</sup> its distinctive nature should cabin any risk of unsettling the dependability of run-of-the-mill FDA drug approvals. In fact, greater judicial skepticism about the work of this agency could offer the industry a real shot in the arm, whether in connection with enforcement, rulemaking, or even licensing of potential competitors.<sup>99</sup> Perhaps the sellers of other FDA-approved products presently buffeted by the culture wars (i.e., contraceptives) might feel particularly threatened,<sup>100</sup> but this seems marginal given the decidedly inhospitable climate that they already face when it comes to tort liability.<sup>101</sup>

Contrary to another argument pressed by the defendants (and the self-anointed “FDA scholars” as their amici),<sup>102</sup> SNDA approval

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commonly used drugs, ranging from amoxicillin and Ambien to prednisone and Paxlovid.”).

98. See Noah, *supra* note 29, at 87 n.41, 92 n.60; see also *id.* at 97 (“[W]hile distracting us with an abortion-related dispute, Justice Thomas finally appears to have succeeded in his still more controversial campaign to collapse the distinction between core and commercial speech.”).

99. See, e.g., *supra* notes 88–90 and accompanying text (discussing industry challenges to the approval of generics).

100. See Sheryl Gay Stolberg, *Contraception Is Next Battle at State Level*, N.Y. TIMES, June 19, 2023, at A1 (discussing some “worrisome efforts to restrict access to birth control”); see also Douglas Belkin & Laura Kusisto, *University of Idaho Curtails Contraception Options*, WALL ST. J., Sept. 30, 2022, at A3 (“The memo [from the university’s general counsel] says condoms may be given out on campus to prevent sexually transmitted diseases but not as contraception . . .”). For instance, when the FDA finally decided to switch the Plan B® (levonogestrel) emergency contraceptive to nonprescription status without any age restrictions, the Secretary of HHS during the Obama administration vetoed that move, which prompted a federal court to order the agency to disregard this unjustified political interference in its expert judgments. See *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 197–98 (E.D.N.Y. 2013).

101. See Noah, *Constitution Constrain*, *supra* note 5, at 216–24 (suggesting that this doctrinal landscape runs afoul of the U.S. Constitution). Then again, the objections have become ever more unhinged: in particular, certain vaccines have gotten attacked either for attenuated links to aborted fetal tissue or imagined safety hazards. See NOAH, *supra* note 15, at 247, 790, 816; see also *id.* at 436–43 (explaining that pre-exposure prophylaxis (PrEP) against HIV has become a lightning rod as well).

102. See, e.g., E-mail from Grossman, *supra* note 61 (explaining their plans to argue that “any defect [in the initial approval] became irrelevant when FDA approved” the REMS SNDA). For a still more implausibly revisionist account of what happened, consider their puzzling argument that the agency had not in fact relied upon the accelerated approval rule, 21 C.F.R. pt. 314(H). The FDA’s approval letter unmistakably invoked these regulations in their entirety. See *supra* note 24 (providing a link



hardly amounts to reissuing the original license, partly because that would upend the operation of market exclusivity periods, which only sometimes would then get extended for the sponsor,<sup>103</sup> or the still more quotidian matter of calculating user fee charges.<sup>104</sup> Simple inertia and an unwillingness to confess error offer more parsimonious accounts for the agency's reticence about revisiting its original licensing judgments when reviewing an SNDA.<sup>105</sup> I do not believe that happened in this particular case, except perhaps insofar as the

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to that letter); see also U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 20, at 14, 25–28 (reading it that way as well).

103. See LARS NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY 1175–76, 1179–80, 1189–91 (5th ed. 2022) (summarizing different forms of market exclusivity); cf. Lars Noah, *Treat Yourself: Is Self-Medication the Prescription for What Ails American Health Care?*, 19 HARV. J.L. & TECH. 359, 390 (2006) (discussing some of the exclusivities tied to SNDA approval); *id.* at 385 (“It might promote clarity to understand such switches [to nonprescription status] as a two-step process: the FDA revokes the NDA for the original drug, which carried prescription labeling, but offers to issue a new (though financially less desirable) license for an OTC version of the same drug as a substitute.”). If SNDA approval did amount to reapproval of the NDA, then haven't the defendants fatally undercut their statute of limitations objection? Even so, having the FDA sign off on a revision to a previously approved NDA strikes me as weaker than, for instance, the more formal notices that it will sometimes publish in the *Federal Register* to clarify that a drug was not withdrawn for reasons of safety or effectiveness. See Noah, *supra* note 81, at 735 & n.184 (using Bendectin as an illustration); *supra* note 87 (citing one such notice related to the antidepressant Serzone).

104. See, e.g., Notice, Prescription Drug User Fee Rates for Fiscal Year 2023, 87 Fed. Reg. 61,063, 61,069 (Oct. 7, 2022) (assessing fees based on the type of application submitted, ranging from more than \$3.2 million for those requiring clinical data to half as much for those that do not, plus almost \$400,000 charged for certain “program fees”); see also *Stat-Trade Inc. v. FDA*, 869 F. Supp. 2d 95 (D.D.C. 2012) (resolving a small drug company's effort to dispute its user fee assessments).

105. See Noah, *supra* note 79, at 357, 378–80, 384, 392–93; *id.* at 393 (“[T]he agency persists in its unproductive strategy of larding up product labels rather than reconsidering the wisdom of its original judgment to authorize OTC availability.”). The relatively stingy approach to the FDA preemption defense in tort litigation, see *supra* notes 94–96 and accompanying text, may take this point too seriously, especially when asking whether a particular approval decision had addressed itself to the specific feature assailed by a plaintiff as defective. See, e.g., *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1674–75 (2019) (discussing allegations that the manufacturer of the osteoporosis drug Fosamax® (alendronate) had failed to warn about the risk of atypical femoral fractures, after the agency had rejected earlier proposals to add information about the possibility of “stress fractures”); *id.* at 1678 (“[T]he drug manufacturer [must] show that it fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning.”); cf. *Steele v. Depuy Orthopaedics, Inc.*, 295 F. Supp. 2d 439, 449–50 n.9, 452–57 (D.N.J. 2003) (holding that supplemental device approval preempted product defect but not express breach of warranty and fraudulent concealment claims).



FDA seemingly cannot bring itself to drop the access restrictions altogether,<sup>106</sup> but it offers still another reminder about the hazards of presenting arguments in too sweeping a fashion.

#### IV. CONCLUSION

Far too many commentators recently have repeated the baseless claim that no judge had ever before invalidated an FDA drug approval decision. If such a prevailing narrative gets uncritically adopted by reviewing courts, then, before you know it, the now accepted conventional wisdom will operate in practice to insulate even questionable product licensing decisions from serious external scrutiny.<sup>107</sup> At the risk of unintentionally giving still more aid and comfort to the enemy,<sup>108</sup> which my work has done far too often,<sup>109</sup>

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106. See Donley, *supra* note 18, at 665–66, 687. Indeed, one could read the FDA’s failure to altogether drop the REMS as demonstrating that it (rightly or wrongly) continues to harbor concerns about “known serious risks” otherwise. See 21 U.S.C. § 355-1 (f) (1). In fact, in the previously mentioned litigation over emergency contraception, the court had distinguished the access restrictions that remained on mifepristone at the time. See *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 182 (E.D.N.Y. 2013) (rejecting as implausible the FDA’s claim that the accelerated approval rules provided a basis for restricting access); *id.* (“Plan B does not fit within the class of drugs [21 C.F.R.] § 314.520 was designed to restrict. . . . Each of the drugs the FDA mentioned is highly toxic and/or has serious health risks associated with its use . . . [including] Mifeprex (known as RU-486 in Europe), which is used to end early pregnancy, [and] causes vaginal bleeding which, in some cases, can only be stopped by surgical procedure.”). This dictum does not, however, establish that mifepristone had in fact qualified for accelerated approval even if the FDA subsequently converted the access restrictions into a REMS, which depends on a different set of eligibility criteria.

107. Cf. Noah, *Mathematical Blunders*, *supra* note 5, at 383 & n.50, 400–04 (offering a couple of examples of minor foundational blunders in tort law that then spread and became doctrinally entrenched); Noah, *supra* note 82, at 607 (“Patently silly mistakes that get published all too often find an uncritical audience that then may replicate the errors and distort the legal academic commentary on a particular subject.”).

108. Cf. U.S. CONST. amend. XIV, § 3 (disqualifying from a return to public office anyone who “shall have engaged in insurrection or rebellion against the [United States], or given aid or comfort to the enemies thereof”); *id.* art. III, § 3, cl. 1 (defining treason to include giving “Aid and Comfort”). We can thank Donald Trump for bringing renewed attention to the largely forgotten Fourteenth Amendment provision designed to deal with the old Confederacy. See Adam Liptak, *Scholars Make Case That Constitution Bars Trump from Office*, N.Y. TIMES, Aug. 13, 2023, at A20.

109. Still earlier in my academic career, after daring to assail the FDA’s effort to tackle cigarette advertising under its authority over restricted medical devices, I got publicly accused of serving as a paid hack for the tobacco industry, which prompted me to push back against such a scurrilous charge. See Lars Noah, *Regulating Cigarettes*:

I find nothing untoward about judicial scrutiny of FDA drug approval decisions even if in this case it proceeded in an over-the-top manner. Among other things, Judge Kacsmaryk plainly erred in thinking that he knew better than the agency's experts, but he hardly deviated from the norm in asking the sorts of questions posed by the petitioners about a license issued by the FDA.

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*(Non)sense and Sensibility*, 22 S. ILL. U. L.J. 677, 687–88 (1998); see also *id.* at 690 (“I would applaud a congressional decision to prohibit the sale of some or all types of tobacco products or, more plausibly, to tax such products into oblivion. That . . . does not mean that I must also applaud an administrative short-cut that attempts to assert undelegated jurisdiction over a product that Congress has decided may be marketed.”); cf. Lars Noah, *Time to Bite the Bullet? How an Emboldened FDA Could Take Aim at the Firearms Industry*, 53 CONN. L. REV. 787, 798–91, 803–05, 820–27 (2022) (using the agency’s assertion of jurisdiction over tobacco products as the inspiration for a radical proposal that it regulate guns and ammunition as “devices”); *id.* at 789 (“I have long railed against the FDA’s seemingly lawless behavior. You know what they say: if you can’t beat them, join them.” (footnotes omitted)); *id.* at 834 (“[T]he FDA’s experience with tobacco products amply demonstrates that something previously unthinkable and ultimately unsuccessful can still bear fruit.”).