



## RESPONSE

# Too Late: Why Most Abortion Pill Administrative Procedure Challenges Are Untimely

Susan C. Morse & Leah R. Butterfield\*

## Introduction

In *Abortion Pills*, Professor David Cohen, Professor Greer Donley, and Dean Rachel Rebouché argue that abortion pills are here to stay.<sup>1</sup> Medication abortion already has transformed access to abortion and shifted control to patients and “abortion providers and activists.”<sup>2</sup> Their Article emphasizes the value of stability, meaning continued access to medication abortion, in existing reproductive rights law.

Their Article also explains that the Supreme Court is considering a case that would upend the legal status quo that *Abortion Pills* describes. This term, the Court will review the Fifth Circuit’s decision in *Alliance for Hippocratic Medicine v. FDA (AHM)*. *AHM* presents administrative procedure challenges to the regulation of mifepristone, a common medication used for abortion, by the Food and Drug Administration (FDA).<sup>3</sup>

*AHM* raises the possibility of abrupt withdrawal of medication abortion access. But there are several legal avenues to resolve *AHM* without this result.

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\* Susan C. Morse is the Angus G. Wynne, Sr. Professor of Civil Jurisprudence and Associate Dean for Academic Affairs at the University of Texas School of Law. Leah R. Butterfield is a member of the University of Texas School of Law J.D. class of 2024. Many thanks to David Cohen, Mechele Dickerson, Tara Leigh Grove, Rachel Rebouché, Elizabeth Sepper, and Stephen Vladeck for helpful conversation and comments. This project has benefited from presentation at the University of Texas School of Law.

1. See generally, David S. Cohen, Greer Donley & Rachel Rebouché, *Abortion Pills*, 76 STAN. L. REV. 317, 322 (2024) (noting the current accessibility of abortion pills).
2. *Id.*
3. *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 245-51 (5th Cir. 2023), cert. granted, 2023 WL 8605746 (U.S. Dec. 13, 2023) (No. 23-235) (considering whether 2016 and 2021 actions were arbitrary and capricious).

One possibility is the plaintiffs' lack of standing.<sup>4</sup> Another possibility is the six-year limitations period of 28 U.S.C. § 2401(a). The Fifth Circuit relied on this statute to time-bar the challenge to the FDA's 2000 approval of mifepristone,<sup>5</sup> and it also should have blocked the challenge to actions taken by the FDA in 2016.<sup>6</sup>

## I. Abortion Pills as Status Quo

As *Abortion Pills* reveals, misoprostol and mifepristone have transformed the landscape of reproductive health care.<sup>7</sup> Medication abortion has rapidly established a new normal in which patients and “informal and underground networks” have more control over access to abortion services.<sup>8</sup> Meanwhile, counterattacks come from federal litigation and state regulation,<sup>9</sup> and availability and sanctions vary because of class and race bias in the application of abortion restrictions and bans.<sup>10</sup>

*Abortion Pills* emphasizes the status quo of expanded access, in which medication abortion is more widely available. Law that maintains the status quo often connects to “traditional conservatism.”<sup>11</sup> But in the case of abortion pills, the value of stability in the law supports, though imperfectly, the progressive goal of reproductive access and freedom. Abortion will be more available if courts leave the FDA rules alone.

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4. See Brief for Federal Appellants at 19-34, *All. for Hippocratic Med. v. FDA*, 78 F.4th 210 (5th Cir. 2023) (No. 23-10362) (arguing that plaintiffs lack associational, organizational, and third-party standing). Intervenor at the district court also claim to have state standing. See Missouri, Kansas, and Idaho's Motion to Intervene, at 2-3, *All. for Hippocratic Med. v. FDA*, No. 2:22-CV-00223-Z, (N.D. Tex. Nov. 3, 2023).
  5. *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 242 (5th Cir. 2023), cert. granted, 2023 WL 8605746 (U.S. Dec. 13, 2023) (No. 23-235).
  6. On 28 U.S.C. § 2401(a) and administrative procedure claims, compare Susan C. Morse, *Old Regs: The Default Six-Year Time Bar for Administrative Procedure Claims*, 31 GEO. MASON L. REV. 191, 218-227 (2024) (arguing for accrual at the time of agency promulgation or other action), with John Kendrick, Note, *(Un)Limiting Administrative Review: Wind River, Section 2401(a), and the Right to Challenge Federal Agencies*, 103 VA. L. REV. 157, 190-92 (2017) (arguing for later accrual for each specific plaintiff).
  7. See Cohen et al., *supra* note 1, at 355-80 (detailing telehealth provision, pharmacist prescription, and other strategies to expand access with reduced involvement from medical gatekeepers).
  8. *Id.* at 317.
  9. See *id.* at 333-34.
  10. See *id.* at 399-400 (explaining criminalization bias).
  11. Edgar Bodenheimer, *The Inherent Conservatism of the Legal Profession*, 23 IND. L. J. 221, 227-28 (1948) (arguing that law tends to resist change and restrain “exercise of power by private individuals as well as by the government”); see, e.g., Cristina M. Rodriguez, *Foreward: Regime Change*, 135 HARV. L. REV. 1, 103-09 (2021) (noting the anti-progressive status quo of immigration law).

The government in *AHM* has emphasized the doctor plaintiffs' lack of standing.<sup>12</sup> But in the Fifth Circuit, a different law has protected the status quo, at least with respect to the FDA's original 2000 approval of mifepristone.<sup>13</sup> This law is 28 U.S.C. § 2401(a), a default six-year limitations period for suits against the federal government. This Essay explores how this limitations period protects the abortion pill status quo—no matter what happens with standing.

A Supreme Court majority might decide *AHM* in favor of the government based on standing and ignore 28 U.S.C. § 2401(a).<sup>14</sup> But any dissenting opinion must consider the limitations period argument before concluding that FDA actions should be invalidated. And getting the limitations period analysis right is important not only in *AHM* but also in *Corner Post*, another case on the Supreme Court's merits docket, in which accrual of the six-year time-bar is the central issue.<sup>15</sup> The *Corner Post* petitioner argues that accrual began no earlier than the time of its incorporation in 2017, so that its 2021 challenge to a 2011 Federal Reserve regulation is timely.<sup>16</sup>

## II. The Policy of the Six-Year Time Bar

All Courts of Appeals that have considered the issue agree that the six-year time bar of 28 U.S.C. § 2401(a) accrues for administrative procedure claims when a rule is promulgated.<sup>17</sup> The statutory text, the status of administrative

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12. See *supra* note 4.

13. *All. for Hippocratic Med. v. Food & Drug Admin.*, 78 F.4th 210, 242 (5th Cir. 2023), *cert. granted*, 2023 WL 8605746 (U.S. Dec. 13, 2023) (No. 23-235). See generally Susan C. Morse & Leah R. Butterfield, *Out of Time at the Fifth Circuit: Why (Most of) the Mifepristone Challenge in Alliance for Hippocratic Medicine is Time-Barred*, YALE J. REG. NOTICE & COMMENT (March 24, 2023), <https://perma.cc/6J4C-5JT6> (arguing that 28 U.S.C. § 2401(a) should block claims).

14. See, e.g., *Steel Co. v. Citizens for Better Env't*, 523 U.S. 83, 94-95 (1998) (discussing the need to decide jurisdictional issues like standing first before reaching the merits).

15. *N. Dakota Retail Ass'n v. Bd. of Governors of Fed. Res. Sys. (Corner Post)*, 55 F.4th 634, 639 (8th Cir. 2022), *cert. granted sub. nom. Corner Post, Inc. v. Bd. of Governors of Fed. Res. Sys.*, No. 22-1008, 2023 WL 6319653, at \*1 (U.S. Sept. 29, 2023). In *Corner Post*, petitioners argue that 28 U.S.C. § 2401(a) accrues when a plaintiff can initiate and maintain a suit in court. See Petition for Writ of Certiorari, at 21-22, *Corner Post*, No. 22-1008, (U.S. Apr. 13, 2023).

16. See Brief for Petitioner, at 8-9, *Corner Post*, No. 22-1008, (U.S. Nov. 13, 2023) (providing chronology).

17. See, e.g., *Corner Post*, 55 F.4th at 637, 639-41 (8th Cir. 2022) (holding time-barred an arbitrary and capricious challenge to a 2011 Federal Reserve regulation); *Texas v. Rettig*, 987 F.3d 518, 523-24 (5th Cir. 2021) (holding time-barred a notice-and-comment challenge to a 2002 HHS regulation); *Alabama v. PCI Gaming Authority*, 801 F.3d 1278, 1292 (11th Cir. 2015) (holding time-barred an APA challenge to Secretary of Interior decisions to take lands into trust in 1984, 1992 and 1995); *Hire Order Ltd. v. Marianos*,  
*footnote continued on next page*

procedure as a public right, and reliance interests all support this earlier-accrual result.<sup>18</sup>

First, consider the statutory text. It's clear that APA claims must be timely. The APA provides that claims cannot be made when a limitations period "precludes judicial review."<sup>19</sup> In the absence of any more specific limitations period, 28 U.S.C. § 2401(a) states that the six-year clock starts ticking when "the right of action first accrues."<sup>20</sup>

The APA clarifies the time of accrual by identifying the "unlawful" event as the "agency action . . . found to be without observance of procedure required by law."<sup>21</sup> The moment of administrative procedure illegality is the moment "without observance of procedure," which must be when the agency promulgates a regulation or issues a rule. Consider a claim of inadequate notice and comment, or a claim of an arbitrary and capricious process that failed to consider all evidence, adequately respond to comments, or sufficiently explain a regulatory change. In each of these cases, the transgression is complete when the agency promulgates the rule. The claim is available to all eligible plaintiffs on the same basis at that time.<sup>22</sup> The right of action<sup>23</sup> does not differ from plaintiff to plaintiff. It accrues for all plaintiffs as soon as any plaintiff can sue.

Second, consider the public nature of the right to administrative procedure. Administrative procedure provides the public with the right to participate in agency decisionmaking and requires agencies to deliberate about

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698 F.3d 168, 170 (4th Cir. 2012) (holding time-barred a notice-and-comment challenge to a 1969 Revenue Ruling); *Sai Kwan Wong v. Doar*, 571 F.3d 247, 263 (2d Cir. 2009) (holding time-barred a notice-and-comment challenge to a 1980 Medicaid regulation); *Preminger v. Sec'y of Veterans Affairs*, 517 F.3d 1299, 1299, 1307-08 (Fed. Cir. 2008) (holding time-barred a notice-and-comment challenge to a 1973 Veterans Affairs regulation regarding political demonstrations at VA facilities); *Harris v. FAA*, 353 F.3d 1006, 1009, 1011-13 (D.C. Cir. 2004) (holding time-barred an arbitrary and capricious challenge to a 1993 FAA Notice); *Cedars-Sinai Med. Center v. Shalala*, 177 F.3d 1126, 1128-29 (9th Cir. 1999) (holding time-barred a notice-and-comment challenge to a 1986 Medicare manual); *Trafalgar Cap. Assocs. v. Cuomo*, 159 F.3d 21, 34-35 (1st Cir. 1998) (holding time-barred an arbitrary and capricious challenge to a 1985 HUD fair market rent assessment); *Sierra Club v. Slater*, 120 F.3d 623, 628, 631 (6th Cir. 1997) (holding time-barred a claim brought under NEPA via the APA to a 1984 Federal Highway Administration Record of Decision).

18. For additional development of these arguments, see *Morse*, *supra* note 6, at 218-27.

19. 5 U.S.C. § 701(a)(1).

20. 28 U.S.C. § 2401(a).

21. 5 U.S.C. § 706(2)(D); see also 5 U.S.C. § 706(2)(A) (identifying the unlawful act or an agency's arbitrary or capricious action).

22. See, e.g., *Abbott Lab. v. Gardner*, 387 U.S. 136, 139-41 (1967).

23. 28 U.S.C. § 2401(a).

their decisions. It provides public participation rights.<sup>24</sup> Because of these public rights, when an agency fails to follow administrative procedure, the resulting injury is “incurred by all persons” at that time.<sup>25</sup> It is a “denial of process to the public at large.”<sup>26</sup> Such an administrative procedure claim is limited by the earlier-accruing six-year limitations period.<sup>27</sup>

The rights to public participation provided by administrative procedure are secured in several ways. The check of private litigation works alongside legislative<sup>28</sup> and executive<sup>29</sup> oversight mechanisms to keep administrative agencies in line. As with election<sup>30</sup> and legislative<sup>31</sup> procedure, the private right to sue to vindicate the public right to legal process is limited in administrative procedure, in part because other oversight mechanisms are also available.

Finally, consider reliance. Limitations periods are a classic way in which the law provides stability,<sup>32</sup> and in an administrative procedure case like *AHM*, this stability protects diverse reliance interests. The reliance interest of

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24. See KRISTIN E. HICKMAN & RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE § 5.3 (7th ed. 2018) (explaining that administrative procedure “provide[s] interested members of the public an opportunity to comment in a meaningful way on the agency’s proposal”); see also KENNETH CULP DAVIS, ADMINISTRATIVE LAW AND GOVERNMENT 121 (2d ed. 1975) (“The system prescribed by § 553 of APA . . . is probably one of the greatest inventions of modern government. The system is informal and efficient, and yet it gives affected parties a chance to influence the content of rules.”).
  25. *Shiny Rock Mining Corp. v. U.S.*, 906 F.2d 1362, 1365 (9th Cir. 1990).
  26. *Herr v. U.S. Forest Service*, 803 F.3d 809, 820 (6th Cir. 2015).
  27. The rule is different for some claims that result from the application of a regulation to a plaintiff. In this case, later accrual applies if the plaintiff’s claim is that the regulation exceeds the authority of a substantive authorizing statute. See *Wind River Mining Corp. v. U.S.*, 946 F.2d 710, 714 (9th Cir. 1991).
  28. See JOSH CHAVETZ, CONGRESS’S CONSTITUTION 61-73 (2017) (discussing Congressional control and oversight of agencies through budgetary and appropriations mechanisms).
  29. See, e.g., Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2253-54 (discussing presidential control and oversight).
  30. Statutes constrain voters’ ability to object to election illegalities. See, e.g., TEX. ELEC. CODE ANN. § 212.022 (2023) (allowing candidate petition); *id.* § 212.024(b)(2) (allowing twenty-five voters to petition); *id.* § 212.028(a) (imposing a deadline of 5 PM on the second day after the election).
  31. For example, there is no practical ability to challenge a revenue act of Congress on the grounds that the House did not originate it if legislative records endorse the statute. See *Field v. Clark*, 143 U.S. 649, 672-73 (1892) (providing legislative journals as evidence of a statute’s validity because of “coequal and independent departments”); see also Tara Leigh Grove, *The Lost History of the Political Question Doctrine*, 90 N.Y.U. L. REV. 1908, 1934-35 n.141 (2015) (explaining that courts apply an evidentiary rule in Origination Clause cases rather than treating them as raising a nonjusticiable political question).
  32. See, e.g., David Crump, *Statutes of Limitations: The Underlying Policies*, 54 U. LOUISVILLE L. R. 437, 442 (2016) (citing “peace” as one reason for limitations).

patients and providers, particularly with respect to the approval of mifepristone in 2000 and expansion of access in 2016, is clear from the *Abortion Pills* narrative.<sup>33</sup> The reliance interest of the pharmaceutical industry is also at stake.<sup>34</sup> In *AHM*, invalidating the FDA's actions would disrupt not only the medication abortion status quo, but also the FDA's regulatory framework and established business and investment decisions across that industry as a whole.<sup>35</sup>

### III. *AHM* Time Bar Analysis

#### A. Timeline

The U.S. Food and Drug Administration sits at the center of the fight over mifepristone. It approved the medicine more than two decades ago.<sup>36</sup>

Leaving aside the generic approval,<sup>37</sup> there are five FDA actions challenged in the *AHM* case.

First, in the “2000 Approval,” the FDA approved mifepristone.<sup>38</sup>

Second, in the “March 2016 Petition Denial,” the FDA denied a citizen petition filed in 2002 by the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) and others, which challenged the 2000 Approval.<sup>39</sup>

Third, in the “March 2016 Amendments,” the FDA modified Risk Evaluation and Mitigation Strategies (REMS) rules for the prescription and distribution of mifepristone. These changes allowed at-home administration, increased the maximum gestational age, and allowed a broader set of providers to prescribe mifepristone.<sup>40</sup>

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33. See Cohen et al., *supra* note 1, at 390-91 (explaining the challenges faced by antiabortion advocates because of the “collateral damage” of abortion bans).

34. Brief for the Pharm. Rsch. and Mfrs. of Am. as Amicus Curiae in Support of Petitioners at 19-21, *U.S. FDA. v. All. for Hippocratic Med.*, Nos. 23-235, *Danco Lab'y LLC v. All. for Hippocratic Med.*, Nos. 23-236 (U.S. Oct. 12, 2023).

35. Brief of Food and Drug Law Scholars as Amici Curiae in Support of Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction, at 26-27, *All. for Hippocratic Med. v. U.S. FDA.*, No. 2:22-CV-00233-Z, (N.D. Tex. Apr. 7, 2023).

36. U.S. FDA, Approval Letter for Mifepristone (Sept. 28, 2000), <https://perma.cc/3LFB-GMDU>.

37. See Petition for Writ of Certiorari at 10, *U.S. FDA. v. All. for Hippocratic Med.*, No. 23-236 (Sept. 8, 2023) (indicating that the generic approval is not at issue).

38. Complaint at 2-3, *All. for Hippocratic Med. v. U.S. FDA.*, No. 22-CV-233, (N.D. Tex. Apr. 7, 2023).

39. See *id.* at 3-4.

40. See *id.* at 4.

Fourth, in the “2021 Petition Denial,” the FDA denied a citizen petition filed in 2019 by AAPLOG and others, which challenged the March 2016 Amendments.<sup>41</sup>

Fifth, in the “2021 Non-Enforcement Decision,” the FDA stated that it would not pursue enforcement action relating to prescription by mail “during the COVID-19 public health emergency.”<sup>42</sup>

The window of time for final agency actions that can be challenged in *AHM* is six years back from November 18, 2022, when the *AHM* complaint was filed.<sup>43</sup> This means that only FDA actions taken after November 18, 2016 may be challenged. Challenges to the 2000 Approval, the March 2016 Petition Denial, and the March 2016 Amendments were filed too late. Challenges to the 2021 Petition Denial and to the 2021 Non-Enforcement Decision are timely. Figure 1, below, summarizes.

**Figure 1**  
Application of Six-Year Time Bar in *AHM*

<u>Time-barred in <i>AHM</i></u>	<u>Not time-barred in <i>AHM</i></u>
<p><b>September 2000</b> FDA approval of mifepristone</p> <p><b>March 2016</b> - FDA denial of 2002 citizen petition re: 2000 approval - FDA issuance of REMS amendments</p>	<p><b>December 2021</b> - FDA denial of 2019 citizen petition re: REMS amendments - FDA non-enforcement action re: prescription by mail</p>
	<p><b>November 2016</b> Cutoff for agency action challenged in November 2022</p>
	<p><b>November 2022</b> <i>AHM</i> complaint filed</p>
	<p>28 U.S.C. § 2401(a) 6-year period</p>

The Fifth Circuit correctly time-barred challenges to the 2000 Approval and the March 2016 Petition Denial.<sup>44</sup> But it incorrectly considered challenges to the March 2016 Amendments. Instead of analyzing whether the March 2016 Amendments were still open to administrative procedure challenge, the *AHM*

41. *See id.* at 5.

42. *See id.* at 5.

43. *See id.* at 1.

44. *All. for Hippocratic Med. v. U.S. FDA*, 78 F.4th 210, 242 (5th Cir. 2023) (holding the 2000 Approval and 2016 Petition Denial likely time-barred).

majority assumed the issue away.<sup>45</sup> The only explanation given was that the parties agreed that the challenge to the March 2016 Amendments was timely. But the record does not reflect any waiver of the time bar by defendants.<sup>46</sup> Instead, they properly raised it in their response to the plaintiffs' complaint.<sup>47</sup>

This is enough to preserve the defense.<sup>48</sup>

## B. Administrative Petitions Do Not Extend Limitations Periods

Without much analysis, the district court decision in *AHM* assumed that the 2019 citizen petition automatically extended the time for challenging the March 2016 Amendments.<sup>49</sup> This was a mistake. Administrative petitions generally do not extend the time to challenge an underlying regulation. Instead, they produce a separate final agency action – such as the 2021 Petition Denial—that is subject to separate judicial review.<sup>50</sup>

The Fifth Circuit did not correct this district court mistake. The Supreme Court should. The Justices, including those dissenting, should not assume that a challenge to the March 2016 Amendments is timely in *AHM*. This would incorrectly suggest that plaintiffs can leverage citizen petitions into an infinite ability to challenge stale administrative procedure foot faults. Ignoring the application of the time bar to the March 2016 Amendments would suggest that a later citizen petition automatically reopens the challenged regulatory action, instead of confining review to whether the agency properly considered and decided the citizen petition itself. It also would step on the Supreme Court's

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45. *See id.* at 245 (assuming parties' agreement that challenge to March 2016 Amendments was timely).

46. Neither the briefs nor the hearing transcripts mention any waiver.

47. *See* FED. R. CIV. P. 8(c) (requiring affirmative defense in answer); Defendants' Opposition to Plaintiffs' Motion for a Preliminary Injunction at 16, *All. for Hippocratic Med. v. U.S. FDA.*, No. 2:22-CV-00223-Z, 2023 WL 2825971 (N.D. Tex. Apr. 7, 2023) (“[A]ll of plaintiffs' claims are untimely or unexhausted.”).

48. A court may decide that an affirmative defense, such as a limitations period, is preserved with a plaintiff has enough notice of the defense and is not unfairly surprised by it, even when technical errors are made in pleading. *See e.g.*, *Smith v. Travelers Cas. Ins. Co.*, 932 F.3d 302, 308-10 (5th Cir. 2019) (holding timely a limitations period defense raised two years after the defendant's initial answer to the plaintiff's complaint); *see also* *Tahoe-Sierra Pres. Couns., Inc. v. Tahoe Reg'l Plan. Agency*, 216 F.3d 764, 788 (9th Cir. 2000) (explaining that if the defendant's allegation of an affirmative defense is vague or defective, it can still be preserved so long as there is no prejudice or unfair surprise for the plaintiff), *overruled on other grounds*, *Gonzalez v. Arizona*, 677 F.3d 383 (9th Cir. 2012).

49. *All. for Hippocratic Med. v. U.S. FDA.*, No. 22-CV-233, 2023 WL 2825871, at \*9 (N.D. Tex. Apr. 7, 2023) (assuming that a citizen petition automatically extends the time to litigate the underlying regulation).

50. *See, e.g.*, *McAfee v. U.S. FDA.*, 36 F.4th 272, 274-75 (D.C. Cir. 2022) (reviewing a citizen petition denial).



separate effort this Term to develop the law on time of accrual for 28 U.S.C. § 2401(a) in *Corner Post*.<sup>51</sup>

The 2021 Petition Denial is itself a “final agency action” which can be reviewed. But the review should apply an arbitrary or capricious review standard to the 2021 Petition Denial—*not* to the March 2016 Amendments.<sup>52</sup> The review must refer to the citizen petition record—*not* the administrative record for the original rulemaking.<sup>53</sup> Finally, the typical remedy is to remand the citizen petition to the agency for reconsideration—*not* to invalidate the original rule.<sup>54</sup>

Allowing plaintiffs to directly challenge the March 2016 Amendments because of the intervening 2019 citizen petition directly contradicts available decisions of at least two Courts of Appeals. The Fourth Circuit time-barred a challenge to a 1989 Federal Highway Administration highway location decision filed by a plaintiff neighborhood association in 1997, despite an administrative complaint filed by the association in 1994.<sup>55</sup> Similarly, the First Circuit time-barred a challenge to a 1985 Department of Housing and Urban Development fair market rent assessment decision filed by a housing rehabilitation project in June 1995, even though the housing project pursued administrative remedies until April 1995.<sup>56</sup>

If neighbors cannot use an administrative petition to extend their time to challenge an earlier highway location decision, and a housing rehabilitation project cannot use administrative remedies to extend its time to challenge an earlier rent assessment, then doctors cannot use a citizen petition to extend their time to challenge the FDA’s March 2016 Amendments that changed the REMS prescription and distribution rules for mifepristone. And this issue extends over all of federal administrative law, because the APA allows general

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51. *Corner Post, Inc. v. Bd. of Governors of Fed. Res. Sys.*, No. 22-1008, 2023 WL 6319653 (U.S. Sept. 29, 2023).

52. *See, e.g., McAfee*, 36 F.4th at 274, 277-78 (noting extremely deferential standard of review for agency petition denial and refusing to require a raw butter exemption from FDA regulations about pasteurization); *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 166 (E.D.N.Y. 2013) (discussing a previous refusal to grant the plaintiff the relief sought because of the FDA’s expertise).

53. *See, e.g., Graceway Pharm., Inc. v. Sebelius*, 783 F. Supp. 2d 104, 114-115 (D.D.C. 2011) (confining review of citizen petition to its record and upholding FDA disposition).

54. *See, e.g., Tummino v. Torti*, 603 F. Supp. 2d 519, 522-24 (E.D.N.Y. 2009) (remanding citizen petition denial after finding undue political influence).

55. *See Jersey Heights Neighborhood Ass’n v. Glendenning*, 174 F.3d 180, 185-186 (4th Cir. 1999) (time-barring claim).

56. *See Trafalgar Capital Assocs., Inc v. Cuomo*, 159 F.3d 21, 34-37 (1st Cir. 1998) (holding that claim accrued before the completion of permissive administrative remedies).

petitions for agency action.<sup>57</sup> It would be astonishing if Section 553(e) of the APA had the capacity to reopen challenges to stale administrative procedure mistakes. If petitions *are* discovered to have this ability, a huge volume of decades-old administrative decisions would be newly opened to challenge on administrative procedure grounds such as inadequate notice and comment.

### C. Constructive Reopening and Equitable Tolling

Even if a citizen petition does not automatically restart the six-year time bar under 28 U.S.C. § 2401(a), plaintiffs can argue for an extension of the limitations period under two headings. One is reopening. The other is equitable tolling. But as the Fifth Circuit correctly held, these do not save the challenges to the 2000 Approval or the March 2016 Petition Denial.<sup>58</sup> They do not save the challenges to the March 2016 Amendments either.

The most straightforward version of reopening is when the agency itself reopens an issue.<sup>59</sup> Agencies reopen an issue by “holding out the unchanged section as a proposed regulation, offering an explanation for its language, soliciting comments on its substance, and responding to the comments in promulgating the regulation in its final form.”<sup>60</sup> This straightforward concept of reopening does not apply in *AHM*, because the FDA did not itself initiate any reconsideration of its mifepristone rules. Rather, *AHM* involves “constructive reopening”—a doctrine developed by the D.C. Circuit, which the Supreme Court has not embraced.<sup>61</sup> “Constructive reopening” applies when an agency “‘significantly alters the stakes of judicial review’ as the result of a change that ‘could have not been reasonably anticipated.’”<sup>62</sup> The magnitude of alteration needed to invoke constructive reopening has been described as a “sea change.”<sup>63</sup>

The *AHM* plaintiffs argued that the March 2016 Amendments constructively reopened the 2000 Approval. But as the Fifth Circuit explained, “the opposite is true. The FDA took the restrictions imposed in 2000 as a given”

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57. See 5 U.S.C. § 553(e) (“Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.”).

58. See *All. for Hippocratic Med. v. U.S. FDA*, 78 F.4th 210, 242 (5th Cir. 2023) (holding the 2000 Approval and 2016 Petition Denial likely time-barred).

59. *Sierra Club v. EPA*, 551 F.3d 1019, 1024 (D.C. Cir. 2008).

60. *Id.* (citing and quoting *Am. Iron & Steel Inst. v. EPA*, 886 F.2d 390, 397 (D.C. Cir. 1989)).

61. *Kennecott Utah Copper Corp. v. U.S. Dep’t of Interior*, 88 F.3d 1191, 1214-1215 (D.C. Cir. 1996) (explaining constructive reopening).

62. *Sierra Club v. EPA*, 551 F.3d 1019, 1025 (D.C. Cir. 2008) (citing and quoting *Kennecott Utah Copper Corp.*, 88 F.3d at 1226-1227 and *Env’t. Def. v. EPA*, 467 F.3d 1329, 1334 (D.C. Cir. 2006)).

63. *Nat’l Biodiesel Bd. v. EPA*, 843 F.3d 1010, 1017 (D.C. Cir. 2016) (quoting *Nat’l Res. Def. Council v. EPA*, 571 F.3d 1245, 1266 (D.C. Cir. 2009) (per curiam)).

when it issued the March 2016 Amendments.<sup>64</sup> There was no significant alteration, let alone one that was not “reasonably anticipated.”<sup>65</sup> *AHM* is like *Natural Resources Defense Council*, in which the EPA changed the details of how to calculate the value of offset credits.<sup>66</sup> This made it easier to meet emissions requirements, within the context of a continuing “basic regulatory scheme.”<sup>67</sup>

Despite Judge Ho’s dissent on this point at the Fifth Circuit,<sup>68</sup> *AHM* is not like *Sierra Club*, in which a rule change removed the requirement that a factory must show that it was doing its “reasonable best” to stay under emission limits in order to obtain a permit to pollute.<sup>69</sup> Removing the “reasonable best” requirement changed a basic prerequisite for a company to receive approval to pollute. In contrast, when the FDA modified prescription and administration terms in its March 2016 Amendments, it did not change any prerequisite for the manufacture and distribution of mifepristone. Moreover, there is nothing in the record—or in Judge Ho’s opinion, which did not consider the point—to suggest that the March 2016 Amendments were unexpected. Instead, there is every indication that the March 2016 Amendments were “reasonably anticipated,”<sup>70</sup> as a logical outgrowth of the FDA’s conclusion that “mifepristone is safe and effective.”<sup>71</sup>

The argument that the 2021 Petition Denial constructively reopened the March 2016 Amendments makes even less sense. The 2021 Petition Denial confirmed the March 2016 Amendments in almost every detail. They did not produce a material change, let alone a “sea change,” let alone an unexpected sea change, to the FDA’s mifepristone rules.

Plaintiffs might argue that the filing of the 2019 citizen petition, and the fact that the FDA considered the petition for about two years, equitably tolled their ability to challenge the March 2016 Amendments.<sup>72</sup> But extended consideration of a petition is not an agency error that would support equitable

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64. *All. for Hippocratic Med. v. U.S. FDA*, 78 F.4th 210, 243 (5th Cir. 2023).

65. *Id.* at 243-44.

66. *Nat’l Res. Def. Council v. EPA*, 571 F.3d 1245, 1263-1266 (D.C. Cir. 2009) (allowing pre-application source emission reduction to count for offset credits).

67. *Id.* at 1266 (holding no constructive reopening).

68. *All. for Hippocratic Med. v. U.S. FDA*, 78 F.4th at 260-263 (Ho, J. concurring in part and dissenting in part).

69. *Sierra Club*, 551 F.3d at 1022-1023 (D.C. Cir. 2008).

70. *All. for Hippocratic Med. v. U.S. FDA* 78 F.4th at 243 (*quoting* *Env’t Def. v. EPA*, 467 F.3d 1329, 1334 (D.C. Cir. 2006)).

71. *Id.* (holding the FDA did not constructively reopen the 2000 approval).

72. *See United States v. Kwai Fun Wong*, 575 U.S. 402, 410-11 (2015) (holding that standard statute of limitations language does not bar equitable tolling even when the text indicates the limitations period is mandatory); *Jackson v. Modly*, 949 F.3d 763, 776-78 (D.C. Cir. 2020) (holding 28 U.S.C. § 2401(a) not jurisdictional).

tolling.<sup>73</sup> And the citizen petition did not prevent the plaintiffs from filing a lawsuit challenging the March 2016 Amendments. Even if the citizen petition had to be resolved before a complaint was filed,<sup>74</sup> it was resolved by operation of law 150 days after filing. After 150 days, the statute deems that FDA has denied the petition through a “final agency action,” thus removing any obstacle to the plaintiffs’ ability to pursue the lawsuit.<sup>75</sup> This would extend the deadline to challenge the March 2016 Amendments from March 2022 to June 2022. The November 2022 challenge to the March 2016 Amendments would still be untimely.

### Conclusion

Abortion pills are here to stay. One reason is the six-year limitations period of 28 U.S.C. § 2401(a), which provides a default time bar for administrative procedure challenges to federal rulemaking. The Supreme Court will consider this time bar when it reviews the Fifth Circuit’s *AHM* decision this Term. When it does, it should conclude that the challenges to the FDA’s 2000 Approval of mifepristone *and* to the FDA’s March 2016 Amendments are time-barred, although the challenge to the FDA’s 2021 Non-Enforcement Order regarding prescription by mail is timely. A careful analysis of the time bar in *AHM* will serve the development of the law on 28 U.S.C. § 2401(a)—which is also before the Court this Term in a different case, *Corner Post*. Limitations periods are traditionally conservative tools in that they block legal action that could produce change. But in *AHM*, this six-year time bar protects established progressive law—the legal status quo of reproductive rights described in *Abortion Pills*.

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73. Compare *Irwin v. Dep’t of Veteran Aff.*, 498 U.S. 89, 95-96 (1990) (denying equitable tolling where plaintiff did not receive a relevant notice), with *Socop-Gonzalez v. INS*, 272 F.3d 1176, 1184-87, 1193-97 (9th Cir. 2000) (granting equitable tolling after INS officer gave incorrect advice to deportee).

74. See, e.g., *Young v. United States*, 535 U.S. 43, 50-51 (2002) (equitably tolling tax collection period while bankruptcy petition precluded collection).

75. See 21 U.S.C. § 505(q)(2)(A) (2012).