

## FIVE ACTIONS TO STOP CITIZEN PETITION ABUSE

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High drug prices are in the news. In some cases, such as AIDS-treating Daraprim<sup>1</sup> and the life-saving EpiPen,<sup>2</sup> the price increases dramatically. In other cases, which have received less attention, the price stays high longer than it should. Either way, anticompetitive behavior often lurks behind inflated prices.

By delaying price-reducing generic competition, this behavior forces consumers to spend billions of extra dollars each year. Brand drug companies have engaged in an array of conduct to delay generic entry. They have entered into agreements by which they pay generic manufacturers to settle patent litigation and delay entering the market.<sup>3</sup> They have engaged in “product hopping,” switching from one version of a drug to another, often to delay generic entry.<sup>4</sup> And they have restricted their distribution systems to prevent generics from obtaining needed samples.<sup>5</sup>

Another one of these strategies, which has flown under the radar until recently, involves “citizen petitions” filed with the U.S. Food and Drug Administration (FDA). Although intended to serve the public interest by bringing safety concerns to the agency’s attention, nearly all petitions today that target generic drugs are denied.<sup>6</sup> Despite the low suc-

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1. Zoë Schlanger, Martin Shkreli on Raising Price of AIDS Drug 5,000 Percent: ‘I Think Profits Are a Great Thing,’ *Newsweek* (Sept. 21, 2015), <http://www.newsweek.com/martin-shkreli-daraprim-drug-prices-374922> [<http://perma.cc/L4LA-RWL4>].

2. Emily Willingham, Why Did Mylan Hike EpiPen Prices 400%? Because They Could, *Forbes* (Aug. 21, 2016), <http://www.forbes.com/sites/emilywillingham/2016/08/21/why-did-mylan-hike-epipen-prices-400-because-they-could/#6d42bdb6280c> [<http://perma.cc/PGQ2-AV49>].

3. E.g., *FTC v. Actavis*, 133 S. Ct. 2223, 2229 (2013) (holding that settlements involving payment and delayed entry could have “significant adverse effects on competition” and violate antitrust law).

4. E.g., *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 643 (2d Cir. 2015) (describing “product hopping” as “conduct by a monopolist to perpetuate patent exclusivity through successive products”).

5. See Michael A. Carrier et al., *Using Antitrust Law to Challenge Turing’s Daraprim Price Increase*, 31 *Berkeley Tech. L.J.* 1379, 1386 (2016).

6. See Michael A. Carrier & Carl J. Minniti III, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 *Am. U. L. Rev.* 305, 308 (2016) [hereinafter *Carrier & Minniti, Citizen Petitions*] (finding that the FDA denies 92% of petitions targeting pending generics).

cess rate, petitions are still able to delay generic entry and hamstringing the FDA. This Piece provides an overview of citizen petitions and the anti-competitive harm they threaten and offers five solutions to address the problem posed by abusive citizen petitions.

### I. THE SETTING

Citizen petitions allow any party to raise safety or effectiveness concerns with drugs the FDA is considering for approval.<sup>7</sup> The petitions, with a foundation in the First Amendment<sup>8</sup> and Administrative Procedure Act,<sup>9</sup> in theory play an important role in ensuring that drugs are safe and effective. In practice, however, brand firms have used petitions to delay generic approval, extending monopolies on their products at a potential cost to consumers of millions of dollars per day. In many cases, petitions offer little incremental value to the review process but require considerable time, with the FDA forced to address the merits of every petition, many of which contain “detailed analysis and precise scientific documentation” and require review by “multiple disciplines” within the agency.<sup>10</sup>

One type of petition has caused particular concern. As part of the Food and Drug Administration Amendments Act of 2007 (FDAAA), Congress created Section 505(q),<sup>11</sup> which applies to “certain petitions that request that the FDA take any form of action” related to a pending Abbreviated New Drug Application (ANDA or “generic application”).<sup>12</sup> Congress intended to reduce delays<sup>13</sup> by requiring petitioners to certify that they did not delay in filing the petition<sup>14</sup> and mandating that the

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7. See, e.g., 21 C.F.R. § 10.25(a) (2016) (“An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.”); *id.* at § 10.30 (specifying requirements of citizen petitions).

8. U.S. Const. amend. I (“Congress shall make no law . . . abridging the freedom . . . to petition the Government for a redress of grievances.”).

9. 5 U.S.C. § 553(e) (2012) (requiring government agencies to provide the public with “the right to petition for issuance, amendment, or repeal of a rule”).

10. The Generic Drug Maze: Speeding Access to Affordable, Life-Saving Drugs: Hearing Before the S. Spec. Comm. on Aging, 109th Cong. 14 (2006) (statement of Gary Buehler, Director, Office of Generic Drugs, FDA).

11. Pub. L. No. 110-85, § 914, 121 Stat. 823, 953–57 (2007) (codified at 21 U.S.C. § 355(q) (2012)).

12. 153 Cong. Rec. 25,047 (2007).

13. Ctr. for Drug Evaluation and Research, U.S. Dep’t of Health and Human Servs., OMB Control No. 0910-0679, Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry 1 (2014) [hereinafter *Guidance for Industry*], <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm079353.pdf> [<http://perma.cc/F9V2-X46A>].

14. See 153 Cong. Rec. 25,047.

FDA take final action no later than 180 days<sup>15</sup> (later shortened to 150 days) after the petition's filing date, unless delay would be necessary to protect the public health.<sup>16</sup>

Brand firms have filed the vast majority of 505(q) petitions, seeking additional testing or questioning whether generics are bioequivalent—that is, able to be absorbed into the body at the same rate.<sup>17</sup> The FDA denied 92% of 505(q) petitions filed between 2011 and 2015, with this figure rising to 98% for petitions filed within six months of the expiration of a patent or FDA exclusivity date.<sup>18</sup> In addition to these general findings, particular examples demonstrate anticompetitive harm in the form of:

- Multiple petitions (such as Teva's eight petitions on MS-treating Copaxone and Shire ViroPharma's twenty-four petitions on the medication treating a life-threatening gastrointestinal infection);<sup>19</sup>
- Late-filed petitions (such as Bayer Healthcare filing a petition one day before the expiration of the patent on Mirena, a long-acting intrauterine device (IUD));<sup>20</sup>
- The combination of citizen petitions and product hopping (as shown by acne-treating Doryx);<sup>21</sup> and
- The combination of petitions and entry-delaying settlements (as shown by Mylan's allergic emergency-treating EpiPen).<sup>22</sup>

To pick one example, in February 2017, the FTC filed its first complaint challenging citizen petition conduct as an antitrust violation.<sup>23</sup> The FTC alleged that ViroPharma “inundated the FDA” with twenty-four citizen petitions and twenty-two other filings, which was “by far the most filings that any firm has ever made to the FDA concerning a single drug

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15. 21 C.F.R. § 10.30(e)(2) (2016).

16. Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 993 (2012). For a discussion of how the legislation has not been successful, see *infra* notes 37–38 and accompanying text.

17. See Carrier & Minniti, *Citizen Petitions*, *supra* note 6, at 328.

18. *Id.* at 333, 341. “FDA exclusivity” refers to a period in which the agency cannot approve other products because of, for example, the development of a drug with a new active ingredient, see 21 U.S.C. § 355(j)(5)(F)(ii) (2012), or the running of new clinical trials, see *id.* § 355(c)(3)(E)(iii).

19. See Carrier & Minniti, *Citizen Petitions*, *supra* note 6, at 344–46; see also *Complaint for Injunctive and Other Equitable Relief* at 14, *FTC v. Shire ViroPharma Inc.*, No. 1:17-cv-00131-UNA (D. Del. filed Feb. 7, 2017), 2017 WL 525426 (noting that twenty-four petitions were submitted to the FDA).

20. Carrier & Minniti, *Citizen Petitions*, *supra* note 6, at 346–47.

21. *Id.* at 347–49.

22. *Id.* at 350–51; Michael A. Carrier & Carl J. Minniti III, *The Untold EpiPen Story: How Mylan Hiked Prices by Blocking Rivals*, 102 *Cornell L. Rev. Online* 53, 64–66 (2017) [hereinafter Carrier & Minniti, *How Mylan Hiked Prices*].

23. *Complaint for Injunctive and Other Equitable Relief*, *supra* note 19, at 14.

product.”<sup>24</sup> The agency alleged that “[t]hese repetitive, serial, and meritless filings lacked any supporting clinical data” but that “ViroPharma’s campaign had succeeded in delaying generic entry at a cost of hundreds of millions of dollars.”<sup>25</sup>

Not only do petitions threaten the public but they also harm the FDA, which has lamented the deluge of petitions that has forced it to expend resources “at the expense of completing the other work of the Agency.”<sup>26</sup> The FDA also bemoaned the “strain on Agency resources” from Congress’s reduction of the response period by 30 days to 150 days, which “affords [the] FDA even less time to evaluate the issues raised in the petitions and to provide a response that articulates the scientific and legal reasoning supporting the Agency’s decision.”<sup>27</sup> In addition, the FDA has revealed frustration with “serial 505(q) petitions, frequently from the same petitioner, about the same specific drug or class of drugs” that require “several separate responses about different issues regarding the same product.”<sup>28</sup>

The FDA’s concerns are accompanied by the public’s difficulty in uncovering information about petitions, which obscures the prevalence of the conduct and the full extent of the delay. The government website [regulations.gov](http://www.regulations.gov) is difficult to navigate,<sup>29</sup> leading to dependence on the privately compiled collection at [FDALawBlog](http://www.fdalawblog.net).<sup>30</sup> Moreover, the FDA does not provide a comprehensive account of delay from petitions targeting generics. In its annual reports to Congress, the FDA has found “delayed approvals” on only ten occasions between 2008 and 2015.<sup>31</sup> The agency, however, does not specify these petitions, nor does it consider a petition delayed if it responds within the 150-day period.<sup>32</sup> Relatedly, the FDA has

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24. *Id.* at 1–2.

25. *Id.* at 2.

26. FDA, Report to Congress: Eighth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2015, at 1–8 (2016) [hereinafter FY 2015 Report], <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ReportsBudgets/UCM517279.pdf> [<http://perma.cc/5UN7-T9NL>].

27. FDA, Report to Congress: Seventh Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2014, at 10 (2015) [hereinafter FY 2014 Report], <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ReportsBudgets/UCM464282.pdf> [<http://perma.cc/XZG8-N5BB>].

28. *Id.*

29. For example, [www.regulations.gov](http://www.regulations.gov) requires a researcher looking for 505(q) petitions to comb through individual petitions filed with the FDA and identify those petitions that include a 505(q) certification statement.

30. FDA Citizen Petition Tracker, FDA Law Blog, [http://www.fdalawblog.net/fda\\_law\\_blog\\_hyman\\_phelps/files/CPTracker.xls](http://www.fdalawblog.net/fda_law_blog_hyman_phelps/files/CPTracker.xls) (on file with the *Columbia Law Review*) (last visited Aug. 15, 2017).

31. FY 2015 Report, *supra* note 26, at 8.

32. FY 2014 Report, *supra* note 27, at 9 (finding that “a petition answered within the [150-day] statutory deadline does not delay approval of a pending application”).

failed to consider that it could be delaying generic approval by not approving the generic until it resolves the petition.<sup>33</sup>

Congress attempted to address concerns presented by citizen petitions in the FDAAA.<sup>34</sup> It allowed the FDA to delay its approval of a generic only if the delay was “necessary to protect the public health.”<sup>35</sup> And it required that the agency provide certain types of information to Congress each year.<sup>36</sup> But this legislation was not successful in its goal of “stop[ping] frivolous petitions from delaying generic entry,”<sup>37</sup> as the number of petitions increased after the law went into effect and has shown no signs of abating.<sup>38</sup> This Piece picks up where the FDAAA left off, proposing five solutions to the citizen petition problem: (1) increasing transparency; (2) shedding light on simultaneous decisions on petitions and generic approval; (3) facilitating the FDA’s summary dispositions of petitions; (4) addressing resource waste; and (5) promoting timely filed petitions.

## II. ENHANCE TRANSPARENCY

The first proposal would increase transparency. The FDA currently is required to provide annual reports to Congress that specify certain types of information:

- “[T]he number of applications that were approved during the preceding 12-month period”;
- “[T]he number of such applications whose effective dates were delayed by [the above-referenced] petitions”;
- “[T]he number of days by which such applications were so delayed”; and
- “[T]he number of such petitions that were submitted during such period.”<sup>39</sup>

Despite this information, the FDA never explains which petitions it believes have resulted in delay. And again, the agency considers a petition to be delayed only if it does not respond within the 150-day period.<sup>40</sup> It is possible, however, that a petition leads to delayed entry even within the 150-day period. The FDA, for example, might approve a generic later than it would have if the petition had not been filed. For

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33. See *infra* Part III.

34. See *supra* notes 11–16 and accompanying text.

35. 21 U.S.C. § 355(q)(1)(A)(i) (2012).

36. See *infra* note 39 and accompanying text (listing requirements of annual reports submitted to Congress).

37. 153 Cong. Rec. 10,924 (2007) (statement of Sen. Debbie Stabenow).

38. See Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 *Cardozo L. Rev.* 249, 282 (2012).

39. 21 U.S.C. § 355(q)(3).

40. *Supra* note 32.

these reasons, Congress should require the FDA to specify additional categories of information, including:

- Every 505(q) petition;
- The timing of the petition in relation to the expiration date of patents listed in the Orange Book<sup>41</sup> for the brand drug referenced by the generic application;
- The time the FDA expended on the petition; and
- The delay (if any) in generic approval caused by the petition and determination of how the delay is calculated.

The FDA can provide this information in its annual report to Congress or on its website (like it does for patents listed in the Orange Book, generic applications, and products requiring Risk Evaluation and Mitigation Strategies (REMS)<sup>42</sup>). Each of the categories would address certain current deficiencies. By providing a list of every 505(q) petition, the FDA would make it significantly easier to research and analyze petitions. Including information on when the petitions were filed would highlight late filings in relation to patents. The third category would, as discussed in more detail below,<sup>43</sup> shed light on FDA resources expended on petitions. And the fourth category would provide more useful information than is currently available on delay from petitions.

In short, these additional categories would provide valuable information that is currently missing and would highlight the significant concerns presented by citizen petitions.

### III. ELUCIDATE SIMULTANEOUS RESOLUTIONS

A second proposal targets a particular instance of transparency, which involves simultaneous determinations. On certain occasions, the FDA denies a citizen petition at the same time it grants generic approval. Some of these decisions occur within a short time (for example, one month) of each other while others occur on the same day. Although the FDA has never acknowledged doing so, industry observers have commented that the agency's "practice for many years has been to simultaneously announce both decisions."<sup>44</sup>

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41. The Orange Book is an annual compilation of drugs and their associated patents. FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* (37th ed. 2017), <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/ucm071436.pdf> [<http://perma.cc/A663-TYBX>].

42. REMS, which often take the form of restrictions on a drug's distribution, ensure that a drug's benefits outweigh its risks. 21 U.S.C. § 355-1(a)(1).

43. See *infra* Part V (discussing the FDA's time and cost expenditure on each petition).

44. Kurt R. Karst et al., *How FDA Announces Drug Approval Decisions: A Broken FDA "System" that Must Be Fixed*, FDA Law Blog 1, <http://www.fdalawblog.net/wp-content/uploads/archives/docs/Drug%20Approval%20Decision%20Paper.pdf> [<http://perma.cc/QF4E-UCM7>] (last visited Jan. 31, 2018).

The FDA's control over the timing of decisions relating to petitions and generic approval has been criticized, with one court lamenting the "mess" that prevented "the opportunity to actually review the FDA's actual decision and actual reasoning" on the citizen petition before the agency reached a decision on the generic application.<sup>45</sup> An industry expert concluded that "the current FDA system to announce . . . hotly contested decisions is broken," with "whatever advantage" the agency "may think it is getting from hiding the ball from the world on the timing and substance of these decisions . . . more than overcome by the criticism the Agency has received from judges."<sup>46</sup>

When the FDA issues simultaneous rulings, one concern is that the generic would have been approved *earlier* absent the petition. As discussed above, petitions often require multiple divisions of the FDA to review detailed documentation, slowing down the approval process.<sup>47</sup> But as long as the decision is reached within 150 days, the FDA does not count these as instances of delay in its annual report.<sup>48</sup> For example, the FDA asserts that there is no delay when the 150-day period ends before the generic is "ready for approval," without considering whether the petition itself *delayed* approval.<sup>49</sup>

This position seems inconsistent with the agency's guidance. In determining whether a petition would delay a generic application (which is allowed only to protect health),<sup>50</sup> it applies a "but for" test to determine delay that asks if the generic would be "ready for approval but for the issues raised by the petition."<sup>51</sup> Given the information currently available to the public, it is not possible for observers to determine this. Applying its "but for" analysis, the agency should make clear when it was likely to have approved the generic absent the petition.

A second concern is that the FDA delays announcing a petition decision it has *already reached* until it formally approves the generic application. In this scenario, the petition does not delay the generic, but the FDA delays the *announcement* of the petition's denial so that it is made simultaneously with the generic's approval. The FDA may engage in this conduct to eliminate the possibility of judicial review of the petition decision.

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45. *Id.* at 5 (citing *AstraZeneca Pharms. LP v. Burwell*, 197 F. Supp. 3d 53 (D.D.C. 2016)); cf. *id.* at 3–4 (citing *Hi-Tech Pharmacal Co. v. FDA*, 587 F. Supp. 2d 1 (D.D.C. 2008)) (expressing "concern that FDA would be making a decision on exclusivity without either company having the ability to challenge that decision before facing irreparable harm").

46. *Id.* at 8.

47. See *supra* note 10 and accompanying text.

48. See *supra* note 32 and accompanying text.

49. FY 2014 Report, *supra* note 27, at 9.

50. 21 U.S.C. § 355(q)(1)(A) (2012).

51. Guidance for Industry, *supra* note 13, at 8.

The FDA has demonstrated concern that rulings on petitions “constitute final Agency action and are subject to immediate review by the courts.”<sup>52</sup> As a result, petition rulings “carry with them none of the procedural rights . . . that attach to a decision to deny” generic approval.<sup>53</sup> Rulings on petitions before decisions on generic approval thus “could interfere with the statutory and regulatory scheme governing the review of applications and related procedural rights of applicants.”<sup>54</sup>

More skeptically, the FDA may be delaying petition rulings so that it is less likely to be sued in court. A petition denied before generic approval may be appealed to the courts, but one announced simultaneously with the approval decision is less likely to be challenged since in that case the generic has received approval and may be on the market shortly thereafter, which would dissuade a brand firm seeking to keep a generic off the market.

Shedding light on the timing of simultaneous decisions—including determinations of (1) when the generic would have received approval absent the petition and (2) when the FDA would have announced the petition decision absent the pending generic application—would help resolve these contentious issues.

#### IV. FACILITATE SUMMARY DISPOSITION

Third, Congress could make it easier for the FDA to quickly dispose of certain petitions. Because the legislature understood that some petitions raised significant concern, it allowed the FDA to summarily dispense with them. This authority, however, has never been used.<sup>55</sup>

The reason is that the standard is too high. Section 505(q)(1)(E) requires the FDA to conclude that a petition is “submitted with the primary purpose of delaying” the generic application and that “the petition does not on its face raise valid scientific or regulatory issues.”<sup>56</sup> But the provision “has neither curbed the filing of petitions submitted with the

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52. *Id.* at 14; see also Amendments to Regulations on Citizen Petitions, Petitions for Stay of Action, and Submission of Documents to Dockets, 81 Fed. Reg. 78,500, 78,504 (Nov. 8, 2016) (“FDA is considered to have taken final Agency action on a petition if either: (1) FDA makes a final decision . . . during the 150-day period or (2) the 150-day period expires without FDA making a final decision.”).

53. Guidance for Industry, *supra* note 13, at 14 (explaining how, after the FDA denies an application for approval, it “must give the applicant notice of an opportunity for a hearing on whether the application is approvable, with a specific timeframe and process”).

54. *Id.*

55. See Sarah Zhang, How Pharma Companies Use ‘Citizen Petitions’ to Keep Drug Prices High, *Atlantic* (Mar. 8, 2017), <http://www.theatlantic.com/health/archive/2017/03/pharma-citizen-petitions-drug-prices/518544/> [<http://perma.cc/735VG7QM>] (“[T]he FDA can summarily deny petitions that it finds frivolous—but it never has.”).

56. 21 U.S.C. § 355(q)(1)(E) (2012).

primary purpose of delay” nor “permitted FDA to dispose of such petitions without expending substantial amounts of resources.”<sup>57</sup>

As the agency has explained, the standards for summary disposition are “extremely difficult to meet.”<sup>58</sup> For starters, the FDA cannot determine a petitioner’s primary purpose based on the petition itself. Merely reviewing such a document, which includes safety or effectiveness concerns, cannot reveal the filer’s purpose, let alone its primary purpose.

Moreover, even a petition that ultimately is denied will tend not to reveal “on its face” that it “does not . . . raise valid scientific or regulatory issues.”<sup>59</sup> Petitions will include language and sometimes documentation challenging a drug’s safety or efficacy that at first glance may sound plausible. The FDA would be hesitant to rule in a cursory review that the petition does not raise valid issues. Its concern is obvious: that erroneously granted summary dispositions result in safety mishaps years down the road.

What can be done? First, remove the two conditions. The FDA cannot determine purpose from the petition itself, nor can it dismiss petitions raising safety or effectiveness concerns based on a document’s “face.”

In place of these requirements, the agency could focus on timing. Legitimate petitions should be filed within a reasonably short time of discovering the safety or efficacy concern. Late-filed petitions raise the concern that the petitioner is gaming the system, often by waiting until a generic is about to enter the market to file even though it was long aware of the information forming the basis of the petition.

As one example, Mylan received widespread notoriety for its price increases on the life-saving epinephrine-autoinjector EpiPen device.<sup>60</sup> Not receiving as much attention was Mylan’s filing of a petition challenging Teva’s EpiPen alternative at least five years after it most likely was aware of the generic product specifications.<sup>61</sup>

Congress could consider replacing Section 505(q)(1)(E) with language emphasizing the filing of petitions within a reasonable time, with one year providing sufficient time to prepare a petition. One potential statutory amendment (which includes a waiver for unusual circumstances<sup>62</sup>) could provide:

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57. FY 2014 Report, *supra* note 27, at 10.

58. *Id.*

59. 21 U.S.C. § 355(q)(1)(E).

60. See Willingham, *supra* note 2.

61. See Carrier & Minniti, *How Mylan Hiked Prices*, *supra* note 22, at 65; see also *infra* notes 69–74 and accompanying text.

62. One such circumstance could include the situation in which (1) a new study shows that a molecule is harmful in population X; (2) two years later, a different study shows that the molecule may also be harmful in population Y, which is similar to population X; and (3) a petition is then filed asserting that a generic should not be

505(q) petitions must be filed within one year of the petitioner learning of the safety or efficacy issue asserted in the petition. FDA may grant a waiver to allow later filing.

Such an amendment would make it more difficult to file questionable petitions. And by focusing on the delay in filing, the analysis would pinpoint concerns based on timing, which raise red flags and can be discerned, rather than the filer's purpose or problems on the petition's face, which cannot readily be determined.<sup>63</sup>

#### V. ADDRESS RESOURCE WASTE

A fourth proposal would require the FDA to disclose the money and time it expends resolving 505(q) petitions. In its Eighth Report to Congress, the FDA was "concerned about the resources required to respond to 505(q) petitions within the 150-day deadline at the expense of completing [its] other work."<sup>64</sup> And in its Seventh Report, it explained that the reduction from 180 to 150 days "increased the strain on Agency resources," which required it "to direct resources away from other important initiatives to attempt to comply with the new shorter deadline."<sup>65</sup>

Putting dollar and time figures on the resource drain from petition responses could offer important benefits. It would make the problems posed by citizen petitions more concrete and provide greater impetus for changes. As it stands now, the theoretical arguments based on freedom of expression and the possibility of raising legitimate concerns with the FDA, combined with inertia and the difficulty of limiting existing procedures, make it more difficult to impose limits on the process. Concrete figures depicting the resources expended on petitions, when considered in the setting of the overwhelming incidence of denials,<sup>66</sup> could pave the way for changes.

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approved for treating population Y. It is arguable that a petition should have been filed two years earlier due to the similarities between populations X and Y. Allowing a waiver eliminates any ambiguity that could be used to reject the petition based on late filing.

63. If challenged, the proposal should survive First Amendment scrutiny as a content-neutral restriction that (1) does not completely block petitioning and (2) serves an important government interest unrelated to the suppression of free expression in (a) solving a public health problem of consumers paying unwarranted monopoly prices from abusive petitions and (b) addressing the failure of prior efforts by the FDA and Congress to remedy the problem. See *United States v. O'Brien*, 391 U.S. 367, 377 (1968); see also *supra* notes 26–28 and 34–38 and accompanying text (discussing previous failures to find a solution). Previous widely acknowledged failures to solve the problem show that the recommendation "promotes a substantial government interest" that would otherwise "be achieved less effectively." See *United States v. Albertini*, 472 U.S. 675, 689 (1985).

64. FY 2015 Report, *supra* note 26, at 8.

65. FY 2014 Report, *supra* note 27, at 10.

66. See *supra* note 18 and accompanying text.

## VI. PROMOTE TIMELINESS

Fifth, Congress could amend section 505(q)(1)(H) to require a petitioner to certify that it filed its objection within a reasonable time—say, one year—of discovering the claim that is the basis of the petition. Currently, the section requires the petitioner to certify that the petition includes “all information and views upon which the petition relies” and “representative data and/or information known to the petitioner which are unfavorable to the petition,” and that it took “reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed.”<sup>67</sup> The petitioner is also required to “certify that the information upon which” the action requested is based “first became known” on a date the party specifies.<sup>68</sup>

Although it would appear that these requirements would result in petitions that are timely filed, that is not always the case. Petitioners sometimes file long after becoming aware of the basis for the petition. One example appears with Mylan’s citizen petition against Teva’s Epi-Pen alternative, filed on January 16, 2015.<sup>69</sup> In a development of which the industry would be keenly aware, Teva filed its ANDA against the Epi-Pen in 2008.<sup>70</sup> And court documents show that Teva produced its ANDA filing in the course of litigation on September 17, 2010.<sup>71</sup> This material included “detailed product descriptions, drawings, and instructions for use” for Teva’s proposed generic.<sup>72</sup>

At the time (and to this day), Mylan (as distributor and marketer) was working hand-in-hand with Meridian/King (manufacturer), with the former taking over Orange Book sponsorship of the drug application and the latter targeting rivals in litigation.<sup>73</sup> It thus seems exceedingly likely that Mylan would have been aware of Teva’s ANDA in 2008 and aware of documents explaining Teva’s product in 2010. In fact, it was *Mylan* that announced the settlement of the litigation, confirming its

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67. 21 U.S.C. § 355(q)(1)(H) (2012).

68. *Id.*

69. Citizen Petition from Mylan Specialty, L.P., No. FDA-2015-P-0181-0001 at 1 (posted Jan. 20, 2015); see also Carrier & Minniti, *How Mylan Hiked Prices*, *supra* note 22, at 64.

70. Larry Smith, *The Promise of the Antares Pipeline is the Basis of My Buy Recommendation*, *Smith On Stocks* (Jan. 25, 2012), <http://smithonstocks.com/the-promise-of-the-antares-pipeline-is-the-basis-of-my-buy-recommendation-ais-2-40> [<http://perma.cc/4UJE-8B8B>].

71. Defendants’ Brief in Support of Their Motion to Dismiss at 6, *King Pharm., Inc. v. Teva Parenteral Meds. Inc.*, No. 09-CV-652-GMS (D. Del. filed Dec. 13, 2010), 2010 WL 7583650.

72. *Id.*

73. Complaint at 2, *King Pharm., Inc. v. Teva Parenteral Meds. Inc.*, No. 09-CV652-GMS (D. Del. filed Aug. 28, 2009), 2009 WL 2849496.

close connection to the case.<sup>74</sup> This connection raises significant concerns that Mylan waited more than four years to file its citizen petition in 2015.

An amendment to section 505(q)(1)(H) to require a petitioner to certify that it filed its objection within one year of discovering the claim underlying the petition would help address the situation. The end of the section could include the following language:

The petitioner must certify that it became aware of the information upon which the action requested is based within one year of the petition.

Putting a timeframe on the obligation could make it more concrete and more difficult to evade. At the same time, one year should be enough time to research potential concerns with the generic drug. A certification requiring filing within one year would make clear that petitions cannot be used to delay generic entry.<sup>75</sup>

#### CONCLUSION

Citizen petitions have recently received attention as a tool by which brand firms have delayed generic entry, allowing them to maintain their monopolies and preventing consumers from enjoying lower prices. The FDA has revealed concern with the resources it expends on petitions and has recently denied nearly all petitions targeting generic entry.

The five proposals offered in this Piece would address the most egregious aspects of the process. They would increase transparency, allow the dismissal of frivolous petitions, and prevent some of the most flagrant instances of delayed generic entry. Given high drug prices, the five proposals are worth attention.

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74. See Mylan and Pfizer Announce Epinephrine Auto-injector Settlement Agreement with Teva, Mylan (Apr. 26, 2012), <http://newsroom.mylan.com/press-releases?item=123144> [<http://perma.cc/V7EX-T49J>].

75. For an overview of the First Amendment implications of this proposal, see *supra* note 63 and accompanying text.