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THE BURDEN ON SOCIETY FROM ELEVENTH-HOUR “CITIZEN PETITIONS” FILED TO SLOW GENERIC DRUGS

ROBIN FELDMAN*

ABSTRACT

The Food and Drug Administration’s citizen petition process provides an avenue for ordinary citizens to raise concerns and participate in the regulatory process. Abuse of that process has been documented as an example of the legal maneuvering used by pharmaceutical companies to protect their brand-name drug revenue streams from the introduction of low-cost generics. To date, the financial cost to society of these delays has not been calculated in the literature, which likely hinders the push for policy solutions. Drawing from a previously published data set on 249 citizen petitions, this Article will identify four petitions that were highly likely to have been the final obstacle to a generic drug entering the market. Specifically, the petitions were denied; the FDA approved the generics within one business day of denying the petitions; and the generics came to market within one week of the FDA’s approval, signaling that the petitions were the final obstacle standing in the way of the generic’s entry to market. Using these four dubious citizen petitions, this Article will find that the total financial cost to society from citizen petition delays was \$1.9 billion or \$3.6 million per day.¹ The total financial cost to government-provided insurance programs in the same period was roughly \$782 million.² This Article will employ a conservative methodology (choosing only four petitions that meet the criteria of “but for” this citizen petition, the generic would have gone to market). Thus, the estimates are likely low. Citizen petitions that contributed to a generic delay as one of many tactics or for which there was not sufficient volume and usage information were eliminated from consideration in this estimate.

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1. *See infra* Section I.B.
2. *See infra* Section I.B.

INTRODUCTION

Abuse of the citizen petition process is one tactic in a large repertoire of legal maneuvering used by pharmaceutical companies to protect their brand-name drug revenue streams from the introduction of low-cost generic equivalents. The citizen petition process at the Food and Drug Administration (“FDA”) can be traced back to a movement in the 1970s to provide opportunities for ordinary citizens to participate in the regulatory agency decision-making process.³ In theory, citizen petitions should provide a method for all voices to be heard, and the process is intended for engaged citizens and scientists to voice concerns about food, drugs, and FDA regulations. In practice, pharmaceutical companies frequently use the system to file baseless citizen petitions—that are subsequently denied by the FDA—in the hopes of delaying generic drugs from reaching the market. In some years, as many as one in five citizen petitions filed at the FDA on any topic (including tobacco, food, and dietary supplements) had the potential to delay the entry of a generic drug.⁴ And the trend is growing.⁵

Often companies file their citizen petition in the months right before their generic competitors’ approval is anticipated. In the vast majority of cases, the FDA denies these petitions.⁶ Yet, the drug companies’ motives are easy to identify: delaying a lower-priced generic from entering the market for even ninety days can earn the companies hundreds of millions of dollars of revenue, making their bogus citizen petitions worth their while.⁷

3. See Clark Byse, *Vermont Yankee and the Evolution of Administrative Procedure: A Somewhat Different View*, 91 HARV. L. REV. 1823 (1978); Reuel E. Schiller, *Rulemaking’s Promise: Administrative Law and Legal Culture in the 1960s and 1970s*, 53 ADMIN. L. REV. 1139 (2001) (describing the development of citizen participation in federal agency practice); see also Administrative Procedure Act, 5 U.S.C. § 553(e) (2012 & Supp. III 2015) (mandating that federal agencies allow the public to petition to change, amend, or repeal an agency rule).

4. Robin Feldman, Evan Frondorf, Andrew K. Cordova & Connie Wang, *Empirical Evidence of Drug Pricing Games—A Citizen’s Pathway Gone Astray*, 20 STAN. TECH. L. REV. 39, 40 (2017) (examining empirical evidence suggesting the citizen petition process has “become a key avenue for strategic behavior by pharmaceutical companies to delay” the entry of generic competition).

5. *Id.*

6. See Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 249, 249–52 (2012); Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U. L. REV. 305, 333 (2016) (finding that the FDA denied 81% of generic-related petitions between 2001 and 2010 and 92% of petitions between 2011 and 2015, with denial rates as high as 92% in 2005, 96% in 2012, and even 100% in 2015).

7. For example, in 2014, Sovaldi, a hepatitis C drug manufactured by Gilead, earned \$7.9 billion in sales, making it the top-earning drug in the United States. At that rate, three additional months of sales would be worth \$1.98 billion. During that same year, Pfizer’s Nexium earned \$5.9 billion in revenue, meaning that three additional months of sales would amount to \$1.48 billion. See Lacie Glover, *Here are the Top-Selling Drugs in the US*, TIME (June 26, 2015), https://money.com/money/3938166/top-selling-drugs-sovaldi-abilify-humira/?xid=soc_socialflow_twitter_money (identifying revenue for Pfizer’s Nexium drug).

Protecting the availability of low-cost generic drugs matters to the American public. Affordable generic drugs, in addition to being critical to public health, translate into huge savings for the American public and government-funded insurance programs.⁸ The availability of a generic equivalent can reduce the price of a prescription drug significantly⁹; more than three-quarters of prescriptions are now filled with their generic equivalents.¹⁰ Thus, bringing generics to market is an essential part of controlling drug costs.

Despite the documented abuse of the citizen petition system,¹¹ the cost to society of these delays has not been calculated, which may hinder the push for policy solutions. Following the analytic techniques that Congress uses for estimating the likely impact of reform, this Article will identify a set of citizen petitions that could be described as the sole, “but for” cause of keeping a particular generic out of the market.¹² It will use the criteria that the petition was denied; the FDA approved the generic within one business day of denying the petition; and the generic came to market within one week of the FDA’s approval, signaling that the petition was the final obstacle standing in the way of the generic’s entry to market.

Drawing from a previously published data set of 249 citizen petitions,¹³ this Article will analyze four petitions from a two-year period that are highly likely to have been the final obstacle to a generic drug entering the market, and for which sufficient volume and usage data exist. Using these four dubious citizen petitions, this Article will show that *the total financial cost to society of citizen petition delays was \$1.9 billion—which equals roughly \$3.6 million per day*.¹⁴ Additionally, this Article will find that the total financial cost to government-provided insurance programs in the same period was roughly \$782 million.¹⁵ Due to the conservative methodology employed¹⁶ (choosing only petitions that met the criteria of

8. See U.S. GOV’T ACCOUNTABILITY OFFICE, DRUG PRICING: RESEARCH ON SAVINGS FROM GENERIC DRUG USE 4 (2012), <https://www.gao.gov/products/gao-12-371r> (reviewing available literature on the savings from generic drug usage, including three groups of studies). Two groups of studies found large cost-savings for the American public including \$1 trillion over eleven years. *Id.* A third group of studies had more mixed results on savings because it considered healthcare savings more generally rather than drug spending exclusively. *Id.*

9. ROBIN FELDMAN & EVAN FRONDORF, DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET 20–24 (2017).

10. *Id.* at 22.

11. Robin Feldman & Connie Wang, *A Citizen’s Pathway Gone Astray—Delaying Competition from Generic Drugs*, 376 NEW ENG. J. MED. 1499–1501 (2017).

12. See, e.g., CONG. BUDGET OFFICE, COST ESTIMATE: H.R. 2374, STOP STALLING ACT 1 (2019), <https://www.cbo.gov/system/files/2019-05/hr2374.pdf> (following the “but for” approach).

13. For details on the methodology of the assembly and analysis of the larger data set, see Feldman & Wang, *supra* note 11, at 1499; see also Feldman et al., *supra* note 4, at 39.

14. See *infra* Section I.B.

15. See *infra* Section I.B.

16. See *infra* Part I.

“but for” this citizen petition the generic would have gone to market), the estimates are likely low. Citizen petitions that contributed to a generic’s delay to market as one of multiple tactics or for which there was not sufficient volume and usage information were eliminated from consideration in this estimate.

This is an extraordinarily narrow method of identifying citizen petitions that contribute to generic drug delays. This approach significantly underestimates the financial impact when pharmaceutical companies misuse the regulatory system by filing baseless citizen petitions. By counting financial costs only associated with citizen petitions that stand alone during the twelve-year period rather than when they may be contributing to the delay as part of an arsenal of tactics, the total cost is undoubtedly underestimated. Moreover, this Article does not include in the calculation any costs to public health that may come from patients foregoing medication due to the lack of a lower cost generic alternative. Nonetheless, these delays bring substantial and sobering costs.

Moreover, these assessments focus solely on the financial cost to the American public. Drug costs also affect the health and well-being of citizens directly, regardless of whether they have insurance. According to the Kaiser Family Foundation, nearly one-quarter of Americans said their family chose not to fill at least one prescription within the last year.¹⁷ In families where members were in poor or fair health, those numbers were even higher.¹⁸ The cost of these delays to the public’s health and well-being is not calculated in the total cost, underscoring that these are conservative estimates. The methodology and results for assessing the financial cost to the American public of citizen petition delays are presented below.¹⁹

I. METHODOLOGY

A. Identifying Citizen Petitions Designed to Delay Generic Drugs to Market

This Article analyzes the historic financial cost to society because of FDA citizen petitions filed at the last hour to delay pharmaceutical competition. Given the extensive tactics that pharmaceutical companies regularly use to thwart competition from generic drugs, only those citizen petitions that were most likely the principal cause delaying generic entry at that point in time were identified. In other words, the calculations included

17. Bianca DiJulio, Jamie Firth & Mollyann Brodie, *Kaiser Health Tracking Poll: August 2015*, KAISER FAM. FOUND. (Aug. 20, 2015), <https://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-august-2015/>.

18. *Id.*

19. See *infra* Part I.A. (explaining the methodology of the paper); *infra* Section I.B. (discussing the results of the calculation).

only those citizen petitions whose timing suggests they were the *final obstacle* standing in the way of generic approval. This Article also only includes citizen petitions for which sufficiently robust volume and price information were available.

This analysis first required examination of citizen petition data that was previously assembled and published on the 249 citizen petitions filed at the FDA during the twelve-year period from 2000 to 2012 with the potential to delay generic competition. Additional criteria were established to select the most relevant citizen petitions.

Specifically, only those citizen petitions that were filed by a pharmaceutical company within six months of their competing generic drug's approval were examined. This six-month window was chosen because in the years between 2007 and 2012, federal law required that the FDA respond to citizen petitions within 180 days (roughly six months).²⁰ Prior to that time, there was no limit on the FDA's response time, and a citizen petition could delay generic entry for longer than six months.²¹ Thus, only petitions filed within six months of when the generic was approved were examined on the theory that those cases most likely represented petitions filed as a last-ditch effort to delay generic competition during the relevant study period.

This supposition is reinforced by the fact that on average for approved generics, the FDA takes four years from the time the generic drug company files its application to the time when the drug is approved.²² In other words, the brand-name drug companies in these cases did not appear to be rushing to the FDA to express urgent concerns about a generic applicant but rather they waited until they exhausted other avenues and filed the petitions as a last-ditch effort.

Within the subset of petitions filed within six months of approval, the data set was further narrowed to include only those petitions for which:

1. The FDA approved the generic within one business day of denying the citizen petition, signaling the likelihood that the petition was baseless; and
2. The generic came to market within one week of the FDA's approval, signaling the likelihood that the petition was the final obstacle standing in the way of the generic's entry to market.²³

20. See 21 U.S.C. § 355(q)(1)(F) (2012 & Supp. III 2015).

21. Congress subsequently reduced the time to 150 days. See Food and Drug Administration Safety and Innovation Act of 2012, Pub. L. No. 112-144, 126 Stat. 993 (codified as amended in scattered sections of 21 U.S.C.). For an explanation of the generic drug approval process, see FELDMAN & FRONDORF, *supra* note 9, at 26–33.

22. Feldman et al., *supra* note 4, at 72, 74 (calculating the average approval time for generic applications in the data set as 16.5 quarters—slightly over four years).

23. Despite the preparation that happens ahead of FDA approval, it is assumed that it can take a little more effort for a generic company to officially enter the market than it takes for the FDA to file the document granting approval. Thus, a window of one week for getting to market

Together, these criteria suggest the citizen petitions were most likely the cause delaying generic entry at that point, and that “but for” the citizen petitions, the generics would have entered the market.

For example, a case in which the FDA denied the petition *after* the generic application was approved and *after* the generic entered the market was removed from consideration. Under those circumstances, the petition filing did not block the generic from approval and subsequent market entry, although the petition could have contributed to the delay process in some manner.²⁴

With the established criteria in place, particular attention was paid to two years—2008 and 2012—each of which contained two citizen petitions that met the criteria. The four petitions related to a drug for treating depression, two drugs for treating high blood pressure, and one drug for treating muscle spasms occurring from multiple sclerosis and spinal cord injury, with the drug for depression having the highest cost impact of the group.²⁵ Exhibit 2 identifies the four drugs and shows the dates the generics filed their application for approval to enter the market (which is known as an Abbreviated New Drug Application or “ANDA”),²⁶ the dates the brand-name drug companies filed their citizen petitions, the date of the FDA’s denial, and the length of the delay to the generic drugs entering the market. For the four citizen petitions that met the criteria, the total delay to getting lower-cost generic drugs to market was 521 days.

was chosen, although some generics do, indeed, get to market within one or two days of FDA approval. In order to find the market entry date, this Article used DrugBank, a free and publicly accessible database with relevant pharmaceutical drug information, including market entry date. *See generally About DrugBank*, DRUGBANK, <https://www.drugbank.ca/about> (last visited Jan. 20, 2020). The market entry data was then cross referenced with the FDA Approval data found on the FDA’s website. *See Drugs@FDA: FDA-Approved Drugs*, FOOD & DRUG ADMIN., <https://www.accessdata.fda.gov/scripts/cder/daf/> (last visited Feb. 9, 2020).

24. *See infra* text accompanying notes 25–30 (explaining that when a citizen petition is part of a series of delaying tactics, each tactic may contribute to the delay to some extent, even if the particular tactic is not the last straw before approval).

25. Mutual Pharmaceutical Co., Inc. Citizen Petition, No. FDA-2007-P-0123-0002 (Nov. 30, 2007), <https://www.regulations.gov/document?D=FDA-2007-P-0123-0002> (filed by the makers of Plendil (active ingredient: felodipine)); King Pharmaceuticals, Inc. Citizen Petition, No. FDA-2008-P-0304-0001 (May 19, 2008), <https://www.regulations.gov/document?D=FDA-2008-P-0304-0001> (filed by the makers of Altace (active ingredient: ramipril)); AstraZeneca LP Citizen Petition, No. FDA-2011-P-0662-0001 (Sept. 9, 2011), <https://www.regulations.gov/document?D=FDA-2011-P-0662-0001> (filed by the makers of Seroquel (active ingredient: quetiapine fumarate)); and Acorda Therapeutics, Inc. Citizen Petition, No. FDA-2011-P-0654-0001 (Sept. 7, 2011), <https://www.regulations.gov/document?D=FDA-2011-P-0654-0001> (filed by the makers of Zanaflex (active ingredient: tizanidine hydrochloride)). These petitions were found by using *Regulations.gov*, which is a government-maintained website allowing third parties to access certain regulation documents, including filed citizen petitions. REGULATIONS.GOV, <https://www.regulations.gov/> (last visited Feb. 9, 2020).

26. For a discussion of the requirements for filing an ANDA along with the ANDA process, see FELDMAN & FRONDORF, *supra* note 9, at 26–33 (describing ANDAs and the role they play in the generic approval process).

One must emphasize that this approach is an extraordinarily narrow method of identifying the citizen petitions that contribute to delays and one that significantly underestimates the financial impact when companies abuse the regulatory system by filing improper citizen petitions. An improper citizen petition is often one tactic in an arsenal of delay tactics a brand can launch against a generic applicant. For example, a generic company needs samples of the original drug to prove to the FDA that the generic and brand are bioequivalent. Brand companies can delay a generic's application by refusing to provide appropriate samples.²⁷ Similarly, when a drug is subject to a safety plan related to labelling or distribution, for example, the FDA will not approve the generic until the companies agree on a plan. As long as the parties do not reach an agreement, the brand remains on the market and the generic is left out in the cold.²⁸ Thus, brand companies have an incentive to delay or create unreasonable demands in the cooperation discussions.

Brand companies also can expand their definition of what a patent covers by adding new "use codes" to the FDA records. These add-on codes are not reviewed by the FDA, and a generic company has to engage in expensive litigation to challenge the addition.²⁹ The tactics abound, and each tactic plays a role in the delay. By counting costs only when the citizen petition stands alone, rather than when the citizen petition may be contributing to the delay as part of many tactics, the calculation does not encompass the full extent to which improper citizen petitions are adversely affecting society. Other citizen petitions not included in this estimate may

27. For a discussion of two cases regarding a brand denying samples, see *id.* at 81–83 (discussing *Actelion Pharm. LTD v. Apotex Inc.*, No. 12-5743, 2013 WL 5524078 (D.N.J. Sept. 6, 2013)) and *Mylan Pharmaceuticals v. Celgene Corp.*, No. 14-cv-2094, 2014 WL 12810322 (D.N.J. Dec. 23, 2014) (showing that Celgene purposefully refused to provide samples to a generic competitor without any "legitimate business reasons" for delaying); see also Kat Greene, *Actelion Settles Row over Giving Drugs to Generic Makers*, LAW360 (Feb. 28, 2014), <https://www.law360.com/articles/514434/actelion-settles-row-over-giving-drugs-to-generics-makers> (explaining *Actelion*).

28. *Cf. In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 675 (E.D. Pa. 2014) (outlining accusations by the generic that the brand demanding "unnecessary, unprecedented and unreasonable" conditions before cooperating constituted anticompetitive conduct); FELDMAN & FRONDORF, *supra* note 9, at 87–90 (discussing unsuccessful labelling and monitoring discussions between the brand maker of Suboxone, the opioid addiction treatment drug, and the generic applicant); see also *CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition: Hearing on S.3056 Before the S. Subcomm. on Antitrust, Competition Policy and Consumer Rights of the S. Comm. on the Judiciary*, 114th Cong. (2016) (statement of Robin Feldman, Arthur J. Goldberg Distinguished Professor of Law at U.C. Hastings Law), <https://www.judiciary.senate.gov/meetings/the-creates-act-ending-regulatory-abuse-protecting-consumers-and-ensuring-drug-price-competition> (discussing such tactics).

29. See ROBIN FELDMAN, *DRUGS, MONEY, AND SECRET HANDSHAKES: THE UNSTOPPABLE GROWTH OF PRESCRIPTION DRUG PRICES* 83–84 (2019) (describing the "use code" tactic and documenting a rise in the addition of use codes by pharmaceutical companies).

contribute to some specific time-portion of the delay or to some degree of the delay overall.

For example, a generic company must fight off each tactic—responding to accusations raised in citizen petitions, filing court actions, and countering other moves such as refusals to transfer samples.³⁰ No company has endless resources and mindshare such that it can respond to all tactics at the same time. Each tactic contributes to the time it takes the company to respond to the full range of assaults. Thus, each tactic accounts for some time-portion of the delay that results from the full range of tactics.

Similarly, to the extent that each tactic plays a role in slowing down the generic company, each contributes to the delay in some degree, even if one could not identify a specific period of time attributable to that tactic. In other words, if a generic drug company spends one year responding to a range of assaults, each assault is responsible for some degree of the delay, even if the company was responding to multiple assaults at any given moment.³¹ Nevertheless, this Article chooses to focus on a group of four citizen petitions in the data that would satisfy a very narrow set of criteria and provide a conservative calculation of societal cost.

B. Measuring the Financial Cost Impact of Citizen Petition Delays

As noted in the previous section,³² in narrowing the twelve-year data set to look for those citizen petitions that would meet the “but for” criteria, the set of citizen petitions was also limited to those petitions related to drugs for which sufficient price and volume information were available. This first required removing instances where multiple and distinct citizen petitions were filed against the same drug in order to avoid duplicating cost estimate calculations for the same drug. Then the additional citizen petitions associated with the same drug were eliminated.

In order to find critical drug pricing and volume information, the dataset was cross-referenced with other sources. In the citizen petition dataset, a generic drug was represented by its ANDA number,³³ and the associated brand drug was represented by its New Drug Application

30. See, e.g., FELDMAN & FRONDORF, *supra* note 9, at 80–82 (describing the *Actelion* case, in which a brand company refused to provide samples of drugs to a potential generic company, preventing the generic from filing an application for FDA approval).

31. From a long-term perspective, potential generics must factor in the need to fend off these assaults in deciding whether to try to develop a generic product. Although more difficult to quantify, these disincentives also generate societal costs.

32. See *supra* Section I.A.

33. See *Abbreviated New Drug Application (ANDA)*, FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda> (explaining ANDAs and their function) (last updated May 22, 2019).

(“NDA”) number.³⁴ The Center for Medicare and Medicaid Services (“CMS”) provided drug pricing and volume information from their drug event data.³⁵ However, drugs are represented in the CMS data only by National Drug Code (“NDC”).³⁶ Therefore, the analysis required a dataset that would link NDA numbers to NDCs.³⁷ After the NDA numbers were linked to NDCs, citizen petitions that did not have active NDCs during the delay period were filtered out.³⁸ In other words, these NDCs were not available in the market during the delay period and thus could not be considered. For other NDCs, there was an absence of complete price and volume information. In sum, the two years and four citizen petitions that were utilized met not only the “but for” filter described above, but also the active NDC code, price, and volume criteria.

To determine the cost of delay across the relevant period, the cost of the drug without the generic in the market was compared to the cost of the generic once it reached the market. The percentage of generic market penetration, that is, the proportion of generics sold out of the total drug sales of each individual drug, was also factored in. Then, by looking at the volume of the drug, the excess amount that society spent on sales of the drug during the delay period was determined. In mathematical terms, the financial cost to society was calculated for each of the four drugs as follows:

$$\text{Financial Cost to Society} = \text{Volume} * \text{Generic Portion of the Market} * \text{Cost Difference} * \text{United States Population}$$

The estimated net price of the branded drug was obtained from information drawn from Medicare Part D drug event data purchased from CMS. A Medicare Part D drug event occurs each time a patient purchases medication from a pharmacy through a doctor’s prescription. The drug

34. See *New Drug Application (NDA)*, FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/types-applications/new-drug-application-nda> (explaining NDAs and their function) (last updated June 10, 2019).

35. CMS is part of the Department of Health and Human Services. See *About CMS*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/About-CMS/About-CMS> (last visited Feb. 9, 2020).

36. See *National Drug Code Directory*, FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory> (explaining NDCs and their function) (last updated Nov. 18, 2019).

37. This Article uses an FDA dataset that includes NDCs and their associated NDA numbers. See *NSDE*, FOOD & DRUG ADMIN., <https://www.fda.gov/industry/structured-product-labeling-resources/nsde> (last updated Mar. 27, 2018).

38. All further mentions of the “delay period” refer to the time between the date of the citizen petition filing and the date of the generic approval—which could be any number of days up to 180 days (or six months).

event data covers a cohort of just under one million patients.³⁹ The list price of the brand drug during pendency of the citizen petition could be determined from the data, after which the average manufacturer rebate in that year was applied to determine the net price of the branded drug. The average manufacturer rebate was found using the annual rebate percentages published by the CMS Medical Trustees report adjusted to reflect rebate percentages for branded drugs only.⁴⁰ For the year 2012, for example, the average manufacturer rebate was sixteen percent.⁴¹ CMS drug event data was also used to calculate the average price of the generic drug in the first year after approval.

Next, a figure for the volume of the drug used during the delay period was established by calculating the number of times a particular drug was dispensed to patients in the cohort during the delay period. Given that the CMS data represents just under one million patients, the volume figure was multiplied by a factor of: total American population divided by one million.⁴²

In this manner, cost and volume figures for patients across the nation as a whole could be estimated. Applying those figures to the delay period, the cost to society of these four baseless citizen petitions is estimated at \$1.9 billion. Given that the estimation in Exhibit 2 for the total number of days of delay was 521, this means the cost *per day* to American citizens of these baseless delay tactics is \$3.6 million.

To get a sense of how much the government—and also American taxpayers—are losing from these bogus citizen petitions, the cost to government-provided insurance programs in the two-year period was

39. For an extensive description of Medicare, CMS data files, and the purchase of CMS Part D data, see Robin Feldman, *The Devil Is in the Tiers*, 28–29 (U.C. Hastings Law Research Paper Series, Paper No. 379, 2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3490065.

40. BDS. OF TRS. FED. HOSP. INS. & FED. SUPPLEMENTARY MED. INS. TR. FUNDS, 2017 ANNUAL REPORT OF THE BOARDS OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY INSURANCE TRUST FUNDS 143 (2017) (expressing the average manufacturer rebates as a percentage of total drug costs, across all prescription drugs). The report notes that “[g]eneric drugs . . . typically do not carry manufacturer rebates. Many brand-name prescription drugs carry substantial rebates.” *Id.* at 143 n.66.

41. The annual rebate percentages found in the CMS Medical Trustees report were adjusted to reflect rebate percentages for only branded drugs as follows: 2006 (10.6%), 2007 (12.0%), 2008 (13.3%), 2009 (14.4%), 2010 (14.7%), 2011 (14.7%), 2012 (16.0%), 2013 (17.9%), 2014 (19.3%), and 2015 (24.2%). *Id.* at 143.

42. *U.S. Population by Year*, MULTPL.COM, <https://www.multpl.com/united-states-population/table/by-year> (last visited June 7, 2019). The numbers from this website are sourced from the United States Census Bureau. See U.S. CENSUS BUREAU, <https://www.census.gov/> (last visited Feb. 9, 2020). This methodology assumes the usage of the drug among the Medicare population is comparable to the usage of the drug among the national patient population as a whole. This methodology also assumes drug companies provide rebates to private insurers at a percentage comparable to the rebates provided to Medicare Part D plans. Other limitations of these results include the small sample size, such that individual petitions in the study might not be representative of the whole, and the fact that information may not be the same in years outside of the period examined.

estimated at roughly \$782 million. This number was calculated by estimating that 41.3% of all claims during the two-year period were covered by government-provided insurance. The 2017 Census data was used to estimate the percentage of government-provided insurance plans including Medicaid (19.3%), Medicare (17.2%), and military coverage (4.8%).⁴³

Most important, this analysis utilized citizen petition data that had been painstakingly assembled from archived information, some of which is no longer available from the FDA in any form or has never been available.⁴⁴ Techniques were developed for triangulating information to pinpoint the time periods for various activities related to FDA filings.⁴⁵

Notably, another estimate that calculates the costs of the delays caused by dubious citizen petitions was done by the Congressional Budget Office (“CBO”) in anticipation of HR 2374, a bill aimed at curbing citizen petition abuse. The CBO estimate suggested a savings to the government of \$117 million over the ten-year period of 2019 to 2029 affecting \$1–2 billion in sales over a decade.⁴⁶ The CBO noted “uncertainty” in their estimate, due in part to the difficulty in predicting the volume of brand-name sales impacted by generic drugs.⁴⁷ Given the large volume of drug business cited above,⁴⁸ the access to drug volume and use data, and the database of citizen petition information utilized in this Article, the findings of this Article can considerably reduce that uncertainty. Thus, this Article provides a more complete picture, as well as one that helps assess the savings to American consumers, rather than simply the savings to government programs. The analysis and estimates presented in this Article are offered to help facilitate discussion of this critical issue.

CONCLUSION

The United States government established the citizen petition process to allow engaged citizens and scientists to file concerns about the safety and regulation of drugs coming to the market. Rather than providing an active sounding board for public health and safety issues, the process is dominated by pharmaceutical companies seeking to delay competition from generic drug equivalents. The financial cost to the American public of only four citizen petitions that were identified as having a high likelihood of being the sole, final cause of delay to market is \$1.9 billion or an average of \$3.6

43. See Edward R. Berchick, Emily Hood & Jessica C. Barnett, *Health Insurance Coverage in the United States*, U.S. CENSUS BUREAU 1–2 (2018), <https://www.census.gov/content/dam/Census/library/publications/2018/demo/p60-264.pdf>.

44. Feldman & Wang, *supra* note 11, at 1499–1501.

45. See Feldman et. al., *supra* note 4, at 64–70 (describing the methodology).

46. See CONG. BUDGET OFFICE, *supra* note 12, at 2.

47. *Id.*

48. See *supra* notes 39–43 and accompanying text (discussing the volume calculations used in this Article).

million *per day*. The cost to government-provided insurance programs in the two-year period is roughly \$782 million. These numbers are highly conservative and the actual cost to society is likely significantly higher. Moreover, these estimates do not account for the costs to public health and well-being due to the lack of low-cost drug options for patients who need medication. Based on this evidence, reforming the regulatory process to prevent exploitation of the citizen petitions will yield sizable savings and benefits to the American public and government-sponsored insurance companies.

EXHIBIT 1: COST TO SOCIETY OF DELAYING GENERICS DUE TO FOUR FRIVOLOUS CITIZEN PETITIONS

	Total Cost	Total Days	Cost per Day
Cost to Society, Overall	\$1.9 Billion	521	\$3.6 Million
Cost to Government Insurers Only	\$782 Million	521	\$1.5 Million

EXHIBIT 2: LENGTH OF DELAY IN GENERICS REACHING THE MARKET DUE
TO FOUR FRIVOLOUS CITIZEN PETITIONS

Branded Drug	Date Generic Drug filed to Enter Market	Date Branded Drug Filed Citizen Petition	Date FDA Denied Branded Drug's Citizen Petition	Date Generic Drug Application Approved by FDA	Total Days Citizen Petition Filing Delayed the Generic Drug
Plendil ^a	Jan. 2007	Nov. 30, 2007	Apr. 17, 2008	Apr. 17, 2008	139
Altace ^b	Apr. 2004	May 16, 2008	June 18, 2008	June 18, 2008	33
Seroquel ^c	Apr. 2004	Sept. 9, 2011	Mar. 7, 2012	Mar. 27, 2012	200
Zanaflex ^d	Mar. 2007	Sept. 7, 2011	Feb. 3, 2012	Feb. 3, 2012	149
				Total Days Delayed	521

^{a, b} Prescribed to treat blood pressure.

^c Prescribed to treat depression.

^d Prescribed to treat muscle spasms.