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Criticism Of FDA Citizen Petitions Is Often Misguided

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In the late 1970's, the U.S. Food and Drug Administration (FDA) established the citizen petition process to implement the First Amendment right to "petition government" in the context of FDA-regulated products and activities. The citizen petition process allows any interested person or organization to formally ask the FDA to take (or refrain from taking) regulatory action on virtually any topic. For nearly 40 years, citizen petitions have been used by a wide variety of stakeholders to initiate important public dialogues about health, safety and public policy.

In recent years, however, the citizen petition process has come under sustained attack by critics, particularly academic researchers, in a variety of press reports,[1] journal articles[2] and public testimony before the FDA[3] and Congress.[4] These critics primarily argue that citizen petitions inappropriately delay FDA approval of competing drug products. As proof, several academic researchers point to statistical analyses showing that (1) many petitions are filed several months before generic drug approval (timing ranges from six to 18 months), and (2) FDA grants only a fraction of petitions filed by pharmaceutical companies (estimates range from 20 percent to 8 percent).[5] From these statistics, the critics infer that many petitions are frivolous and filed simply as a last-ditch attempt to impede competition. The critics thus have called on policymakers to reform the petition process through regulatory or legislative changes.

The legal, regulatory and policy issues raised by citizen petitions are complex, implicating the public health, the First Amendment and free competition. Accordingly, it is vitally important that the information and evidence presented to policymakers is accurate, balanced and rigorous. Too often, policy discussions can be sidetracked by inaccurate or misleading information and research that initially garners widespread media attention but is later debunked.[6] Unfortunately, that seems to be happening in the citizen petition context as well, with critics mischaracterizing the relevant legal requirements, ignoring relevant data from the FDA and relying upon inaccurate or unsupported inferences based upon complex statistical analyses.

First, and most significantly, the critics fail to acknowledge that, as a legal matter, the filing of a citizen petition cannot delay the approval of a competing product. The law was amended in 2007 to prohibit the FDA from delaying approval of a pending abbreviated new drug application (ANDA) or 505(b)(2) application during its review of a citizen petition (the law recently was amended to afford this same protection to biosimilar applications).[7] The only exception is if the FDA determines that a delay "is

necessary to protect the public health."[8] Accordingly, except in very limited circumstances, the FDA's review of a citizen petition and its review of a generic drug application are required to be completely separate processes that proceed down separate tracks with distinct requirements and timelines.

Critics, however, either ignore or do not understand this critical aspect of the law. For example, some have argued that Congress should address alleged delays caused by petitions by creating a "parallel timing track for ANDA approval and citizen petition review."[9] But the law already does this and has done so since 2007.

Second, critics overlook or ignore the FDA's own data, which demonstrates that the 2007 changes to the law are working as intended and that the FDA almost never delays approval of an ANDA or 505(b)(2) application simply because of the filing of a citizen petition. According to the FDA's latest annual report on drug-related citizen petitions, of the 537 ANDAs and 505(b)(2) applications approved in fiscal year 2015, less than 1 percent were delayed because of a citizen petition (2/537).[10] This is consistent with other fiscal years going back to fiscal year 2008 (10/4008). Moreover, for the eight years spanning fiscal years 2008 through 2015, only 9 of the 175 drug-related petitions — 5 percent — resulted in the delay of a generic drug approval.

Although delays are rare, they do occur. Such delays, however, typically are short and, as required by the law, are justified by public health concerns. Under the 2007 law, the FDA can delay the approval of an ANDA or 505(b)(2) application because of a petition only if it determines that a delay is "necessary to protect the public health."[11] This exception recognizes that the FDA should not approve a competing drug if there are outstanding scientific or medical issues that implicate patient welfare and safety. Since fiscal year 2008, the FDA has delayed the approval of only 10 applications because of a petition, and in every instance, the agency determined that the delay was necessary to protect the public health. Accordingly, it appears that the system is working as intended and that the FDA is striking the proper balance between expediting approvals for competing drug products and protecting the public health.

Despite the above evidence, critics nevertheless contend that the petition process is subject to abuse because "FDA denies the requested action for approximately 80 percent of citizen petitions filed by competitors against drug companies."[12] But these statistics are presented out of context. In fact, the success rate of petitions filed by pharmaceutical companies is well in line with — and by some measures significantly higher than — the success rate for petitions filed by other stakeholders. For example, according to one recent study, only 12.7 percent of petitions filed by individuals or nonmanufacturer organizations (e.g., nonprofits, state governments) between 2001 and 2013 resulted in a favorable outcome.[13] This is significantly lower than the 20 percent success rate for pharmaceutical company petitions filed during a similar time period (2001-2010) and generally in line with success rates from more recent years (8 percent). The fact is that administrative agency inertia is strong, and the FDA rarely reverses course based on a citizen petition — any citizen petition. The FDA, however, appears to grant petitions filed by pharmaceutical companies more often than petitions filed by other entities.

Moreover, there are good reasons to believe that academic researchers are reporting denial rates for pharmaceutical company petitions that are artificially inflated. First, the critics often count "non-substantive denials" as true denials. In recent years, the FDA has adopted a practice of issuing nonsubstantive denials in which the agency "denies" the petition without indicating whether or not it agrees with the substance of the petition.[14] The agency typically does this when it is not ready to make a decision on a pending ANDA or 505(b)(2) application but the 150-day deadline for answering the petition is about to expire. A nonsubstantive denial is thus a way for the FDA to meet its statutory deadline without actually making a substantive decision. In essence, the FDA just kicks the can down the

road. In order to obtain a substantive decision, a company thus may need to resubmit its citizen petition, sometimes multiple times. By counting these nonsubstantive denials as true denials, however, the critics artificially inflate the rejection rate and artificially depress the success rate.

Critics also fail to recognize that the FDA is not always the last word on issues raised in citizen petitions. Citizen petitions serve the critical function of assuring the opportunity for meaningful judicial review of the FDA's policies and decisions. Consequently, citizen petitions often are filed by pharmaceutical companies to exhaust administrative remedies and to define and create an administrative record for purposes of judicial review. In many cases, the FDA's denial of a petition is reversed when reviewed by a federal court. For example, in 2016, a United States district court reversed the FDA's decision that a combination drug product was not eligible for new chemical entity (NCE) exclusivity.[15] Critics of the citizen petition process, however, never look beyond the FDA's decision to account for judicial reversal of the FDA decisions on petitions.

Finally, the various criticisms of the citizen petition process often overlook or downplay the importance of petitions to the drug approval process. Both branded and generic companies utilize citizen petitions to raise a wide variety of important medical, scientific and legal issues relating to the approval of new drug products through the NDA, ANDA and 505(b)(2) approval pathways. The issues raised in petitions by pharmaceutical companies often relate to significant public health and safety concerns, such as active ingredient sameness or bioequivalence requirements or application of the FDA's combination drug rule.

Moreover, the citizen petition process allows these important scientific, legal and public policy issues to be raised in a transparent public process. Indeed, the FDA interprets a citizen petition as the required pathway for bringing certain requests regarding abbreviated applications to the FDA.[16] Furthermore, the public nature of the citizen petition process affords all affected stakeholders, including the general public, an opportunity to provide input on issues raised in a petition. The transparent public nature of the citizen petition process thus contributes to both an informed agency and an informed and engaged public. Citizen petitions thus help the FDA achieve its mission of protecting and advancing the public health.

The citizen petition process is not perfect, and there may be ways to improve it. But any assessment of the need for improvement should be based upon a clear understanding of the law and how it has actually operated over the last several years. Too often, the criticisms currently being leveled against the petition process do not measure up.

DISCLOSURE: *The author of this article was actively involved in passage and implementation of section 505(q) of the Federal Food, Drug and Cosmetic Act discussed above.*

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[1] How Pharma Companies Use "Citizen Petitions" to Keep Drug Prices High, Sarah Zhang, The Atlantic Magazine (March 3, 2017), available at https://www.theatlantic.com/health/archive/2017/03/pharma-citizen-petitions-drug-prices/518544/.

[2] A Citizen's Pathway Gone Astray – Delaying Competition from Generic Drugs, Robin Feldman, J.D. and Connie Wang, New England Journal of Medicine (March 1, 2017), available at http://www.nejm.org/doi/full/10.1056/NEJMp1700202.

[3] Testimony of Prof. Michael A. Carrier, Rutgers Law School, at the FDA Public Meeting on Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access, Docket No. FDA-2017-N-3615 (July 18, 2017) available at https://www.fda.gov/downloads/Drugs/NewsEvents/UCM567752.pdf.

[4] Testimony of Prof. Aaron Kesselheim, M.D., M.P.H., Harvard Medical School, before the House Judiciary Committee (July 27, 2017), available at https://judiciary.house.gov/wp-content/uploads/2017/07/REVISED-Kesselheim-Testimony.pdf.

[5 A Citizen's Pathway Gone Astray – Delaying Competition from Generic Drugs, Robin Feldman, J.D. and Connie Wang, New England Journal of Medicine (March 1, 2017), available at http://www.nejm.org/doi/full/10.1056/NEJMp1700202.

[6] Lassman SM, Shopshear OM, Jazic I, et al. Clinical trial transparency: a reassessment of industry compliance with clinical trial registration and reporting requirements in the United States BMJ Open 2017;7:e015110. doi: 10.1136/bmjopen-2016-015110.

[7] 21 U.S.C. § 355(q)(1)(A).

[8] Id. § 355(q)(1)(A)(ii).

[9] Comments of Prof. Robin Feldman & Rabiah Oral, Docket No. FDA-2017-N-3615, pp. 6, 13 (Sept. 18, 2017).

[10] FDA's Eighth Annual Report to Congress on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2015 (July 29, 2016).

[11] 21 U.S.C. § 355(q)(1)(A)(ii).

[12] A Citizen's Pathway Gone Astray – Delaying Competition from Generic Drugs, Robin Feldman, J.D. and Connie Wang, New England Journal of Medicine (March 1, 2017), available at http://www.nejm.org/doi/full/10.1056/NEJMp1700202. A more recent analysis contends that FDA denies 92 percent of such petitions. Citizen Petitions: Long, Late-Filed, and At-Last Denied, Carrier M and Minnitti C, 66 American Univ. Law Review 305 (2016).

[13] Petitioning the FDA to Improve Pharmaceutical, Device and Public Health Safety by Ordinary Citizens: A Descriptive Analysis, Chen B., Yang, T. et al., PLOS One (May 12, 2016) available at http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0155259.

[14] FDA, Guidance for Industry: Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act, p. 14 (Nov. 2014) ("we do not interpret section 505(q) to require a substantive final Agency decision ...").

[15] Ferring Pharmaceuticals Inc. v. Burwell, Civ. Action No. 15-0802 (RC) (Sept. 9, 2016).

[16] 21 U.S.C. § 355(q)(1)(A).