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Food and Drug Law, Regulation and Education



2016 ANNUAL CONFERENCE RECAP





The Citizen Petition Process: An Engine for Democracy and Debate

by G. Gregg Webb

FDA Commissioner Dr. Robert M. Califf opened the 2016 FDLI Annual Conference with a rousing keynote address, reviewing FDA's many accomplishments over the past year and detailing his ambitious and innovative agenda for the agency in the months and years ahead. Dr. Califf also reminded the record number of assembled stakeholders of the important opportunity presented by the Annual Conference itself, observing "there are few events that encompass such a longstanding tradition and offer as important and meaningful an opportunity to talk about FDA policy as the annual meeting of the Food and Drug Law Institute."



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No component of the Conference more fully embodied Dr. Califf's observation than the main-stage panel devoted to FDA's citizen petition process. This article summarizes the issues and discourse arising from that panel, which led to one of the most spirited question-and-answer sessions of any panel during the Conference. Entitled "Ploy or Policy Tool: A Look at the Citizen Petition Process," the session featured a mix of in-house and outside counsel with diverse citizen petition experience, including moderator Chad Landmon, Axinn, Veltrop & Harkrider, and panelists Marc Scheineson, Alston & Bird LLP; Mitch Neuhauser, VP and Assistant General Counsel-Regulatory, RAI Services Company; and Justin Mervis, VP and General Counsel, KIND LLC.

Panel themes encompassed: (1) origins of the modern citizen petition process; (2) its pros and cons; (3) best practices for preparing and submitting petitions; (4) case studies of recent petitions; and (5) the significant controversy that certain petitions have created, particularly in the drug approval context.

First Principles

The citizen petition process arises from the founding principles of American government. Mr. Landmon and Mr. Scheineson explained the birth of the modern citizen petition. Emanating from the First Amendment right to petition the government, in 1975 Congress introduced the citizen petition through the Administrative Procedures Act, requiring that government agencies provide a direct avenue for individuals, companies, and other stakeholders to be heard by the agencies.¹ In 1979, FDA published its “citizen petition rule,” which through multiple subsequent amendments, continues to offer stakeholders a means for asking the agency “to issue, amend or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.”²

Whether viewed as a “tool,” a “ploy,” or both, the FDA citizen petition embodies a fundamentally democratic notion. As Dr. Califf observed in his keynote remarks, FDA oversees a regulatory landscape involving, by some counts, 20 cents of every consumer dollar, in addition to its core responsibility for the health and safety of every American. FDA’s regulatory mandate is vast. But resting at the heart of the citizen petition process is the principle that no government agency is too large, and no stakeholder is too small, nor too isolated or unpopular, to be heard by its government, even by an agency as large and as busy as FDA.

A Tool for Democracy

Citizen petitions are one tool for interacting with FDA and can be a valuable one. Mr. Scheineson outlined for attendees some of the potential advantages, including: (1) an established process for getting the agency’s attention, especially where a party seeks to advocate policy or regulatory change; (2) a forum for reaching

an even broader audience, including interested parties and the public, due to the public nature of the petition process; (3) the ability to integrate a petition into a larger regulatory and legislative agenda for securing government action, including providing possible leverage in negotiations with FDA; and (4) when agency administrative processes fail, offering the “keys to the courthouse,” since FDA rejection of a citizen petition is considered final agency action permitting judicial review.

But citizen petitions are no magic wand. As a practical matter, panelists observed that petitions often have “few teeth” and are frequently denied by the agency. Petitions create additional work for FDA staff and decision-makers that may sour relations with the agency.

The public nature of the process, while one of its potential strengths, also may invite negative reactions from a party’s opponents, including sparking comments that undermine or at least distract from a party’s objectives. Other dispute resolution mechanisms may be faster or more suited for particular issues, such as personal meetings with agency reviewers, formal dispute resolution procedures, and even congressional intervention.

Honing the Tool

In addition to addressing the pros and cons of citizen petitions, both panelists and audience members offered practical tips for increasing the likelihood of receiving a (reasonably) prompt and favorable response from FDA to a citizen petition. Mr. Scheineson

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FDA Chief Counsel Elizabeth H. Dickinson — Keynote Address

noted the critical importance of submitting well-reasoned, well-researched, well-written, and well-documented petitions and emphasized the value of interacting with the agency on multiple levels, including by emailing copies and summaries of petitions to FDA decision-makers and requesting meetings to discuss the contents.

A member of the audience identifying himself as a part of FDA's citizen petition intake staff offered illuminating comments about FDA's formal intake process, including the agency's recent efforts to improve its intake procedures. He explained that staff members endeavor to complete the intake process within three hours of receiving a citizen petition (though noting that intake may take up to three days). Echoing the panelists, the staff member encouraged petitioners concerned with delays in the review process to contact the agency, since many delays may be procedural in

nature and capable of resolution through clear communication.

The Tool in Action

Because the citizen petition is such a flexible instrument, those who actually have used the process can provide a crucial perspective for understanding it. Mitch Neuhauser, RAI Services Company, and Justin Mervis, KIND LLC, each offered their accounts of navigating the process in recent years on behalf of their respective companies.

Mr. Neuhauser described his company's "journey" in seeking different warning language for smokeless tobacco, an effort that took nearly four years from filing of the original petition to receiving a final response from FDA. For Mr. Neuhauser, the citizen petition represented an avenue for bringing to FDA's attention a body of scientific literature showing that smokeless tobacco presents diminished and different risks than cigarettes. The company filed a petition

to initiate rule-making for new warning language. FDA opened a docket and solicited public comments, the company responded through a supplemental filing, and in May 2015, FDA issued its response to the citizen petition, concluding that no changes to the smokeless tobacco warning would be proposed at that time. While the result was not what the company sought, Mr. Neuhauser emphasized the value of the citizen petition process as a means to bring attention to important issues and to obtain FDA's point of view. He also noted that petitioners and other interested parties should be prepared for a lengthy deliberative process and should not expect an immediate substantive response from the agency.

Offering a different case study on the real-world potential for citizen petitions was Mr. Mervis of KIND LLC. In March 2015, his company received a Warning Letter from FDA contending that its "Fruit and Nut" line of nutrition bars,

among others, made improper claims involving the term “healthy” and other nutrient content based on the level of fat present in nut ingredients used in the bars. The Warning Letter led to the near-immediate filing of numerous private class actions across the country, ultimately centralized in multidistrict litigation in federal court. Facing both FDA and private legal challenges, Mr. Mervis guided the audience through KIND’s decision to submit a citizen petition asking FDA to update its rules for the use of “healthy” on product labeling, which rules, Mr. Mervis described, rely on thresholds for fat content without accounting for nutrient-rich foods, such as nuts, salmon, and avocados, whose health benefits are widely recognized in modern science and culture.

Mr. Mervis highlighted several aspects of the citizen petition process that he found particularly compelling, including that it provided a means for his young company to request changes to long-standing agency rules and provided a forum in which the company could pursue agency action in its own best interests, while also acting in what it perceived as a larger public interest. Since the Conference, in a public statement issued May 10, 2016, FDA has announced its intention “to reevaluate regulations concerning nutrient content claims, generally, including the term ‘healthy.’” In its statement, FDA pointed to the submission of a citizen petition, along with “evolving nutrition research” and the new final rules on Nutrition Facts Labeling, as grounds for the reevaluation. The agency also stated its intent to solicit public comments.

Both case studies emphasized the value of the citizen petition process when used for legitimate purposes to focus FDA’s attention on significant regulatory issues that it otherwise might not have addressed or that might have been

addressed without an equivalent level of public transparency and awareness.

A Ploy?

The citizen petition process is not without controversy. Much of the public attention directed towards citizen petitions over the past decade and more has centered on alleged abuses by brand-name drug manufacturers filing citizen petitions challenging generic drug applications. Such petitions may lead to delays in Abbreviated New Drug Application (ANDA) approvals, slowing the entry of generic competitors into the marketplace and burdening FDA with responding to citizen petitions that critics claim are unfounded. Commentators cite statistics reflecting that over two-thirds (68%) of citizen petitions filed from 2001 to 2010

were filed by brand manufacturers, and 78% of those brand petitions targeted generic drugs, as evidence of large portions of the citizen petition pipeline being misappropriated for improper purposes.³

Panelists discussed this controversy, describing key measures taken by Congress and FDA to address alleged abuses and the effectiveness of those measures. One such measure was adopted in the Food and Drug Administration Amendments Act (FDAAA), enacted in September 2007, which added Section 505(q) to the Food Drug and Cosmetic Act. Section 505(q) applied specifically to citizen petitions involving pending ANDAs and 505(b)(2) applications. The measure was intended to reduce the backlog of petitions under review and minimize delays in the approval process. In essence, as

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Mr. Landmon explained, Section 505(q) instructed the agency not to slow down the approval process even in the face of a pending citizen petition, except when “necessary to protect the public health.”⁴ Section 505(q) required the agency to respond to certain citizen petitions within 180 days and required petitioners to certify when they first learned of the information underlying their petitions, disclose information known to be unfavorable to the petition, and identify parties funding such citizen petitions, among other measures designed to deter abuse.⁵ In addition, if FDA determined that a citizen petition had a “primary purpose” of delaying a pending application and otherwise lacked merit, then it could deny the petition immediately.⁶

In September 2012, Section 1135 of the Food and Drug Administration Safety

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and Innovation Act (FDASIA), a further measure aimed at controlling citizen petitions in the drug context, went into effect. The provision amended Section 505(q) to (1) shorten the time in which FDA had to respond to citizen petitions subject to 505(q) from 180 days to 150 days; and (2) expand the scope of section 505(q) to include certain petitions related to biosimilar applications.⁷ FDA issued a revised final guidance document interpreting 505(q) in November 2014.⁸

The results of this regulatory

tightening have been mixed. Mr. Landmon noted that the number of citizen petitions subject to Section 505(q) has remained steady since 2007, meaning the measure has not reduced the volume of petitions as hoped, and he cited FDA’s acknowledgement that the additional obligations imposed by Section 505(q) have required the agency to redirect limited resources from other initiatives to focus on meeting these statutory requirements. Citing FDA’s most recent Report to Congress, covering Fiscal Year 2014, Mr. Scheineson noted that the agency had handled 28 petitions subject to Section 505(q), no ANDAs were delayed, and only one 505(b)(2) application was delayed due to a Section 505(q) petition, and then only for five days.⁹

In that same Report, the agency surveyed its own handling of petitions subject to Section 505(q) following enactment of FDAAA in 2007—from FY2008 to FY 2014—noting that of the 160 such petitions it had received, the agency responded to all but nine within the 150- or 180-day period. The agency expressed concern, however, that Section 505(q) “is not discouraging the submission of petitions that are intended to delay the approval of competing drug products and do not raise valid scientific issues,” and FDA emphasized that Section 505(q) was forcing it to prioritize petition review over other critical public health responsibilities.¹⁰



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A Hope

Befitting its democratic origins, the fate

of the citizen petition process in coming years will rest with those who use and guide it. In his keynote remarks, Dr. Califf identified his “top programmatic priority” at FDA as “developing a system for evidence generation” that leverages technological advancements in the collection and analysis of data with developments in research methods to generate “[h]igh quality scientific evidence” to guide “optimal decisions about health and health care by patients, healthcare providers, and the public.” The citizen petition process should stand as a valuable—if perhaps unconventional—component of Dr. Califf’s evidence-based vision for FDA’s regulatory future. When used properly, the citizen petition represents a pragmatic tool for facilitating public access to FDA, elevating issues *and evidence* of concern to agency

decision-makers, and promoting dialogue among stakeholders across nearly every area of the regulatory landscape.

But, as with any genuinely democratic device, the citizen petition process only works when participants use it for appropriate ends and with a larger public interest in mind, even when seeking purely private objectives. Citizen petitions can divert regulatory focus and deplete FDA’s precious resources, especially if misused. Ultimately, the success of this tool rests with the same community of stakeholders that made the citizen petition panel at this year’s Annual Conference so worthwhile and memorable. ▲

1. 5 U.S.C. § 553(e).
2. 21 C.F.R. 10.25(a) and 10.30.
3. Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 249, 271 (2012).
4. 21 U.S.C. 355(q) (commonly known as

- “Section § 505(q)”).
5. *Id.*; 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* (June 2011) (final guidance document covering implementation of Section 505(q)).
6. Section 505(q)(1)(E).
7. See 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* (Nov. 2014) (revised final guidance document incorporating FDASIA amendments).
8. *Id.*
9. See 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* (Aug. 3, 2015) at 1, 5. FDA’s Report jointly counted citizen petitions pursuant to 21 C.F.R. 10.30 and petitions for stay of agency action pursuant to 21 C.F.R. 10.35. *Id.* at 3.
10. *Id.* at 10.

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