market-based price. It would also streamline the process by which generic applicants can receive a waiver from the single-shared REMS process if they are able to demonstrate that negotiations were not successful after 120 days.

Another bill, introduced in the Senate during the summer of 2016, also focused on the same two main forms of REMS abuse.[68] It differed from the House bill, however, in that it created a designated cause of action for litigation to be brought against offending pharmaceutical companies, as well as mandating the sale of samples and instituting a specific REMS waiver program.[69] The Senate bill adopts the approach of assigning different roles to different branches. The FDA remains responsible for evaluating safety, both the REMS plan itself and the ability of the generic to handle the drug appropriately; the courts are responsible for resolving disputes among the parties. Although the process adds complication, it echoes the assignment of roles that exists throughout the Hatch-Waxman regime.

B DELAY VIA CITIZEN PETITION

Citizen petitions offer one of the most ubiquitous ways to create obstacles to generic entry. Such petitions connect to delay tactics ranging from product hopping to REMS abuse. Since the 1970s, the FDA has allowed the public to request that the agency "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action."[70] Although the program applies to all products under the FDA's jurisdiction, the majority of citizen petitions are related to pharmaceuticals, rather than food, cosmetics, or medical devices.[71]

What was likely meant to be a mechanism for concerned citizens and scientists to raise questions about drugs, food, and FDA regulations, however, has turned into a playground for pharmaceutical companies to challenge drug applications, especially those related to generics.

Some of these petitions are relatively benign. A number ask the FDA to allow a generic to reference a drug that is no longer on the market or to allow approval of a generic that differs slightly[72] from the brand-name drug in terms of characteristics such as strength or dosage form.[73]

[68] *See* CREATES Act, S. 3056, 114th Cong. (2016).

[69] For commentary on the Senate bill by one of the authors, *see CREATES Act: Ending Regulatory Abuse, Protecting Consumers and Ensuring Drug Price Competition: Hearing before S. Comm. on the Judiciary Subcomm. on Antitrust, Competition Policy, and Consumer Rights*, 114th Cong. (2016).

[70] 21 C.F.R. § 10.30 (1979).

[71] Hyman, Phelps & McNamara PC, *FDA Citizen Petition Tracker*, FDA L. Blog (last visited Sept. 5, 2016), www.fdalawblog.net/fda_law_blog_hyman_phelps/files/CPTracker.xls.

[72] These are known as "ANDA suitability petitions." Kurt R. Karst, *FDA Rejects Requests to Initiate Rulemaking for (505)(b)(2) NDA Therapeutic Equivalence Rating Decisions*, FDA L. Blog (July 28, 2014), www.fdalawblog.net/fda_law_blog_hyman_phelps/2014/07/fda-rejects-requests-to-initiate-rulemaking-for-505b2-nda-therapeutic-equivalence-rating-decisions.html.

[73] *See ibid.*