administration, nevertheless, made its opprobrium clear by referring the company's conduct to the Federal Trade Commission for review.[98]

Despite the FDA's complete rebuttal of all of the brand-name company's claims, the citizen petition resulted in five months of delay in the time it took for the petition to be denied. Given sales of approximately $1.5 billion in 2012, the five months of delay was possibly worth more than $600 million in unchallenged sales to the brand-name company.[99] That is a remarkably strong incentive for companies to engage in this type of tactic. As always, the consumer pays the cost in the form of higher health insurance premiums, taxes (to compensate for soaring Medicare costs), and prices.

The FDA and the Federal Trade Commission have long recognized that the citizen petition process could be subject to abuse, expressing concerns and proposing modifications as early as 1999.[100] Congress attempted to curb such abuse by enacting a new section of FDA regulation in 2007, frequently known as "Section 505(q)." Section 505(q) states that when a citizen petition could delay generic approval, giving it a special designation as a 505(q) petition, the FDA must take final action on the petition within 180 days, unless the delay is necessary to protect the public health.[101] The Food and Drug Administration Safety and Innovation Act ("FDASIA"), passed in 2012, further shortened the approval period to 150 days.[102] To discourage baseless or strategically timed petitions even more, petition filers must also make a certification and verification that the petition is not frivolous, acknowledging that all information favorable and unfavorable has been provided and that the petition was

[98] FDA Response to Reckitt Benckiser, *supra* note 96, at 16. FTC proceedings were initiated against Reckitt Benckiser. *See FTC v. Reckitt Benckiser Pharm., Inc.* No. 14-MC-005, 2014 WL 4792175 (E.D. Va. Sept. 24, 2014) (court proceedings over release of documents for the FTC's investigation).

[99] *Suboxone Sales Data*, Drugs.com (Feb. 2014), www.drugs.com/stats/suboxone. As with all calculations of the value of delay in this book, the assumption is made for the sake of ease that, without the delay, generic competition would immediately drop Reckitt's revenues on Suboxone to zero.

[100] *See* Darren S. Tucker, *FDA Citizen Petition: A New Means of Delaying Generic Entry?* 20 Antitrust Health Care Chron. 10, 11 (2006); Citizen Petitions; Actions That Can be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action, 64 Fed. Reg. 66822-01 (proposed Nov. 30, 1999) (to be codified at 21 C.F.R. pt. 10) (withdrawn); *Comment Letter on Citizen Petition; Actions That Can be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action* Fed. Trade Comm'n (Mar. 2, 2000), www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-food-and-drug-administration-concerning-citizen-petitions/v000005 .pdf.

[101] Codified at 21 U.S.C. § 355(q) (2012), *amended by* Improving Regulatory Transparency for New Medical Therapies Act, Pub. L. No. 114–89, 129 Stat. 698 (2015); 21 U.S.C. § 355(q)(1)(A)(ii) (2012) (establishing the public health exception); *see also* Kurt R. Karst, *The Coming 505(q) Citizen Petition Cliff and Some Interesting Petition Strategies*, FDA L. Blog (Sept. 4, 2012), www.fdalawblog.net/fda_law_blog_hyman_phelps/2012/09/the-coming-505q-citizen-petition-cliff-and-some-interesting-petition-strategies.html (presenting more details about the 2007 and FDASIA changes).

[102] 21 U.S.C. § 355(q)(2)(A) (2012) (establishing the 150-day deadline for agency action).