

if actually having the petition accepted is unlikely.⁴ Although the most current legislation requires that citizen petitions with the potential to affect generic approval must be considered within 150 days,⁵ those approximately five months of delay could be worth hundreds of millions of dollars in additional monopoly revenues as the generic sits on the sideline waiting for approval.⁶ It is not billions, but it will do. In short, the new strategies might impact a shorter term with lower rewards, but their minimal cost makes them worth a try when the potential rewards are substantial.⁷

In addition, some of these strategies could conceivably approach the high-flying numbers of pay-for-delay settlements. Take the example of the events that led to *In re Flonase Antitrust Litigation*.⁸ At its peak, Flonase, an extremely popular steroid nasal spray for allergy treatment, reached \$1.3 billion a year in sales.⁹ Through a complicated series of citizen petitions to the FDA, GlaxoSmithKline was able to stave off generic entry for 23 months.¹⁰ Thus, the delay achieved through citizen petitions was worth approximately \$2.5 billion, assuming it maintained the peak \$1.3 billion in sales per year until generic entry occurred. In two class action lawsuits that were later filed against Glaxo, the company settled for a total of \$185 million.¹¹

⁴ See Darren S. Tucker, *FDA Citizen Petition: A New Means of Delaying Generic Entry?* 20 ANTITRUST HEALTH CARE CHRON. 10, 11 (2006) (citing Comment of the Staff of the Bureau of Competition & the Office of Policy Planning of the Fed. Trade Comm’n before the Food & Drug Admin. In the Matter of Citizen Petitions; Actions That Can Be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action, FDA Docket No. 99N-2497, at *4, 6–7 (Mar. 2, 2000), www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-food-and-drug-administration-concerning-citizen-petitions/v000005.pdf).

⁵ 21 U.S.C. §355(q)(1)(F); Food and Drug Administration Safety and Innovation Act, Pub. L. 112–44, 126 Stat. 993 (2012); see also U.S. Food & Drug Admin., GUIDANCE FOR INDUSTRY: CITIZEN PETITIONS AND PETITIONS FOR STAY OF ACTION SUBJECT TO SECTION 505(Q) OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT 3 (Nov. 2014), www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm079353.pdf (discussing Section 505(q)(1)(F)).

⁶ This calculation assumes the same \$1 billion in annual sales for a top 100 drug used previously in the chapter.

⁷ Granted, the cost of these strategies could climb much higher as companies begin to face antitrust litigation for their actions and must expend millions on legal fees after the fact. Until these cases are regularly ending in settlements worth billions to the plaintiffs, however, these “games” are still valuable for brand-name drug companies.

⁸ *In re Flonase Antitrust Litig.*, 951 F. Supp. 2d 739 (E.D. Pa. 2013) (approving direct purchaser settlement); *In re Flonase Antitrust Litig.*, 291 F.R.D. 93 (E.D. Pa. 2013) (approving indirect purchaser settlement).

⁹ Tracy Staton, *GSK Reaches \$150M Deal in Flonase Antitrust Case*, FIERCEPHARMA (Dec. 20, 2012), www.fercepharma.com/story/gsk-reaches-150m-deal-flonase-antitrust-case/2012-12-20.

¹⁰ See Seth C. Silber, Jonathan Lutinski, & Rachel Taylon, *Abuse of the FDA Citizen Petition Process: Ripe for Antitrust Challenge?* ANTITRUST HEALTH CARE CHRON., Jan. 2012, at 26, 33–35, www.wsgl.com/PDF/Search/silber0112.pdf (describing the delay mechanisms used by GSK).

¹¹ Carolina Bolado, *Judge Approves \$150M Flonase Antitrust Accord*, LAW360 (June 14, 2013, 6:57 PM), www.law360.com/articles/450443/judge-approves-150m-flonase-antitrust-accord; Jonathan Randles, *Judge Gives Final OK to \$35M GSK Flonase Settlement*, LAW360 (June 19, 2013, 5:00 PM), www.law360.com/articles/451604/judge-gives-final-ok-to-35m-gsk-flonase-settlement.