

months right before generic approval, and the claims are eventually denied by the FDA. That bitter Seville orange juice *does* increase absorption and peak drug concentration, after all. The bigger question: does it really matter? The FDA rarely thinks so. Papers by Michael Carrier, Daryl Wander, and Carl Minniti found that the FDA denied 81 percent of generic-related petitions between 2001 and 2010, and 92 percent of petitions between 2011 and 2015, with denial rates as high as 92 percent in 2005, 96 percent in 2012, and even 100 percent in 2015.⁸³ It is hard to argue that these pharma-authored petitions are vocalizing legitimate concerns when the denial rate is so high. In many cases, the ulterior motives are just too hard to ignore.

Citizen petitions have played a prominent role in other obstruction strategies as well. Chapter 3 described a clause in which Endo Pharmaceuticals agreed to pay a company only if sales of Endo’s drug Opana ER dropped below a certain level, a threshold that would only be met if the market for the drug significantly lessened – through a product hop, for instance. It turns out that Endo’s product hop involved a switch from “Opana ER” to “Opana ER CRF,” a crush-resistant form of the drug. As an opioid painkiller, Opana had been abused by people snorting the drug – the crush-resistant form was meant to solve this problem. Unfortunately, this change merely led abusers to begin injecting the drug instead, leading to a severe HIV outbreak covered on NPR’s *All Things Considered*.⁸⁴

The switch, however, may have had benefits for the company and raises suspicion in a number of ways. In particular, the switch to a new formulation occurred right as Endo was nearing generic competition, and the company completely removed the old, non-crush-resistant version from the market as soon as it received approval for the new version. The company then filed a citizen petition asking the FDA to deny any non-crush-resistant generic forms of Opana ER, also asking it to certify that Opana ER was withdrawn from the market for safety reasons to block future generic certifications.⁸⁵ Then, worried about impending generic entry (while also advancing a safety-related argument), it *sued* the FDA to speed up review of

⁸³ Carrier & Wander, *supra* note 74, at 274 (2012) (examining petitions filed between 2001 and 2010); Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U. L. REV. 305, 333 (2016) <http://ssrn.com/abstract=2832319> (examining petitions filed between 2011 and 2015). “Generic-related petitions” excludes “suitability petitions” filed by generics in the 2001–2010 paper, and it also excludes any petition not designated by the FDA as a “505(q)” petition in the 2011–2015 period.

⁸⁴ Tom Dreisbach, *How a Painkiller Designed to Deter Abuse Helped Spark an HIV Outbreak*, NPR: ALL THINGS CONSIDERED (Apr. 1, 2016), www.npr.org/sections/health-shots/2016/04/01/472538272/how-a-painkiller-designed-to-deter-abuse-helped-spark-an-hiv-outbreak.

⁸⁵ Citizen Petition from Endo Pharm., Inc., to Div. of Dockets Mgmt., U.S. Food and Drug Admin., No. FDA-2012-P-0895 (Aug. 10, 2012), www.regulations.gov/document?D=FDA-2012-P-0895-0001.