

not intentionally delayed, while also providing the date when the filer first became aware of the concern and the names of those funding the petition.¹⁰³

Finally, the FDA also was granted the power to deny a petition at any time if it believes a petition was “submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues.”¹⁰⁴

In the case of *Suboxone*, however, the regulatory process worked entirely as intended, and the brand-name company’s petition was denied exactly 150 days after the date it was filed. Nevertheless, the petition resulted in five months of delay and an estimated \$600 million of higher priced sales for the company.¹⁰⁵ Thus, even when the bell rings on time as Congress intended, brand-name companies still can use the process to engage in costly delays.

Moreover, the various amendments do not seem to have discouraged the filing of nonmeritorious citizen petitions that request the delay of a generic. Between fiscal years 2008 and 2014 – the period during which the amendments have been in place and for which data are available – 149 delay petitions were filed and *only* 8 were fully granted.¹⁰⁶ Thirty-nine of these petitions were granted in part. However, as Carrier and Wander note, these “mixed decisions” are often a formality and not truly a partial finding in favor of the petitioner, with the stunning “orange juice” petition we found serving as an illuminating example.¹⁰⁷ The requests “granted in part” are often trivial requests for bioequivalence studies that either have already been completed, are in progress, or would certainly be required by the FDA even in the absence of the citizen petition. It is like asking a teacher to assign homework – when the homework is listed on the board – yet the teacher is forced to spend months reaching a conclusion, and, in the meantime, everyone but the teacher’s pet is indefinitely banished to detention.

The number of citizen petitions requesting delay also has not declined since passage of the 505(q) amendments.¹⁰⁸ As we will discuss further in [Chapter 5](#), we have undertaken our own extensive empirical study of the timing of citizen petitions. In simply collecting petitions for our database, a clear trend emerged – the number

¹⁰³ 21 U.S.C. § 355(q)(1)(H)-(I) (2012).

¹⁰⁴ 21 U.S.C. § 355(q)(1)(E) (2012).

¹⁰⁵ See *Suboxone Sales Data*, *supra* note 99 (listing Suboxone sales as \$1.5 billion in 2012, or \$600 million over five months).

¹⁰⁶ U.S. FOOD & DRUG ADMIN., SIXTH ANNUAL REPORT TO CONGRESS ON DELAYS IN APPROVALS OF APPLICATIONS RELATED TO CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION FOR FISCAL YEAR 2013, at 6–7 (2014) [hereinafter FDA SIXTH ANNUAL REPORT FOR FY 2013], www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ReportsBudgets/UCM423291.pdf. Carrier & Wander, *supra* note 74, at 266–68.

¹⁰⁷ Carrier & Wander, *supra* note 74, at 266–68.

¹⁰⁸ FDA SIXTH ANNUAL REPORT FOR FY 2013, *supra* note 106, at 5; see generally Carrier & Wander, *supra* note 74.