entry of generic competition, now that the pay-for-delay route appears less and less promising. And, as described in Chapter 4, the delay achieved through a citizen petition, even if the petition is ultimately unsuccessful, can be worth hundreds of millions of dollars in revenue for a drug company.

A METHODOLOGY

1 *Overview*

As described previously, anecdotal evidence has emerged over the years suggesting that drug companies are abusing the citizen petition process as a delay tactic to keep generics off the market.[3] We set out to take a quantitative look.

To approach the question, we analyzed the timing of when citizen petitions are filed during the generic drug approval process and the frequency with which certain petitions – those that have the potential to delay – are filed. We hypothesized that such petitions would be filed toward the end of the approval process to put up one more roadblock in the path of successful approval of a generic drug.

Assembling the information from the FDA's publicly available materials is tremendously difficult. Although the FDA publishes a large amount of information on its public website, and more in hard copy, much important information is missing. The necessary information often must be pieced together or estimated; in some cases, it simply cannot be located.

Some of these gaps are downright puzzling. For example, the FDA does not always publicly reveal the date on which a generic application was filed. We tracked down many of those dates by reading through PDFs of thousands of letters in the files, looking for places in which the dates were mentioned in passing. For many others, however, we had to develop a method of identifying the likely quarter in which an application was filed by working backwards from the FDA's complicated file numbering systems. It just should not be that hard for the public to get basic information.

The FDA files also do not always link to or indicate which specific generic application a citizen petition relates to, information that is important for tracking the timing of citizen petitions in relation to the application process for a particular drug.

[3] *See, e.g.*, Ameet Sarpatwari, Jerry Avorn, & Aaron S. Kesselheim, *Using a Drug-Safety Tool to Prevent Competition*, 370 NEW ENG. J. OF MED. 1476, 1476-77 (2014) (discussing, as an aside, a citizen petition from Celgene Corporation to the FDA 17-18 (September 20, 2007)), www.regulations.gov/document?D=FDA-2007-P-0113-0002). Most important, Carrier and Wander, who documented a rise in citizen petitions in general, suggested that the rise might be a sign of delay behavior. *See* Carrier & Wander, *Citizen Petitions*, *supra* note 2, at 269-270, 283-286 (documenting empirically a rise in citizen petitions and detailing two anecdotal examples of petitions that resulted in delay, one related to the depression drug Wellbutrin and one related to the insomnia drug Ambien).