

- The number of quarters between when the generic application was filed and when the citizen petition was filed (“Quarters Since Generic Filing”);
- The number of months between when the citizen petition was filed and the eventual approval of the relevant generic drug (“Months Before Approval”);
- The total time it took for the generic drug to gain approval, from start to finish (its “Total Approval Time”).¹⁹

We used quarter-years as the standard measurement basis for “Quarters Since Generic Filing” and “Total Approval Time,” because those metrics required generic filing dates, many of which had to be estimated. For estimating generic filing dates, a year was not specific enough to tease out useful insights, and we did not have enough information to measure time in monthly increments. Meanwhile, we were able to use months rather than quarters for the “Months Before Approval” metric because, unlike with generic filing information, exact dates to the specificity of month and day were available for both citizen petition filing and generic approval.

Examining these core metrics will reveal trends of how citizen petitions interact with the generic approval process.

B RESULTS

As described in the opening section, the results of the study provide empirical evidence that the citizen petition process at the FDA has become a key avenue for strategic behavior by pharmaceutical companies to delay entry of generic competition. The following sections describe the core results.²⁰

1 *Rise in Citizen Petitions with the Potential to Delay*

First, as [Table 5.1](#) demonstrates below, it is notable just how many citizen petitions seem to have the potential to delay generic entry. Looking at the overall number of citizen petitions filed at the FDA on any topic, fourteen percent have the potential to delay a generic drug application, climbing to roughly twenty percent in some years. That means one in five of *all* citizen petitions to the FDA – not just those

¹⁹ As an example, Petition FDA-2007-P-0418 was filed on November 9, 2007, the fourth quarter of 2007. We estimated that its relevant generic application, ANDA No. 78441, was filed in the third quarter of 2006. It was approved on May 14, 2009, the second quarter of 2009. Between the third quarter of 2006 (generic application filing) and the fourth quarter of 2007 (citizen petition filing), five quarter-years had passed, so the value of “Quarters Since Generic Filing” for this citizen petition is “5.” Eighteen months and five days passed between November 9, 2007 (citizen petition filing) and May 14, 2009 (generic approval), so “Months Before Approval” for this petition is “18.” Its “Total Approval Time,” from the third quarter of 2006 to the second quarter of 2009, is eleven quarter-years.

²⁰ For a full reporting of the results, see Feldman, Frondorf, Cordova, & Wang, *supra* note 4.