the 2007 Amendments. As long as the benefits of 180 days of delay (or even 150 days of delay) can be worth hundreds of millions of dollars, companies will be tempted to follow this path, and consumers will continue to pay the price. A different approach is needed.

C THE ROAD AHEAD

As the results demonstrate, the citizen petition process has been hijacked by pharmaceutical companies as a route to frustrate generic approvals. We found evidence that many citizen petitions are not filed as soon as potentially worrisome information about a drug is discovered, but are instead filed near the later stages of the generic approval process. Nearly half of potentially delay-related citizen petitions between 2000 and 2012 were filed within a year and a half of approval, with numbers even higher when the data are restricted to the period after the 2007 Amendments. In fact, 46 percent of the post-2007 Amendment citizen petitions were filed within a year of final approval of the generic drug, and 24 percent were filed within six months. These findings suggest that the citizen petitions were some of the last barriers to approval for some generics.

Also troubling is that citizen petitions appear to be a significant catalyst and foundation for attempting a variety of other obstructionist delay strategies. Many of the delay tactics outlined in Chapter 4 operate through the citizen petition process. Thus, citizen petitions are now a key portal through which pharmaceutical companies attempt to make changes and raise concerns (often spurious ones) to obstruct or delay generic approval. At the moment, the FDA appears powerless to stop it, but what pathways would be more effective?

Looking at the nature of the problem, one could imagine three types of approaches to curb the behavior of filing citizen petitions to delay generic entry. These might include (1) a simple prohibition on competitors filing citizen petitions related to generic entry, if one were to conclude that most behavior represented by this type of petition is likely to be inappropriate; (2) procedural blocks to ensure that the behavior cannot create suboptimal results; or (3) punitive measures as a deterrent. The following sections describe each and set out mechanisms for accomplishing the goals. The details of the mechanism are less important, however, than choosing among the pathways and identifying the proper incentive structures and the optimal institutional actors.

1 *A Simple Prohibition*

The simplest approach for curbing abuse of the citizen petition process would be to prevent competitors from filing citizen petitions related to generic applications.