

samples for generic approval may be the rare exception to the rule, getting past *Trinko* would be difficult.

In short, Congress or the Supreme Court would have to be willing to alter anti-trust doctrines in a manner sufficient to allow antitrust actors to bring successful litigation – without, of course, breaking the bank in the process. A punitive measure that costs exorbitant amounts to activate will have very little deterrent effect.

4 Transparency

No approach is a perfect or permanent solution. Fixing abuse of the citizen petition pathway may require a combination of these approaches. Moreover, this book shows that when the legal system closes off one pathway, pharmaceutical companies will search for others. Thus, whatever paths and approaches are chosen to curb citizen petition abuse, it will be critical to ensure that regulators, legislators, and courts can see new techniques as they emerge. A little sunshine goes a long way.

In particular, greater transparency from the FDA could be tremendously effective in exposing new drug pricing schemes early on. Although the FDA makes a wealth of information publicly available, there are significant gaps in the system. For example, as described in [Section A](#), there is no systematic way to find the date on which a generic application was filed. Perhaps all generic applications should be posted when filed, along with the date of their filing, and the public should not have to wait until the generic is approved to find that information, if it even appears in the approval letter. As it stands now, the more effective a drug company is at blocking generic competition, the longer that company has before anyone outside of the FDA can see what is being done.

At the very least, however, once a generic application has been approved, the public should be able to tell easily when the application was filed. Specifically, all approval letters should be posted on the FDA website, and the FDA website should always list filing and approval dates for every generic, and not just in these letters.

Unfortunately, the FDA appears to be moving in the opposite direction and lessening transparency. For our study, we were able to extract filing dates from some of the approval letters that the FDA posted and back fill many others through our estimation technique when the FDA approval letters did not mention the filing date. The FDA recently changed its protocols, however, so that the public will no longer be able to do even that. According to one report, the FDA has initiated a new

(June 14, 2016), <https://truthonthemarket.com/2016/06/14/senator-lees-prescription-for-regulatory-failure-in-the-generic-drug-market> (describing *Trinko* as an impediment to antitrust cases regarding refusals to provide samples to generic applicants).