

protocol in which it will omit from approval letters any mention of the filing date of the original generic application.⁵³

Other basic information could improve transparency as well, including more complete labeling of citizen petitions themselves, and full information on generic application numbers and how they are assigned. Finally, the massive Freedom of Information Act (FOIA) backlog at the FDA also operates to mask improper behavior. When we inquired for our research, Agency personnel were wonderfully helpful but noted that FOIA requests would require approximately two years for a response.

Making full data on generic applications quickly and clearly available to the public is essential for curbing inappropriate behavior. Particularly if the FDA is not assigned the full task of policing competition, other actors – including state and federal regulators, legislators, academic researchers, public interest groups, and generics companies themselves – must have easy access to the relevant information. Transparency efforts such as these, along with the types of approaches described here for curbing attempts to delay generic competition through citizen petitions, are essential for addressing the problems. Without such endeavors, we will continue to see a citizen's process diverted to the service of pharmaceutical companies playing games to hold off generic entry as long as possible. Consumers, of course, pay the price. In our [Conclusion](#), we will scale some of our specific citizen petition recommendations to address the larger problem of pharmaceutical delay in general. In other words, where do we go from here?

⁵³ Pollock, *Do You Notice Something Missing?* *supra* [note 11](#).