This would be analogous to the per se rules in antitrust. If one concludes that the vast majority of behavior within a certain category is likely to be improper, societal resources may be better served by declaring the category per se off limits, rather than weighing each instance.

This approach carries a certain cynicism regarding the likelihood that companies would have society's best interests in mind when commenting on whether the FDA should trust their competitors to enter the market. The approach implies that in these circumstances, one should consider competitors to be somewhat like the fox offering to guard the henhouse.[45] The incentives are not well aligned with the desired outcome.

Although banning competitors from filing citizen petitions is a simple approach, it is also simplistic. Pharmaceutical companies are likely to argue that, as the actors in the field most familiar with a drug, they are best positioned to sound the alarm when problems are on the horizon. Nor would this approach necessarily be fully effective. Companies could still submit generalized citizen petitions before any generic applications. They could also file petitions that have the effect of delaying entry – for example, by asking the FDA to reconsider all labeling related to the drug – without specifically requesting a delay.

2 *Procedural Blocks*

An alternative approach would involve enacting procedural blocks to channel the behavior into positive, rather than suboptimal, results. In other words, one might preserve the citizen petition process for all – including competitors – while ensuring that citizen petitions filed by competitors do not delay generic entry.

For example, one might direct that citizen petitions filed by competitors must be filed within a year of when the generic company files for approval.[46] Given that the average length of time for a generic application to move from filing to approval is roughly four years, citizen petitions filed within a year of when the generic application was filed are less likely to delay final approval.

Similarly, when competitors raise an issue related to the drug in general, the rule could be that the generic application goes forward on a timeline unrelated to the citizen petition. In other words, the generic can receive approval if the FDA determines that the drug meets the Agency's standards, and whatever issue is raised

[45] *See The CREATES ACT: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition: Hearing Before the S. Comm. On the Judiciary Subcomm. on Antitrust, Competition Policy and Consumer Rights*, 114th Cong. 58 (2016) (transcript of statement of Robin Feldman, using fox analogy in response to a senator's question) (transcript on file with author).

[46] This would require that the FDA make all generic applications public and easily searchable when they are filed.