can be resolved after that approval, if necessary. After all, the branded drug remains on the market under the current requirements for the drug, which suggests that the issues raised in the citizen petition, at least in some cases, are not of such magnitude that the drug cannot be offered to the public. Thus, whatever issues must be resolved would be resolved as to all forms of the drug – generic and brand-name – on a timeline unrelated to the generic's approval. One could refer to this as the "band plays on" rule. Even for issues related to whether the generic is bioequivalent or satisfies the FDA's requirements, one could once again conclude that the Agency is generally the best judge of that – at least with issues so serious that approval must be denied.

One concern is that although most citizen petitions are denied, some are granted. This suggests that occasionally, legitimate issues are at stake, and safety must remain the FDA's primary focus. Looking at concerns from the other direction, a "band plays on rule" still may squander some societal resources. The FDA must spend time responding to each concern raised. Similarly, branded companies could still use the tactic of filing citizen petitions to raise their rivals' costs.[47] In other words, generic competitors conceivably could be forced to spend time and money responding to spurious issues raised. Nevertheless, with the prospect of delayed entry off the table, such a procedural block could substantially reduce a brand-name company's incentives to engage in this behavior. Of the choices discussed here, this may, indeed, be the most effective.

3 *Punitive Deterrents*

The third approach would be to adopt some form of punitive measure designed to deter abuse of the citizen petition process, through either the courts or the FDA. Thus, parties that engage in behavior to try to block or delay generic entry through citizen petitions could be subject to a penalty calibrated to deter all but the hardiest of souls from engaging in the behavior in the first place.

In contemplating this approach, the initial question would involve determining the proper adjudicatory body to task with deciding whether the behavior falls beyond bounds. In theory, one might suggest that the FDA is the proper adjudicatory body. After all, the FDA has the greatest expertise for evaluating whether the issues raised in a citizen petition are spurious or well-founded.

The FDA, however, has proven more effective at evaluating patient safety than party behavior. Since 2007, the Agency has had the power to summarily deny any petition

[47] *See, generally,* Thomas G. Krattenmaker & Steven C. Salop, *Anticompetitive Exclusion: Raising Rivals' Costs to Achieve Power over Price*, 96 Yale L.J. 209 (1986) (seminal work identifying ability of competitors to impose costs on rivals without similarly incurring such costs).