

Empirical Evidence of a Citizen's Pathway Gone Astray

Chapter 4 described anecdotes and concerns that have swirled around the citizen petition process at the FDA. The FDA's citizen petition process and similar programs at other agencies were created in the 1970s. The movement was part of an effort to fashion more participatory regimes, in which ordinary citizens could have a say in the decisions made by regulatory agencies.¹ The hope was that such a participatory structure would prevent regulatory agencies from being captured by the very industries they were intended to police. Evidence suggests, however, that the FDA's citizen petition process may have taken a different turn.

In contrast to its lofty goals, this mechanism designed for citizens and scientists to raise concerns about food, drugs, and FDA regulations has turned into a playground for pharmaceutical companies to challenge drug applications, especially those related to pending generic applications. In many cases, the “concerned citizen” behind a petition is actually a large pharmaceutical company, seeking to stop or delay approval of a generic drug through a variety of different means. These include direct attacks against the generic's application and its bioequivalence or clinical data, appeals to safety, and calls to preserve or add new exclusivities for the brand-name drug. Some petitions raise important or necessary issues; many others, however, seem frivolous or questionable in their aims.

In this chapter, we examine what is happening on a systemwide basis, looking beyond cases and anecdotes to undertake an empirical analysis. (Numbers are all

¹ The following germinal texts describe the movement and debate its consequences. Christopher Edley Jr., *ADMINISTRATIVE LAW: RETHINKING JUDICIAL CONTROL OF BUREAUCRACY* (Yale 1990); Antonin Scalia, *Vermont Yankee: The APA, the D.C. Circuit, and the Supreme Court*, 1978 SUP. CT. REV. 345 (1978); Clark Byse, *Vermont Yankee and the Evolution of Administrative Procedure*, 91 HARV. L. REV. 1823 (1978); see also Sidney Shapiro & Richard Murphy, *Eight Things Americans Can't Figure Out about Controlling Power*, 61 ADMIN. L. REV. 5 (2008); Paul Verkuil, *The Wait Is Over: Chevron as the Stealth Vermont Yankee II*, 75 GEO WASH. L. REV. 921 (2007); Reuel Schiller, *Rulemaking's Promise: Administrative Law and Legal Culture in the 1960s and 1970s*, 53 ADMIN. L. REV. 1139 (2001).