sense. Specifically, we will discuss delay mechanisms including drug labeling changes, using FDA safety requirements as a guise to restrict generic access, extending a drug's life through minor dosage and formula changes, as well as what we call "multiplicity tactics," in which a number of these mechanisms are exploited at once. Of course, once companies develop new obstacle strategies, they can be bargained away, and we are beginning to see new settlement agreements to that effect. Once again, the brand-name drug company can play the role of the "boy scout," agreeing to behave well but doing it in a way that prevents further competition in the market.

Despite all of the troubling anecdotes, just how prevalent are these obstructionist strategies? In Chapter 5, we will share results from our deep look into drug-related citizen petitions submitted to the FDA. We identify trends over the last decade and demonstrate empirically that a process intended to allow ordinary citizens to petition the FDA has become a key avenue for strategic behavior by pharmaceutical companies to delay entry of generic competition. We also attempt to show empirically whether generic-related petitions are timed to delay the generic approval process.

Our Conclusion finishes with ideas for reforming the generic entry pathway. These ideas borrow from systems theory – looking from the perspective of how different systems interact to create opportunities and incentives to correct suboptimal behaviors. Moreover, to move the system away from hide-and-seek games, this section proposes the addition of standards-based legal rules. Most important, to avoid "death by tinkering"[101] – that is, adjusting doctrines a little here and a little there without comprehensive logic until the entire area collapses under its own weight – this section suggests a deeper look and a more comprehensive overhaul of different intersecting regimes. We also suggest a dramatic increase in pricing and FDA transparency so regulators have the information they need to make informed decisions and the market functions better by resolving long-standing information gaps. Sunshine laws about pricing are already being considered by numerous legislatures across the United States.

Hatch–Waxman was indeed a brilliant legislative innovation, heralding nothing short of a miracle in the reduction of drug costs. Now, it is time to consider the next generation of the regime so those miracles are not swept away.[102]

[101] *See* Robin Feldman, *A Conversation on Judicial Decision-Making*, 5 Hastings Sci. & Tech. L.J. 1, 2 (2013) (introducing the phrase "death by tinkering" to describe patent jurisprudence in the Federal Circuit).

[102] *See generally* Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch–Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 Yale J. Health Pol'y L. & Ethics 293 (2015) (presenting a recent article reviewing the history of Hatch–Waxman and suggesting improvements).