

Conclusion

A Call for Systematic Reform

Thirty years of the Hatch-Waxman regime have produced an extraordinary revolution in the introduction of generic drugs. The progress, however, has not been without resistance. As detailed throughout the book, pharmaceutical companies have engaged in three waves of behaviors to stave off generic competition as long as possible. The first generation involves paying generic companies to delay their entry into the market – that is, sharing a portion of monopoly profits with a generic in exchange for an agreement to delay competition. With antitrust scrutiny of such behaviors on the horizon, pharmaceutical companies developed a further generation of behaviors centered on multiple side deals, in which the companies settle many cases at once or agree to provide overvalued or undervalued services to each other as a way to camouflage the value of the transfers occurring in exchange for delayed entry. Each of these approaches is a clever way to try to obfuscate the nature of the behavior. Finally, Generation 3.0 games no longer focus on colluding with generic competitors; instead, the games rely on microobstructions against generic companies. These include using administrative processes, regulatory schemes with connections to Hatch-Waxman, and drug modifications to obstruct generics from getting to market. Further, they often combine a number of these tactics to create a multiplicity effect. Of course, Generations 2.0 and 3.0 can be combined by developing obstructive behaviors and then promising not to engage in them, using what we call boy scout clauses.

Of all of the approaches, the boy scout clauses are perhaps the most cynical. Here, a brand-name company engages in collusive behavior to prevent competition while trying to insulate itself from attack by claiming that it is behaving honorably. While boy scout clauses may be particularly cynical, all of the Generation 3.0 approaches threaten a new wave of behaviors that will be difficult for Congress, the courts, and regulatory agencies to control.