

Shkreli's previous company, Retrophin, bought the rights to a rare kidney-disorder drug called Thiola. Retrophin increased the price of the drug 2000 percent from \$1.50 to \$30 a pill, but it also created a still-active closed distribution system known as "Thiola Total Care."⁵⁴ This system requires a patient and the patient's doctor to fax enrollment forms to Retrophin, which then manages direct shipments not through an online system but only over the phone.⁵⁵ Notably, although it may be a technical error, the enrollment form on the Total Care Hub Web site automatically fills in the bubble for "dispense as written," which would prevent a pharmacist from substituting a generic form of the drug for Thiola.⁵⁶ Documents that Turing turned over to Congress in advance of the infamous February 2016 hearing revealed that, internally, it was known that "exclusivity (closed distribution) creates a barrier and pricing power."⁵⁷

That is what this book is about: the schemes, strategies, and tactics – not competition, not R&D – that pharmaceutical companies use to keep prices high and generic drugs off the market, denying consumers billions in cost savings and health benefits every year. It is about more than price, revenue, and profit. These issues of regulation may be prosaically dry on paper but they are enormously important in effect. Astounding technological advances in medicine dominate the headlines and rightfully draw our attention. Legal and regulatory environments, however, play a huge role in how well these advances actually serve the public. Policy choices on issues as esoteric as how similar a generic drug's fed-state bioavailability must be to its branded equivalent's bioavailability can have just as large an impact on the quality of health. Hidden among these technical details are strategies for sky-high pricing. All consumers suffer, and for the less fortunate, the lack of generic competition can force patients to make a decision between refilling prescriptions and making rent.

From our perch at the UC Hastings Institute for Innovation Law, less than a mile from the esteemed Westin St. Francis, we have researched the strategies and tactics that have appeared over the years. These tactics range from downright illegal collusive settlement agreements between brand-name companies and generics, to complex webs of deals, to the profoundly absurd (a dispute over the *type* of orange juice used to test the safety of a generic), to truly puzzling patents (like one for an

⁵⁴ *Ibid.*

⁵⁵ *Thiola Total Care Hub*, THIOLA, www.thiola.com/hub.

⁵⁶ *Patient Enrollment Form for Thiola Total Care Hub*, THIOLA, www.thiola.com/assets/pdf/TH1010V2.pdf.

⁵⁷ See Carrier, Levidow, & Kesselheim, *Using Antitrust Law*, *supra* note 50, at *21 (citing Memorandum from Democratic Staff to Democratic Members of the Full H. Comm. on Oversight and Gov't Reform Regarding Documents Obtained by Comm. from Turing Pharm. 3 (Feb. 2, 2016), <http://democrats.oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/Memo%20on%20Turing%20Documents.pdf>).