

ineffective capsule that dissolves before it reaches the drug's absorption site), to a single new sentence on a drug label claiming that the medication is better absorbed when taken with food, with the last scenario potentially preventing consumers from enjoying up to \$3 billion in cost savings.

During this era of heated discussion of pharmaceutical pricing policy, it is critical to detail the behind-the-scenes mechanisms contributing to rising pharmaceutical costs. In the legal arena, it is also a time of immense litigation and conversation about the legality of certain delay tactics, with cases even reaching the U.S. Supreme Court. These policy discussions heighten the importance of revealing the complex webs that have been woven.

Further, as completely new types of drugs emerge, far different from the old-school pills and capsules we are accustomed to using, it is important to ensure that a robust competitive market of brand-name and generic medication exists, and that existing regulation is not being used to manipulate these markets. This book is not an exhaustive look into how pricing decisions are made, how pharmaceutical companies decide what drugs to develop or produce, or other issues related to drug costs including insurance policies, potential overprescription, and misuse. Each of those issues could fill its own tome. Instead, we focus on the mix of antitrust, regulatory abuse, intellectual property law, and clever marketing that encompasses the world of generic pharmaceutical delay and obstruction. Before we begin, however, we provide an overview of the unique landscape of pharmaceutical economics and a brief primer of how generic entry and distribution are currently regulated.

With that, we will never mention the Westin St. Francis or the 33rd Annual J. P. Morgan Healthcare Conference in stunning San Francisco again. Promise. We reserve the right, however, to return to Mr. Shkreli. Sorry.

B A NOTE BEFORE WE BEGIN

Despite the excesses and concerns we detail in this book, pharmaceuticals have contributed immensely to improved health and quality of life across the world. Many treatments are now an essential part of everyday life. Every year, we see new cures developed through private invention. Despite pricing controversies, Sovaldi is essentially a miracle cure for hepatitis C. Research and development *are* expensive, and intellectual property systems are essential for incentivizing spending and innovation.

The concern, of course, is that pharmaceutical companies are shifting away from innovative activity, choosing instead to manipulate legal and regulatory pathways that sustain existing sources of monopoly revenue. This activity fails to improve medicine and health care, while subverting the intent of the patent system and the balance society has chosen between private incentives and the public good. It also blocks creative, new innovators from entering the market. A similar problem is at