DRUG WARS

While the shockingly high prices of prescription drugs continue to dominate the news, the strategies used by pharmaceutical companies to prevent generic competition are poorly understood, even by the lawmakers responsible for regulating them. In this groundbreaking work, Robin Feldman and Evan Frondorf illuminate the inner workings of the pharmaceutical market and show how drug companies twist health policy to achieve goals contrary to the public interest. In highly engaging prose, they offer specific examples of how generic competition has been stifled for years, with costs climbing into the billions and everyday consumers paying the price. Drug Wars is a guide to the current landscape, a road map for reform, and a warning of what’s to come. It should be read by policy makers, academics, patients, and anyone else concerned with the soaring costs of prescription drugs.

Robin Feldman is an award-winning teacher and scholar who has published more than forty articles and books. Feldman has been cited by the White House, members of Congress, and numerous federal agencies, and she has testified before committees of the U.S. House and Senate, as well as the California legislature. In 2016, Feldman was named one of the Women Leaders in Law & Technology, the only academic to receive the honor.

Evan Frondorf’s legal work with Professor Feldman has been published in journals at Harvard and Stanford, including papers on patent demands and generic pharmaceuticals. He studied economics at Yale and graduated Phi Beta Kappa and magna cum laude, and he was named a Rhodes Scholar finalist in 2015. He is also the current sports writer for the Yale Alumni Magazine. At Yale, he was heavily involved in sports broadcasting and served as a deputy sports editor at the Yale Daily News.
Drug Wars

HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET

ROBIN FELDMAN
University of California Hastings College of the Law

EVAN FRONDORF
University of California Hastings College of the Law
This book is dedicated to my husband, Boris Feldman, in our thirtieth year of marriage, and to our children, Natalie, Talya, Eli, Sam, and Adam. – Robin

To my supportive family and friends, wherever I go. – Evan
## Contents

<table>
<thead>
<tr>
<th>List of Table and Figures</th>
<th>page ix</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acknowledgments</td>
<td>xi</td>
</tr>
</tbody>
</table>

**Prologue: Big Scandals, Higher Prices**
A. Pharma under Fire  
B. A Note before We Begin  
C. The Strange Economics of Pharmaceuticals  
D. Generics – A Brief Primer

**Introduction: The Winding Road to Generic Entry**

1. **“Generation 1.0”: The Rise and Fall of Traditional Pay-for-Delay**
   A. The Basic Contours of Pay-for-Delay  
   B. Pay-for-Delay as a Bottleneck to Entry  
   C. Is Pay-for-Delay Actually Wrong? Pharma Heads to the Supreme Court

2. **“Generation 2.0”: Complicating Pay-for-Delay**
   A. Already Steps Ahead of Actavis  
   B. *In re Lipitor*: Everything but the Kitchen Sink  
   C. The Post-Actavis Landscape, Contract Clauses, and *King Drug*

3. **“Generation 3.0”: New Tactics for Active Obstruction of Generics**
   A. A New Generation of Pharmaceutical Delay  
   B. Product Hopping and the Purple Pill  
   C. New Examples of Product Hopping  
   D. Scout’s Honor in Product Hopping
# Contents

4  “Generation 3.0”: Continued Obstruction of Regulatory Pathways  80  
   A. REMS-Based Delay  80  
   B. Delay via Citizen Petition  91  
   C. Preventing the “Skinny Label”: Blocking Carve-Outs  102  

5  Empirical Evidence of a Citizen’s Pathway Gone Astray  113  
   A. Methodology  115  
   B. Results  122  
   C. The Road Ahead  131  

Conclusion: A Call for Systematic Reform  137  
   A. Societal Harms  138  
   B. Systems, Simplification, Sunshine, and Standards-Based Doctrines  139  

Index  145
Table and Figures

**TABLE**

5.1 All Delay-Related Petitions, by Year  
*page 123*

**FIGURES**

5.1 Months from Citizen Petition Filing to Generic Approval, 2000–2012  
5.2 Months from Citizen Petition Filing to Generic Approval, 2000–2007  
5.3 Months from Citizen Petition Filing to Generic Approval, 2007–2012  
*124*  
*127*  
*127*
Acknowledgments


We wish to express our thanks to Drew Amerson, Alice Armitage, Matt Avery, Michael Carrier, Scott Hemphill, Cheryl Johnson, Kurt Karst, Mark Lemley, Joe Lukens, and Daryl Wander for their comments, suggestions, and clarifications. We are grateful beyond measure to Grace Bradshaw, Jonathan Cohen, Isil Selen Denemec, Gabriella Gallego, John Gray, Aya Moshiri, Betty Chang Rowe, Naira Simmons, Omar Vaquero, and Connie Wang for their insights and research, and, above all, to Andrew Cordova for research design and coordination of the research. Rosie Buchanan was instrumental in guiding us through the coding process for our empirical work, and John Gray’s data insights were critical to the analysis. Nanette McGuinness provided incomparable proofreading, and Sarah K. Delson created the fabulous cover design. While the book was in process, Evan Frondorf completed his position at the University of California Hastings College of the Law, began a full-time position at Stripe, and thus, had to bow out of the final stages of the book production. His contributions to the book were immeasurable.

In accordance with the protocols outlined in the Harvard Journal of Law & Technology Open Letter on Ethical Norms, all of the data is publicly available

Acknowledgments

for future use by other academics on SSRN.com. In further accord with the Open Letter, donation information for the University of California Hastings Institute for Innovation Law, which Robin Feldman directs, can be found at http://innovation.uchastings.edu/about/funding/funding-for-academic-year-2015–2016/. No private or corporate donor accounts for more than 10 percent of the institute’s budget.