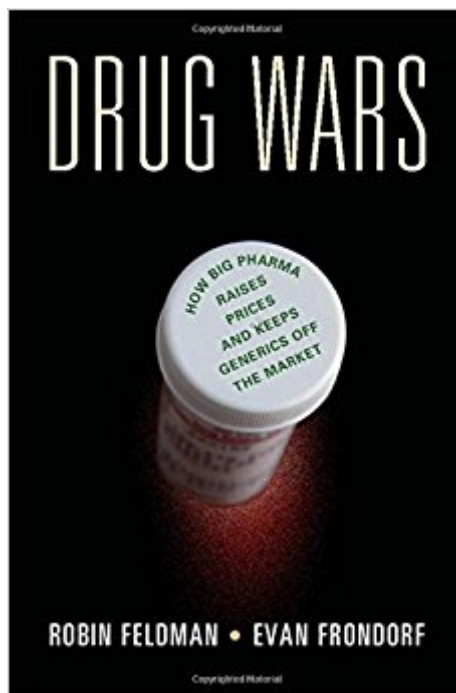




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# Drug Wars: How Big Pharma Raises Prices And Keeps Generics Off The Market



## Synopsis

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 roadmap for reform, and a warning of what is to come. It should be read by policymakers, academics, patients, and anyone else concerned with the soaring costs of prescription drugs.

## Book Information

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'An important book and a compelling read. The authors show how pharmaceutical companies have twisted a law designed to protect invention into a regulatory nightmare that only protects profits.'

Mark A. Lemley, William H. Neukom Professor, Stanford Law School, California  
'A fascinating and incisive study of the inner world of the pharmaceutical industry. A must read for anyone interested in the relationship between drug pricing, regulation, and its impact on public health.'

Sonia K. Katyal, Chancellor's Professor of Law, University of California, Berkeley

The cost of pharmaceuticals in the United States has continued to skyrocket, leaving many people without access to lifesaving medications. In their new book, Feldman and Frondorf explore the

complex mix of strategies used to create barriers to generic competition in the US pharmaceutical market.

A measure of just how perverse US pharmaceutical markets have become is the “reverse payment” in which the original manufacturer sues the maker of the new generic version for patent infringement, then settles by paying the generic maker to go away for several months before launching its version. If that is intriguing instead of revolting, Drug Wars is for you. Feldman and Frondorf have researched all the Food and Drug Administration’s generics files going back to the turn of the century, and found a treasure trove of manipulation, waste and greed that prove why we need an FDA in the first place. That the FDA is being crippled by all these shenanigans is criminal. To the tune of billions of dollars a year. The name of the game is delay. Every month of delay can mean tens of millions of dollars from consumers and insurers overpaying. A year’s delay can easily mean a billion dollars’ profit. The frightening total is that 45% of Pharma revenues worldwide come from American patients. Because no other country lets them get away with this. Some of the tactics Big Pharma uses: -claiming its drug is so dangerous it can only be handled in and by a single named drugstore, making it unavailable generally, and specifically not to a generics firm wishing to examine it -delaying selling a sample to a generics firm for years, until they go away -changing one tiny aspect of the drug so the generic no longer copies it (could be the packaging or the directions). Business process patents have nothing to do with drug efficacy, but count in patent law -filing a citizen petition questioning the methodology to measure the generic’s performance. The FDA routinely rejects them (some years 100% of them), but Big Pharma keeps filing to keep delaying -when a drug firm removes a drug completely, the remaining generic is disqualified from most formularies because there is no alternative to it. It (ironically) defaults to brand status itself, and goes unfilled. Pharma then releases a new version, free of generic competition. Big Pharma fills the courts with frivolous suits, loads down the FDA with nonsensical complaints (demanding tests that are already required, for example) and applications, and stalls. A finding that a drug might be dangerous may not be filed for years until a generic appears on the scene. Bogus applications that slow down generic approvals are routinely rejected but they serve the purpose by taking up valuable time, at taxpayer and patient expense. While Drug Wars has a worthy conclusion packed with sensible recommendations, it is clear Congress will not act on them, and that lifesaving drugs should not be left to the “free” market. David Wineberg

This article originally appeared on The Magical Buffet's website on 06/28/2017. When you read that I'm about to discuss a book called "Drug Wars" your mind probably goes straight to America's war on illegal drugs, but you would be mistaken. There is a war involving prescription drugs going on right now that many of us had no idea existed. It's one where pharmaceutical companies always win and the public always loses. A long time ago, before the mid-80s (I can't believe I called that a long time ago!) people realized that very few generic drugs were coming onto the market. Wait, let me back up for those of you who aren't constantly on meds like myself. So in the fashion world designer label Louis Vuitton sells its "Saint Michel" purse for \$1,700. It's a bag, it holds stuff. You can also find on your better handbag websites what are subtly referred to as "knock off" versions for a couple hundred dollars. It's also a bag. It also holds stuff. That's essentially prescription drugs and their generic versions, except in this case the FDA makes sure that the bags are made of the same primary material. A prescription drug can be hundreds of dollars, but a generic drug is nearly identical at a fraction of the price. With the state of health insurance then, and now, there is an interest in generics for public consumption. Thus in 1984 The Drug Price Competition and Patent Term Restoration Act, often called the Hatch-Waxman Act, went into effect to stimulate a generic drug market. The Hatch-Waxman Act is a great idea. It attempts to strike a balance between capitalism and the common good. When a pharmaceutical company goes to market with a new chemical that company is given 5 years of exclusivity. It also streamlined the process for companies looking to bring a generic version to the market. Thus the originator gets 5 years of market dominance to recoup research costs, etc. while providing the eventual competition of a generic to make things easier on the consumer's pocketbook and encourage pharmaceutical companies to get back to the drawing board to innovate and bring another new drug to market that again gets 5 years of competition free existence. Pretty elegant, right? What no one saw coming, but let's face it, those in the know probably did, was that pharmaceutical companies found ways to extend their periods of exclusivity, which of course makes things harder on us sickos of America. The use of lawsuits to stall generics going to market is common, and not surprising once you're reading "Drug Wars". What was shocking was the collusion between the manufacturers of the original drug and the companies making the

generics. When these companies are in litigation they can fight it out, or settle. Oddly the settlement involves the manufacturer of the original drug paying obscene sums of money to the generic, and the generic agreeing to hold off going to market for several more years. There many ways safe and effect generic drugs are delayed from becoming available, and *Drug Wars* does an amazing job highlighting them. The authors, Robin Feldman and Even Frondorf, also make recommendations on how to fix these issues. If you're into intricate bureaucracies, healthcare in America, and a few laugh out loud absurdities then you need to read *Drug Wars: How Big Pharma Raises Prices and Keeps Generics Off the Market* by Robin Feldman and Even Frondorf.

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