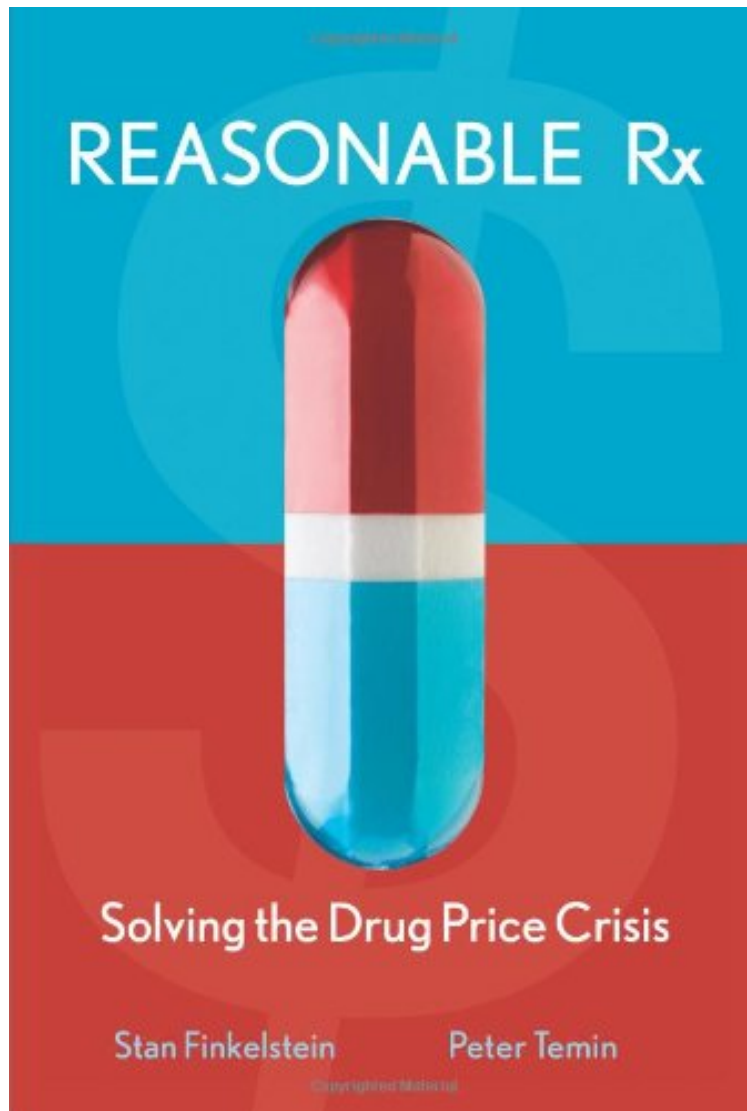


Reasonable Rx: Solving the Drug Price Crisis

Stan Finkelstein, Peter Temin

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Stan Finkelstein, Peter Temin : Reasonable Rx: Solving the Drug Price Crisis before purchasing it in order to gage whether or not it would be worth my time, and all praised Reasonable Rx: Solving the Drug Price Crisis:

0 of 0 people found the following review helpful. Four StarsBy Jason L. AcevedoGreat review of the current drug pricing crisis3 of 3 people found the following review helpful. Fannie and Freddie for drugs? No, thanksBy AthanThe purpose of the book was to introduce a proposal for the restructuring of the American pharmaceutical industry. The authors identify two major problems with the US market for medicine.They acknowledge that most of the world's new medicine has been discovered and continues to be discovered in American labs, and that this is a tribute to the

capitalist model. The potential rewards that make smart people work hard to cure illness are to a great extent financial. But the authors believe that we have arrived at the end of the road on two fronts. First, the costs of new medicines is now so high that normal Americans and the US government will struggle to pay for them going forward. Second, we are not discovering new medicines at the rate at which this used to occur. The reason for this, according to the authors, is that the pharmaceutical giants pursue blockbusters, which is what makes sense for them financially. Blockbusters are drugs that don't eliminate an illness, but rather treat a condition forever and ever, and for as wide a population as possible. Like drugs that control the cholesterol in your blood for the rest of your life, for instance. This analysis sounds logical; if that's what works for Hollywood (which has exactly the same business model) it probably works for large pharma too. But of course there is a human angle here. Hollywood is entitled to do as it pleases, because it does not handle matters of life, death, illness and cure. On the other hand, medicine is not an indulgence. Here's what they don't like with the blockbuster model: 1. Lots of "me too" drugs get developed, whose additional usefulness to society is much smaller than their usefulness to the companies that develop them, and at the expense of other potentially useful cures; meanwhile, any potential price benefits to the public are captured by the oligopolistic distributors who want to be able to shop from a couple options, but fail to pass on the savings to patients. 2. Promising drugs that would only help a few people or would only help poor people get put on the back burner. 3. Drugs get approved for the minimum possible dosage and it is left to doctors to then go ahead and find other ways they can cure patients in higher dosage. You'd never, ever target the illness where the higher dosage helps. 4. Blockbusters are marketed to consumers directly, rather than the medical community, introducing a whole host of new issues. You could not market something very specific on TV, it would not be cost-efficient, but blockbusters are made for it. The authors argue (persuasively) that this has not been good for doctors and patients. 5. Big Pharma stocks have done unbelievably well since the introduction of the blockbuster model. The authors run some stat tests that in their view prove there is no longer any risk in running a large pharma company, and that there is therefore an imperative to make the industry work for its bread. Yes, the capitalist model works, but this looks to the authors like monopoly returns, rather than perfect competition. The authors also describe the very lengthy (currently 13 year) three-stage process from when a new cure is discovered to when it has gone through the necessary toxicity tests, efficiency tests and efficacy tests (don't ask) to be ready to go for FDA approval. Apparently 13% of drugs that enter this process survive the 13-year process to make it to the stage where the FDA has a look at them. And it can apparently be an unsavoury process. Drug companies often bury bad results, as they would not want to spare their competitors the bother of pursuing blind alleys, and there have also been occasions when they have been so eager to bring a drug to market that they may have buried bad results in the interest of actually releasing a drug to the public. Testing is done by an industry of lesser-quality panels that the authors describe in detail (and disgust), rather than top scientists and universities, the main objective being low cost. Once a drug is presented to the FDA for approval, the next process starts whereby the pharmaceutical companies have basically revealed to the market the existence of the new drug, and the process of marketing essentially starts. This process once involved pharmaceutical companies selling directly to doctors, but these days there are three avenues. They also advertise straight to the public, and (predominantly) distribution is in the hands of an oligopoly of three corporations that sit between the pharmaceutical companies and the HMOs and pharmacies. The authors don't have too many compliments for this part of the chain either... So what is their solution? Well, you spend the whole book waiting for it. I really think the authors ought to have outlined it in the introduction. It would have allowed me to read the entire book with half my brain attuned to how all the issues they touch upon would relate to the solution, but it's not what the authors chose to do. And when you get to the solution, you kind of figure out what cause their shyness. On the other hand, had they put it in the introduction, there's every chance I would never had read the book and that would not have served me well either... They propose that the industry is cut in half, at the waist, so to speak. Companies should either work toward bringing new drugs up to the point where they are ready for FDA approval or they should be in the business of marketing drugs, starting from the FDA approval onwards. This of course begs the question of why this split would stop the guys who come up with the drugs from beavering away to produce the blockbusters that the marketing behemoths crave. The second innovation proposed by the authors addresses this. It's an agency that has the exclusive right to buy the drugs from the companies that develop them and the exclusive right to auction them off to the marketers. This company would not pursue profit. It would sometimes sell on the rights with strings attached on price, would discourage me-too drugs, would not actively pursue blockbusters, would overpay for cures for illnesses there's no profit in, but large public benefit etc. The authors basically propose that we stick government somewhere in the middle. But of course it would not be government, it would be a PRIVATE agency. Like, wait for it, Fannie and Freddie. And that's where the authors lost me, frankly. I did read it till the end, but I was so deflated. That said, hopefully somebody picks up from the authors and finds some other solution. The points they have made about what does not work seem valid. But the events of 2008 are solid proof that government agencies are a recipe for private profit and public risk. Perhaps regulation can be introduced that can be made an industry split to work. The book did convince me that there is merit to the idea of separating the marketers from the scientists, or at the very least there is merit to not involving marketers from the very start. Dunno, perhaps a government competitor could be introduced. In the media business, every UK resident is familiar with the BBC, for instance. I find it does a stellar

job. My wife, on the other hand, who works in media, believes it renders the UK a media wasteland compared to her native America. The book leaves me with more questions than answers, but hopefully with better questions than I had before...5 of 6 people found the following review helpful. Mix of good and bad ideas

By Peter McCluskey

This book provides a mediocre analysis of what is wrong with drug prices, and presents a solution that is probably a nontrivial improvement on the status quo, but isn't the most thoughtful solution I've seen. The most important complaint of the book boils down to the fact that knowledge about drug safety and effectiveness is a public good, and the current method of rewarding drug companies for producing that knowledge is mediocre (although the book presents it less clearly than that and seems as interested in blaming drug companies' lack of altruism as it is in analyzing the incentives). For example, it is sometimes possible to identify biomarkers which indicate that a drug will be ineffective in a patient, but that would often reduce sales of the drug. They complain that the current focus on producing a few very profitable drugs is an obstacle to creating personalized treatments. But they do little more than imply that drug companies are misjudging the available opportunities, without presenting any clear evidence that the authors' have better judgment about what's feasible. Their proposed changes to the drug industry involve separating drug development and drug marketing/manufacturing into two different sets of companies, and using a combination of subsidies and contractual price controls (negotiated by a government sponsored nonprofit) to lower the prices of drugs. They didn't convince me that splitting drug companies will produce any significant benefits, although I also don't see it producing harm. The subsidies and price controls are likely to help mitigate some of the problems created by the patent system. Their attempts to show that this solution is better than Kremer's patent buyout proposal suggest they don't understand how much harm patent monopolies cause. Their subsidy mechanism isn't clearly tied to benefits (unlike proposals for prizes based on Quality Adjusted Life Years). They claim drug prize proposals set arbitrary values for drugs and that their auction system produces a less arbitrary market price, but the subsidy part of their part of their system is at least as arbitrary, and their market based prices reflect the value of an arbitrary patent duration. Their claim that Medicare savings will pay for their subsidies seems deceptive. When estimating the Medicare savings, they appear to rely on an assumption that prices of existing drugs will drop by a large amount. Yet when estimating the subsidy costs, they appear to count only the costs of subsidizing newly introduced drugs. They are too quick to complain about drug companies medicalizing conditions that are mere inconveniences. E.g. they say Flomax does nothing more important than reduce sleep disturbances. This ignores the evidence that sleep disturbances cause significant health problems. The chapter "Are Drug Companies Risky?" is pointless because it only evaluates the most successful companies (i.e. those whose gambles have already paid off).

A Real Plan for Making Drugs Affordable—and Promoting Innovation, Too

"This book is a necessity for understanding the pharmaceutical industry. Both the pluses and minuses of the present system are set forth with a judicious combination of historical narrative, economic analysis, and statistical data. The highly original proposals for reform will be a major stimulant to analysis and policy-making."

—Kenneth Arrow, Nobel Laureate in Economics, Professor Emeritus, Stanford University

"This is a timely book by authors who know what they are talking about. They tackle a big problem: rising drug prices that are threatening to overwhelm us all—and especially those with limited or absent health care insurance. Will we drive people overseas for healthcare? Will there be social unrest? This book describes the problem and then offers a solution. Worth a careful read by everyone, pharmaceutical manufacturers and government policymakers especially."

—Roger Williams, M.D., Chief Executive Officer of the United States Pharmacopeia and a former senior official of the Food and Drug Administration

"This book confounds two sets of skeptics: Those who say there's no way to resolve the conflict between the need to fund pharmaceutical research and our desire to keep medicine affordable; and those who think that economics never has anything good to say."

—Honorable Barney Frank, Congressman from Massachusetts

"This book comes at the right time and could become the starting point of discussions, which will eventually lead us into new era in the healthcare care industry. It will without a doubt become a must for insiders of the pharma- and biotech industries."

—Dr. Jürgen Drews, retired President of Roche Pharmaceutical Group

Global Research

Acknowledgments viii About the Authors ix Introduction xi

Chapter 1: Drugs and Drug Prices 1 Chapter 2: The American Way to Discover Drugs 21 Chapter 3: The Drug Industry Today 39 Chapter 4: Are Drug Companies Risky? 59 Chapter 5: How Not to Lower Drug Prices 77 Chapter 6: Squandering R D Resources 103 Chapter 7: How to Lower Drug Prices 129

Appendix: Our Solution in Detail 155 Index 177

From the Back Cover

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Reasonable Rx

INTRODUCTION

The age of effective medicinal drugs, which dawned about 50 years ago, transformed the health care industry. Americans have become used to taking a pill to cure many diseases and improve their lives in other ways. Many senior citizens, though, can recall growing up in a world where there were no easy cures for many serious conditions that today are regarded as little more than irritations. President Calvin Coolidge's son died from an infection he picked up while playing in the White House rose garden. There's no reason anyone in America should face that risk today. But good drug therapies are only as good as patients' access to them. The best cures in the world are of no use if exorbitant prices put them out of reach. It is no exaggeration to say that we are past being on the verge of a crisis. No one reading this book can honestly deny that the prices of drugs are high and are getting higher. Even for those fortunate enough to have health insurance that pays part of the cost of prescription drugs, the co-payments keep increasing and insurers put more and more restrictions on what therapies they'll cover. As a revolution in science and technology unfolds that brings us new drugs that are targeted almost to the individual patient, the magnitude of the crisis only grows. In the not-too-distant future, perhaps just around the corner, we might be faced with the following scenario: new, more effective, "personalized" drugs that address small patient groups but are priced beyond what any individual can afford and what any insurer is willing to pay. If that happens, then the federal government will intervene to control prices; which the experiences of Europe and Canada have shown kills innovation. What has gotten us to this point? The culprit is a broken system that we've let languish for too long without fixing. It's a flawed system that combines three components that all too often work against each other. The first component is money. It costs a fortune to develop a new drug, but the potential profits are huge. Not unexpectedly, the pharmaceutical industry is driven to maximize those profits and firms are racing to develop the next big blockbuster drug that will bring in \$1 billion or more in sales. The second component is science. New scientific discoveries about how diseases work, coupled with new technologies, are leading to new therapies that work better for specific patients. We can even know in advance how likely the outcome of a therapy will be with a given patient. But that means selling a drug to smaller numbers of people. If a company's objective is blockbusters, this busts the business model. The third component is incentives. Simply put, we have the wrong ones. The choices that research-driven pharmaceutical firms make today about which drugs to pursue in their discovery and development programs are just too far afield of what society needs most. For every slight variation on a blockbuster antihistamine for hay fever that the industry pursues, a pressing societal need gets ignored. The incentives, through no direct fault of the industry, are seriously askew. No wonder we see so many instances where business decisions encroach on science. This is a situation that cannot stand. Some serious changes need to be made; before it's too late. Lots of people are worried about this situation. Rising drug prices are increasing the cost of health insurance because drugs continue to grow as a share of overall health costs and insurance reimbursements. Those of us who have insurance worry that premiums will increase to the point where we can no longer afford our coverage. State governments that operate Medicaid are finding their costs rising so fast that it puts pressure to restrict the funds available for other purposes. And if all the estimates hold, the federal government, which operates Medicare, will find that the cost of the new Medicare Part D drug benefit to senior citizens is significantly larger than anticipated. A spate of recent books by distinguished doctors and editors of the prestigious *New England Journal of Medicine* address these high drug prices and even recommend ways to lower them. 1 Our book is different, however. Here we propose a comprehensive solution that honors the tremendous innovation of the pharmaceutical industry, takes full advantage of today's scientific revolution, and speaks directly to how society can ensure we all get the drugs we need. In doing so, we aim directly at a profound misconception: that high drug prices are a prerequisite if we are to continue to make medical

advances with pharmaceuticals. No, the real issue is risk—and who bears it. Just as we rely on private industry to produce our clothes, houses, cars, and other things that enhance our lives, we rely on a private pharmaceutical industry to create our medicines. But don't be confused by the word "private;" the U.S. government has long been part of the process of drug discovery, manufacture, and sale. In fact, the government's involvement predates the revolution in drug therapies and goes back to the beginning of the twentieth century. And since it's both a private and government effort today, it stands to reason that any solution to the crisis we've described should also be public and private. That solution begins with risk. Americans face a lot of risks in their lives. In the United States, people accept risks in order to obtain the potential rewards. Even if the economy doesn't always work as it's supposed to, it's designed to allow you to choose your education and career. It is structured for business enterprises to choose where and how they produce their products. True, some government constraints exist in the form of rules and standards, sometimes called "regulations." After all, you couldn't drive your car safely down the street if we didn't have a rule about driving on the right-hand side. The price to pay for successful management of many risks is having rules and behaving in common with other people. In the world of finance, risk is rampant, and the government plays a big part in making sure things run well. For instance, you can invest in companies with the assurance that they will honor their contracts with you because of government regulations. The government participates in the risk of investing in many other ways, too. Take bankruptcy, a way to limit the cost of unsuccessful gambles. No one wants to declare bankruptcy, but it reduces the losses that will be incurred if a risky enterprise fails. It eases the cost of risk-taking by ordinary people as well as of companies.

2 Health is no different when it comes to the issue of risk. Everyone runs the risk of getting sick, of course, and there's also the risk that someone may not recover if he or she gets sick.

3 In your role as a patient or potential patient, you tend to focus on keeping yourself healthy—that is, avoiding the risk of getting sick—and on how you're going to ensure treatment if you do get sick. Another kind of risk in the world of health involves whether the drugs you take are safe and effective. That's where federal involvement with prescription drugs began. People without medical training typically know little about the effects of potent drugs and seldom know how much to take, at least not without some guidance. If the government didn't intervene to assure you that drugs are safe to swallow, there would be greater risks in taking them. (To be sure, the government regulators are sometimes criticized legitimately about dropping the ball, but overall prescription drugs are safe and effective when they make it to market.) The government today regulates both drug companies and how drugs are made available to their customers. Government programs encourage and regulate the activities of pharmaceutical companies as they discover, test, and manufacture drugs. The Food and Drug Administration (FDA) has the final say on which drugs can be sold and regulates whether you need to get a prescription for the most powerful medicines. A pharmacy that sells a prescription drug without a prescription is breaking the law—a law enforced so tightly that even alleged violations are rare. In all these ways, the government reduces your risk when you take your medicine.

4 When it comes to how much those medicines cost, though, the government has largely had a hands-off policy. Yes, some intermittent attention to the issue has been paid. Almost 50 years ago, Senator Estes Kefauver held hearings to investigate why the first generation of new drugs cost so much. In 2003, Congress debated the cost of the new Medicare drug benefit. But the United States has never had a consistent policy on drug costs. The pharmaceutical companies have been left to charge what the market will bear for their products. That was fine as long as people only took prescription drugs occasionally, mostly for acute episodes of illness. Today, thanks to tremendous scientific advances, medicines are taken at a much greater rate; some medicines are taken every day for a lifetime. Rising usage and growing prices fuel a widening discussion about how to solve a problem that more and more people recognize is at a crisis point. But the discussion seems to have reached an impasse. Doctors complain about the costs of drugs on behalf of their patients and so do patients themselves. The pharmaceutical industry responds that high drug prices are needed to finance the discovery of new medicines to benefit the patients. As the two sides talk past each other, recommendations consistently focus only on changing the details of drug distribution. Rising usage and growing prices fuel a widening discussion about how to solve a problem that more and more people recognize is at a crisis point. But the discussion seems to have reached an impasse. It's time for a new debate on new terrain. In this book, we assess recent changes in the pharmaceutical industry in depth—not only the expanding scientific revolution, but also the business of pharmaceuticals. We look at the lack of progress that results from the blockbuster mentality. We explain how the drug industry operates, how new drugs are discovered, and how the government affects and controls these processes. These are the prerequisites to understanding how to lower drug prices. Our examination shows that changes—built on the best aspects of today's pharmaceutical industry but fixing what's broken in our system—can reduce prices and improve the flow of new drugs that best serve society's needs. Sounds implausible? The pharmaceutical industry's mantra that high prices are the only way to ensure innovation has certainly permeated the psyche, but there really is an alternative. It requires bold, but achievable, action. We have a plan that will lower prices while ensuring access for all citizens to today's great medicines and tomorrow's new, revolutionary drug therapies.

Endnotes
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