If taxpayers fund most of the innovative research, Angell questions why consumers have to pay the drug companies excessive prices for the final product. "The much-repeated assertion that it costs on average $802 million to bring a new drug to market is wildly off the mark," she says. "I would have no objection if drug companies admitted that they depend on publicly funded university and government labs for the earlier stages of research, but they don't. By implying that they are the source of the basic research, as well as the later development phase of R&D, they can get away with charging exorbitant prices."

**Rx for Big Pharma**

From Angell's perspective, the prognosis for big pharma isn't good. She sees a staggering giant that continues to make outrageous profits, but is desperately in need of intervention. Americans are fed up with exorbitant prices for prescription drugs, she says, and there is growing political pressure to legalize the importation of cheaper drugs from Canada (see sidebar). Many top-selling drugs are scheduled to go off patent in the next few years, and she says there are very few new drugs in the pipeline ready to take the place of the profitable but aging blockbusters.

Angell suggests several reforms that would steer big pharma back to its original purpose of making new, better, and affordable prescription drugs. Most important, she says, is to change the FDA's standards of review so that new drugs have to be compared with similar older drugs. "If FDA approval were at least partially contingent on how a new drug compares with an older one for the

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**Help from Above**

Drugs are cheaper in all other democratic countries, including — as we all know — Canada. Last year more than a million Americans bought their prescription drugs from Canadian pharmacies, and there's growing political pressure to legalize the importation of drugs from abroad. Alan Sager and Deborah Socolar, codirectors of the Health Reform Program at the School of Public Health, have been investigating solutions to the problem of high drug prices. "Importing drugs from Canada has political support now," says Sager; an SPH professor, "but we don't really think that it is a durable and effective long-term solution. It provides enormously valuable short-term relief to people who are being crushed by high drug prices in the United States, but it's not going to work for 300 million people." Nevertheless, the promise of cheaper drugs from abroad has "persuaded just about every American that our drug prices are simply too high, and that high prices are not natural or inevitable."

Drug makers warn that importing drugs would sharply curtail funds available for R&D. But Sager and Socolar say that if 45 percent or more of the medicine purchased from Canada were new prescriptions — not replacements for prescriptions previously bought in the United States — drug companies' revenues would actually increase. "If we cut prices to Canadian levels, medications will be much more affordable, more people with private insurance could afford to fill their prescriptions, and more people's drug benefits could be covered by private and public insurance," Sager says. "The better coverage and lower price together would replace the revenues that the drug makers lose through the price cuts."

But SMG Professor lain Cockburn disagrees. "If profits would really go up by lowering the price," he says, "then the companies would have done it already." If so many Americans are being priced out of the market, he wonders, why don't more people rush to buy drugs when they go off patent? Prozac had a sticker price of about $2 a pill when it was on patent, but the generic versions of the drug called fluoxetine cost only $.20 a pill. When Prozac went off patent, "the total number of fluoxetine pills on the market didn't change," he says. "It rarely does. The presence of the generic doesn't seem to bring any new people into the market."

Cockburn strongly opposes importing as an assault on the patent system. "The proposed legislation to legalize importing will start causing drug shortages in Canada," he says.

Facing a supply emergency, Cockburn says, Canadians may allow generic production of drugs before their patents expire, which is called compulsory licensing. This is what South Africa did with AIDS drugs in 2001. "The danger with these efforts to import drugs from elsewhere," he says, "is that it puts pressure on the world patent system."

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consultant to the Pharmaceutical Research and Manufacturers of America, supports high prices for prescription drugs for this reason. “The reality is that this is a highly risky business,” he says, “and it’s very expensive for drug companies to bring a product to market.” In a recent Boston Globe op-ed piece, Kotlikoff argues that “to develop each of the high-priced drugs that we buy, the pharmaceutical companies pay, on average, almost $1 billion. Like it or not, the drug companies need to recoup these costs, and we need to let them. If we don’t, we’ll be doing a grave disservice to ourselves in limiting the prospects of new cures for painful and often life-threatening diseases.”

A growing number of Americans are questioning that rationale, though, and Angell is leading the charge. Her book reveals that drug companies spend far less on R&D than they would have us believe. “Research and development is a relatively small part of the budgets of the big drug companies,” she says. “They spend over twice as much on marketing and administration, and they actually make more in profits than they spend on R&D.” In 2002 the top ten drug companies spent 14 percent of sales on R&D, but 31 percent on marketing and administration.

“You can’t call an industry risky when it has consistently been the most profitable in the United States for over two decades,” she says, noting that last year big pharma fell from first place to third. “As long as they have those immense profits left at the end of the year, they are doing better than fine.”

The enormous profits drug companies make on blockbuster drugs are supposed to encourage innovation. But Angell says big pharma is hardly innovative. “The Food and Drug Administration classifies new drugs according to whether they are likely to offer anything better than drugs already on the market,” she explains. “In the past six years, of the 487 drugs that entered the market, 379 — 78 percent — were considered no better than older drugs. And most of those were not even new compounds, just old ones in new combinations or formulations.”

The vast majority of new drugs entering the market are so-called me-toos, minor variations of blockbuster drugs. When one company discovers a breakthrough drug, Angell says, its competitors jockey to cash in on the lucrative market with their own me-too versions. The upshot is whole families of me-too drugs, such as the six different cholesterol-lowering drugs called statins and the five different selective serotonin re-uptake inhibitors that are variations of Prozac. Pfizer’s Lipitor, the fourth statin on the market, is now the top-selling drug in the world, but Angell points out that there’s little scientific evidence that it is any better than the other me-toos at comparable doses.

While drug companies churn out me-toos, she argues, the truly innovative research is carried out at universities and small biotech companies, which are supported in large part by the federally funded National Institutes of Health (NIH). At least one-third of big pharma’s new drugs are now licensed from outside sources, she says, and many of the most important breakthrough drugs have been developed in this way. Taxol, the best-selling cancer drug in history, is a case in point. The brand name for paclitaxel, Taxol was first derived from the Pacific yew tree in the 1960s, and the National Cancer Institute, a branch of the NIH, spent nearly thirty years and $183 million laying the groundwork of basic research on the compound. Then in 1994, Bristol-Myers Squibb licensed the drug from the NIH. The company did none of the basic research on Taxol, but projects the image of having developed a life-saving drug.