The Dope on Drugmakers

In the past few years, the pharmaceutical industry has been increasingly asked to explain why it charges Americans far higher prices for prescription drugs than people in other countries.

At the same time, investigators have taken a close look at the practices and arguments of "Big Pharma," as the industry is often called. One such analyst is **Marcia Angell**, a physician and former editor of the *New England Journal of Medicine* who is now a senior lecturer in social medicine at Harvard University Medical School.

Angell has written a new book, *The Truth About the Drug Companies: How They Deceive Us and What to Do About It* (Random House). Patricia Barry of the *AARP Bulletin* interviewed her recently.

Q&A

Why can't the U.S. government negotiate lower prices with drug companies, as governments in other countries do?
Because the industry won't stand for it, and it nearly always gets its way. Big Pharma has huge influence in Washington—with more lobbyists at times than there are members of Congress to lobby—and contributes heavily to political campaigns.

As a result, Congress dutifully wrote into the new Medicare law a provision that explicitly forbids Medicare from regulating drug prices in any way. So drug companies can charge whatever they want.

The drug industry argues that lowering U.S. prices to the levels in other countries would undercut vital research. Is this true?
Absolutely not. The big drug companies consistently spend less on research and development [R&D] than they make in profits—sometimes much less. They spend at least twice as much on "marketing and administration" as on research. That includes advertising and other promotions, lavish sums for the "education" of doctors, huge executive salaries and legal and lobbying costs. So when they warn that lowering prices will cut into R&D, why should it? Why not cut these other expenses instead?

The industry says the United States leads the world in new drugs because innovation can only flourish in a free market.
This is a global industry, not an American one. Of the top 10 drug companies, five are European—GlaxoSmithKline, AstraZeneca, Aventis, Novartis and Roche—based in countries that regulate prices. All of them price their drugs much higher in the United States because they can get away with it here.

It's true that some of these companies locate their R&D operations in the United States. But it's probably not the so-called free market that draws them here but the very opposite: our unparalleled, publicly sponsored research enterprise that they're able to feed off.

But could we miss out on new cures if prices were lowered?
The industry's best-kept secret is that it's not very innovative at all. In 2002 the Food and Drug Administration approved 78 new drugs, of which only seven were truly innovative—defined as containing new active ingredients and likely to be better than drugs already on the market to treat the same condition. And not one of the seven came from the major American drugmakers. Instead, they came from European companies or biotech firms.

In fact, of all the drugs the FDA has approved over the past six years, fully 78 percent were classified as unlikely to be better than existing ones. And 60 percent didn't even contain new active ingredients. They were just old drugs in slightly different forms—"me-too" drugs.

Much of the really creative work in inventing new drugs is done at universities and government labs, then licensed to industry. So Big Pharma's "innovation" is mainly public relations. The problem is that the drug companies are rewarded—with exclusive rights, tax breaks and high prices—as though they *were* innovative.

Does the government have the right to demand lower prices for drugs invented by publicly funded research?
It certainly does. In 1980 Congress passed the first of several laws that permit universities and the National Institutes of Health to transfer the fruits of publicly funded research to drug companies for further development and marketing. In exchange for exclusive rights, the companies are supposed to make the resulting drugs "available to the public on reasonable terms." That provision is widely ignored.

Look at Taxol—a very important cancer drug. It was developed almost entirely at the National Cancer Institute over some 30 years at a cost to taxpayers of $183 million. It was then synthesized by NIH-funded researchers at Florida State University.

Yet, after Bristol-Myers Squibb was given exclusive rights to the drug through an agreement with

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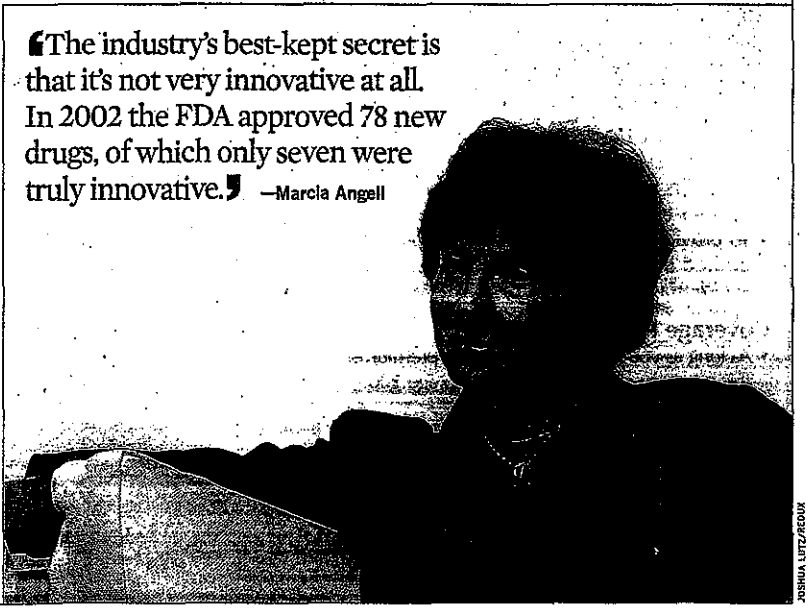

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NIH, the company priced it at $10,000 to $20,000 for a year's treatment. Hardly "reasonable terms." Up to last year, the company had paid royalties to NIH of only $35 million on its $9 billion in sales of Taxol.

If drug companies aren't inventing many new drugs, what are they spending their money on?
It's hard to know exactly how they spend money, because the industry keeps so much information secret. But a lot of it goes to developing and promoting me-too drugs. A reasonable guess is that about 25 to 30 percent of sales goes to marketing, much of which targets doctors and often masquerades as education.

Why so much marketing? Mainly because they need to convince doctors and the public to buy one me-too drug instead of another, when there is really no reason to prefer one.

For example, when AstraZeneca's Prilosec [for heartburn] came off patent, the company poured hundreds of millions of dollars into trying to convince people to switch to Nexium, a more expensive form of the same drug with a long patent life ahead of it. A cure for cancer, say, would not need to be promoted like that.

But don't me-too drugs provide choice and hold down prices?
You'd expect that me-too drugs *would* lower prices, but there's little evidence they do. They're rarely marketed as being cheaper than the others. They're marketed as being "better." Have you ever heard Lipitor [to lower cholesterol] advertised as being cheaper than Zocor, or vice versa? I haven't.

Yet there's usually no good evidence that one is better than another because companies don't compare their own me-too drugs against their competitors' at equivalent doses. Nor do they do tests to find out if one me-too drug is more effective in people for whom similar drugs didn't work. Perhaps two or three me-too drugs do provide some needed backup, but there's little excuse for four or six or eight, which is often the case.

In your book you say if you could choose only one reform, it would require new drugs to be compared with old ones for the same condition. Why?
Before a drug can be sold, the manufacturer has to show the FDA in clinical trials that the drug is "effective." But compared with what? The only requirement is that it has more effect than a placebo [a sugar pill]—that is, better than nothing. That's a very low hurdle, and it encourages companies to turn out me-too drugs.

But if they had to show that these drugs were better in some real way than older drugs to treat the same condition—safer, more effective, substantially more convenient—far fewer me-too's would be approved. Drug companies would then have to turn their attention to discovering truly important, innovative drugs. And they'd no longer need to spend enormous sums on marketing.

You also suggest a new agency to oversee the clinical testing of drugs. How would that help?
It would lessen the influence of Big Pharma on the scientific evaluation of drugs. At present, drug companies not only plan and pay for trials of their own drugs but also play a large part in analyzing and publishing the results. This obvious conflict of interest has introduced bias into research, so that many drugs look better than they are. There have even been instances of companies trying to suppress results they didn't like.

A "National Institute for Prescription Drug Trials" could be established within NIH to administer clinical trials as a publicly accountable agency, independent of the industry. That would go a long way to restoring public trust in drug research.

What's ahead for drug prices?
Drug companies can't continue to jack up American prices at the current rate. What we really need is a system for controlling the inflation of drug prices, just like every other advanced country. ■

For more on drug prices and industry practices, see AARP's "Rx Watchdog Report," www.aarp.org/watchdog.

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