

## The Truth About Marcia Angell

By Dr. Henry I. Miller : 01 Sep 2004

I never knew my maternal grandparents. During the nineteen-teens, my maternal grandmother died of a wound infection following a routine gall-bladder operation. A few years later, her husband suffered a fatal stroke brought on by untreated high blood pressure. Both were in their thirties.

Neither occurrence was uncommon back then, but a half-century of new drugs has changed that. Thanks to a research-intensive (and, therefore, capital-intensive) pharmaceutical industry, pharmacy shelves now contain dozens of antibiotics and blood pressure medications. Similar treatments are available as well for other medical problems, such as arthritis, hypertension, abnormal lipids, and heart failure, and new vaccines have virtually eradicated many dreaded childhood illnesses. Moreover, greater understanding of the molecular mechanisms of disease has provided the wherewithal to make these drugs far safer and more effective.

These stunning successes notwithstanding, the pharmaceutical industry has become a lightning rod for critics. In her new book, *The Truth About the Drug Companies: How They Deceive Us and What to Do About It*, Marcia Angell, Harvard Medical School lecturer and former editor of the *New England Journal of Medicine*, blasts the drug industry, accusing it of profiteering, having become a marketing machine to sell drugs of dubious benefit, and using its wealth and power to co-opt every institution that might stand in its way, including the U.S. Congress, the FDA, academic medical centers, and the medical profession itself.

Dr. Angell maintains that the pharmaceutical industry's reputation for innovation is a myth, that in fact it feeds off the NIH and that new drugs nearly always stem from publicly supported research. She makes much of the fact that the drug industry, corrupted by easy profits and greed, has high marketing and administrative costs, and blames the companies for the paucity of genuinely innovative and affordable new drugs.

Many of these accusations are questionable; some are patently unfair or untrue.

In 1999, the NIH thoroughly investigated whether its research funding commonly leads to the development of pharmaceuticals, the profits from which taxpayers might be entitled to share. Of 47 drugs that had earned revenues of \$500 million or more, NIH support had figured significantly in only four, two of which were actually the same drug. The NIH supports primarily pre-commercial, fundamental research into the biochemistry, physiology and molecular biology of cells and organisms, in health and disease.

Dr. Angell's analysis of companies' profitability downplays their huge investments in R&D. The U.S. research-based pharmaceutical industry (that is, excluding companies that make generic

drugs) currently spends upwards of \$33 billion annually on R&D. Moreover, it invests in research and development a far greater percentage of sales (17.7 per cent) than any other industrial sector, including electronics (6.0 per cent), telecommunications (5.1 per cent), and aerospace (3.7 per cent).

The vast expenditures on R&D are not surprising, given the uncertainty of success of a new drug candidate. Only one of every 5000 products screened is ultimately approved as a new medicine; the others drop out because of concerns about safety, efficacy or profitability. But the most sobering statistic of all is that because of the enormous costs of bringing a new drug to market, only three in ten drugs that *are* approved and marketed ultimately produce revenues that recoup their R&D costs.

This state of affairs encourages drug companies to focus increasingly on financial blockbusters -- usually treatments for chronic conditions that affect large populations -- and to neglect products with more modest prospects, no matter how medically important or technically feasible they may be. For example, although they are tremendously critical and cost-effective, antibiotics and vaccines are out of favor.

The pharmaceutical industry has structural problems, to be sure. As Dr. Angell points out, drug companies do develop too many me-too drugs that differ little from earlier products, and spend disproportionately on marketing and promoting them.

But in large part these strategies are the result of the industry's being the *victims* of government policies, not, as Dr. Angell argues, their beneficiaries. In spite of increasingly powerful and precise technologies for drug discovery, purification and production, development expenses have soared: On average, including both out-of-pocket expenses and opportunity costs, it now costs more than \$800 million to bring a new drug to market.

One important reason for these debilitating costs goes all but unmentioned in Dr. Angell's account: The highly risk-averse FDA keeps raising the bar for approval, especially for innovative, high-tech products and technologies. Immunotherapy tailored to individual patients, human gene therapy, and biopharming -- the production of drugs in gene-spliced crop plants and animals -- have been hit especially hard. But Dr. Angell's prescription is for regulators to become even tougher and less accommodating -- according to her, there is now far too much emphasis on speed at the FDA. But this would only push R&D costs higher and reduce further the number of drugs approved.

Instead of Dr. Angell's snake oil, what we need is regulatory reform to lower the costs and time of drug development. That would stimulate the formation of new companies and enable them to pursue more drug candidates, including some that are medically needed but offer only modest revenues.

As for the accusation that the industry has bought off the political process, history argues otherwise. The companies have tended to defend the public policy status quo instead of using their prodigious lobbying muscle for reform. They squandered a stunning opportunity during the mid-1990's, for example, when Congress undertook regulatory reform: The pharmaceutical and biotech industries lobbied for, and got, the worthless, toothless FDA Modernization Act of

1997.

Having incorrectly diagnosed what ails the drug industry, it's hardly surprising that Dr. Angell prescribes the wrong remedies. She calls, for example, for regulators to require that new drugs be tested not against placebos, but against other drugs for the same condition -- an inappropriate and far higher standard. This change in policy would reduce both the overall number of drugs approved and the availability of backup drugs -- for example, for patients who might be allergic or otherwise intolerant to a first-line drug, or who develop resistance to an antibiotic or anti-cancer treatment.

Moreover, this proposal fails to take into consideration that a drug initially approved for one purpose often is subsequently found to have other important uses; for example, preliminary studies suggest that the antidepressant Zoloft may be an effective treatment for bulimia. This not uncommon situation argues against Dr. Angell's proposal, which would lead to the initial approval of far fewer drugs, and thereby reduce the likelihood that alternative applications could be discovered later. It would be a profound disservice both to physicians and patients.

Dr. Angell wants to end drug companies' control [over] the clinical testing of their own drugs, because this practice biases the research in favor of the sponsor's drug. Instead, she suggests the creation of a federal Institute for Prescription Drug Trials within the NIH to administer clinical trials of prescription drugs by contract[ing] with independent researchers in academic medical centers. However, this function lies far outside the mainstream of the NIH's current functions. What makes this proposal a particularly difficult pill to swallow is that drug companies would no longer decide which products should be developed: That responsibility would belong to federal bureaucrats, who might prioritize trials on the basis of unbiased expert advice.

How would we fund Dr. Angell's new multi-billion dollar bureaucratic behemoth? Easy: Drug companies would support it, but their contributions would not be related to particular drugs.

Incensed at the lust for profits of the drug industry, and at the supposed protections and subsidies afforded it by government, Dr. Angell feels it should be regarded much as a public utility, complete with price controls. Is it possible that Dr. Angell does not understand that free markets and competition discipline costs, stimulate innovation, and enhance the quality of the product on offer? She is old enough, after all, to recall a time when telephone service was regarded as a public utility: Phones had few features and were connected to the wall by a cord, and rates were sky-high. Moreover, as economist Arnold Kling has written, just because you run an industry as a utility does not mean that it will be regulated by a Platonic philosopher-king who discerns the public interest. On the contrary, it means that you take away the consumer sovereignty of the market and replace it with the backroom deal-making of the lobbyist.

Dr. Angell's proposals to, in effect, nationalize the American system of drug development reflect almost inconceivable naiveté. They are reminiscent of economist Milton Friedman's example of a flawed syllogism: Capitalism has worked everywhere it has been tried; socialism has failed everywhere it has been tried; therefore, let us try socialism.

A spirited diatribe can educate and entertain, but in *The Truth About the Drug Companies*, Dr. Angell does neither. Her diagnoses are wrong, and her remedies -- which are reminiscent of the government controls and centralized planning of the old Soviet Union -- are far worse than the disease.

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